An Analysis of the Patent Landscape Related to Diagnostic Devices and their Consumable Parts

Patents and Published Applications Potentially Directed to GeneXpert, AlereQ, and OraSure Devices and Consumables for Detection of HIV, HCV, Mycobacterium, and Other Infections

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I. Introduction

The provision of effective and appropriate medical treatment requires firstly, that an accurate diagnosis be made and secondly, that the necessary follow-up treatment is provided. In rural communities and resource-poor settings, point-of-care diagnostics can help contribute towards both these objectives. Unlike laboratory testing, point-of-care diagnostics provide a rapid, "on-the-spot" diagnosis, enabling people to commence same-day treatment after only one visit to the local health clinic. This helps to ensure that people are diagnosed correctly and receive the necessary treatment as soon as possible. Although laboratory-based testing has it's place and is an important component of a healthy laboratory system, limited and slow sample transportation and results delivery, and the reliance of the person to return for their results, mean that, particularly in rural communities, results delivery may be too slow to improve outcomes and interrupt transmission and loss to follow-up a high risk. Point-of-care diagnostics are therefore integral to the ability of MSF and others working in more remote settings to provide the best possible care. An example of three important point-of-care tests currently used by MSF include the: Xpert MTB/RIF (Cepheid), Alere q HIV-1/2 Detect (Abbott) and OraQuick HCV Rapid Antibody Test (OraSure). It is for this reason that they were used as examples for this more in-depth patent landscape.

To operate, point-of-care diagnostic devices use compact device technologies and consumable parts, including cartridges, to generate precise and rapid results. Generally, a patient's specimen is placed onto the relevant consumable part before it is inserted into the point-of-care diagnostic device for analysis. In terms of intellectual property protection, therefore, the relevant intellectual property protections are not limited to the device but will also affect the consumable parts. Process patents may also be relevant consideration in jurisdictions where such patents are awarded. As a result, the patent protections for point-of-care diagnostic devices and their consumable parts greatly outnumber the amount of patent protections that are ordinarily granted for a medicinal drug. In addition, diagnostic devices and their consumable parts also exhibit a much wider variety in the way of patented technology types, with technologies that also relate to mechanical engineering, electrical engineering and so on.

Yet, despite this foundational knowledge, little research has been done in the way of patent landscaping for point-of-care diagnostics and their consumable parts. As a result, the actual impact

of this patenting behaviour remains relatively under-explored. Moreover, unlike the pharmaceutical industry where a single patent may significantly impair the ability of a competitor to bring a competitive product to the market, in the medical device industry it is common practice to "design around" any significant technological impediments.[1] Yet, despite more patents and patent holders than ever before, it remains unclear whether these intellectual property rights have impaired the innovation and development of new research tools,[2] such as point-of-care diagnostics and their consumable parts, or indeed feature as a significant cost-driver.

One of the primary concerns over this proliferation of patents relates to the possible anti-commons that may arise as a result, particularly where patenting on upstream innovations hinders the ability to develop new technologies downstream.[3] The concern being that the combination of multiple patents may result in a breakdown of licensing negotiations or may, alternatively, lead to a level of royalty stacking that makes end product development either commercially unfeasible or worse yet, impossible.[4] As described by Shapiro (2000), the result of such a patent system is the creation of "patent thickets", meaning 'an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.'[5] For instance, a striking example can be found in the cellular phone technology, where every new product development includes literally thousands of essential patents.[6]

In contrast, a study by Walsh (2003) found that, despite the increased number and complexity of patent protections, there was little evidence that projects were stopped due to patent protections, at least in relation to the development of biomedical research tools.[7] With licensing said to be routine, royalty stacking or negotiation break-down were not considered as limiting new technological developments or innovation.[8] However, at least with regards to point-of-care diagnostics, technological development has been slow and competition weak. As a result, the prices are often unaffordable for the communities that have the greatest need for such technologies, namely, the remote and vulnerable communities in the some of the least-developed and developing parts of the world.

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[1]GMTA, 'Patents for Medical Devices and Pharmaceuticals' (19 March 2012) Global Medical Technology Alliance: Innovating for a Healthier World 1.

[2]John P. Walsh et al., Research Tool Patenting and Licensing and Biomedical Innovation (2003) in a book called "Patents in the Knowledge Based Economy", 333.

[3] Michael A Heller and Rebecca S Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomerdical Research (1998) 280 (5364) *Science* 698, 698.

[4]John P. Walsh et al., Research Tool Patenting and Licensing and Biomedical Innovation (2003) in a book called "Patents in the Knowledge Based Economy", 287.

[5] Carl Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting' (2000) in Adam B. Joffe et al. (eds) *Innovation Policy and the Economy* (1st ed, MIT Press, 2001) 119.

[6]Mark A Lemley and Carl Shapiro, Patent Holdup and Royalty Stacking (2006-2007) 85 *Texas Law Review* 1991, 1992.

[7]John P. Walsh et al., Research Tool Patenting and Licensing and Biomedical Innovation (2003) in a book called "Patents in the Knowledge Based Economy", 333.

[8]John P. Walsh et al., Research Tool Patenting and Licensing and Biomedical Innovation (2003) in a book called "Patents in the Knowledge Based Economy", 322-323.

To determine if the myriad of patents is potentially blocking innovation in this specific field, a first step was undertaken to perform a patent landscape analysis on three point-of-care diagnostics that are particularly pertinent to MSF and others working in low- and middle-income countries. The first two, GeneXpert (made by Cepheid) and AlereQ (made by Alere) rely on PCR-based technology. The third device, OraQuick (made by OraSure) relies on a chromatography method. The technology underlying these devices is well known in the field and will be described in more detail below.

In addition, the patent landscape includes the important patents on the consumable parts that are used with those point-of-care diagnostic devices. For example, the GeneXpert and AlereQ devices rely on cartridges in which human samples are placed and chemical reactions occur. By patenting the consumable parts, this could result in a significant, ongoing cost for users of the machines. On the other hand, machine users could potentially enjoy dramatically reduced cost if consumable parts, such as cartridges, could be made inexpensively by third-party providers without the threat of patent infringement litigation; assuming that this party either have had worked around or successfullyy challenged any blocking patents, or would be able to negotiate a deal for transfer of the needed proprietary technologies including know-how, produce the identical product more cheaply, and be prepared to sell it at a lower price (given that the diagnostics industry is not subdivided into originator and generic products, as is more commonly seen with medicines).

This study represents a first step in understanding the relevant patent landscape related to three point-of-care medical devices and their consumable parts, including cartridges. The landscape reveals 32 representative families of patents and patent applications directed to both the devices and consumable parts. Because the patents were owned by a diverse set of companies, there is a significant possibility that the manufactures of the various devices have licensed technology from these third parties, although such licenses are often not public, and not easily searchable, even if they are. Additionally, assessing the patent status in low- and middle-income countries was often quite difficult due to the lack of patent database resources in the relevant jurisdictions. Accordingly, blocking patents from high-income countries may not be present in low- and middle-income countries. The absence of blocking patents in low- and middle-income countries may provide an avenue for device manufacturers to bring competing devices to market.

This report is limited to the objective of providing a technical scoping of the most relevant patents associated with the three identified diagnostics. The report does not provide Freedom to Operate conclusion and advice, nor provide broader policy analysis around the issue of access to more affordable diagnostics. Due to the limitation of access to information, it does not cover an analysis on possible license agreements attached to the concerned technologies. Due to the limitation of information from potential competitors' technologies, the report also does not provide a conclusive definition of the potential, specific blocking patents. Further research is suggested after this first step to explore and establish further understanding about the potential intersection between patents and the other contributing factors, such as licensing, to the cost and access challenges facing end-users.

A number of additional steps are suggested to further develop this work to address the issues below:

(1) Identify possible exclusive or highly restricted license agreements associated with the key technologies;
(2) Further analysis on competitors' approach in order to define potential blocking patents or blocking patent thickets;
(3) The effect of relevant patenting on blocking follow-on innovation and/or competition;
(4) The potential contribution of the cost of pursuing, maintaining and obtaining patents on the cost of goods of the final diagnostics;
(5) The effects of patents on the limiting the freedom of choice of product available to end-users (e.g. as with Myriad and their BRCA1+2 lab test in the USA).

II. Executive Summary

The objectives of this document are to:

1. Identify the most relevant patents and published applications that may cover the GeneXpert, AlereQ, and OraSure devices and consumable parts; and

2. Identify which countries have pending applications or issued patents related to the most relevant patents and applications.

This document and the appended chart identify the most relevant patents and published applications that may cover one or more aspect of the GeneXpert, AlereQ, and OraSure devices. The patents and applications are organized into two categories. The first category includes patents and published applications that may cover one or more aspect of the GeneXpert and/or AlereQ devices and their consumable parts (cartridges). The second category includes patents and published applications that may cover one or more aspect of the OraSure device (which does not use cartridges). Within each category, the patents and published applications are arranged in order of relevance, with the first patent/application being the most relevant and the last patent/application being the least relevant.

Patents and published applications that may cover the GeneXpert and AlereQ devices and cartridges are grouped together because these devices rely on very similar base technology, *e.g.,* the polymerase chain reaction ("PCR"). Accordingly, a single search was conducted to capture patents and published applications that may cover both of these devices and their cartridges.

The OraSure device uses a technology that is different than that used by the GeneXpert and AlereQ devices. In particular, the OraSure device uses a technique called lateral flow chromatography (described in more detail below). For that reason, patents and published applications directed to the OraSure device are included in a separate category.

II. The Devices

The GeneXpert (Cepheid), AlereQ (Alere), and OraQuick (OraSure) devices are point of care machines capable of rapidly diagnosing a patient with one or more disease, *e.g.*, hepatitis C ("HCV"), HIV, tuberculosis, and mycobacterium infections. These devices use known diagnostic techniques to detect the presence of infection in a patient's sample. Although the underlying

diagnostic techniques are well known, the manner in which these devices use the known techniques is the subject of the present analysis.

A. GeneXpert and AlereQ

Both the GeneXpert and AlereQ devices use a technique called the polymerase chain reaction ("PCR") to amplify target deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) present in a patient's sample. These devices amplify and then detect the presence of pathogenic (*e.g.*, mycobacterium, HCV, or HIV) DNA and/or RNA in a sample.

PCR was first invented in 1985 and relies on the enzymatic amplification of a DNA fragment in a sample. By employing PCR, the GeneXpert and AlereQ devices are able to amplify a minute amount of DNA that is unique to a particular pathogen. By amplifying the pathogen DNA, the devices create a sufficient DNA signal that can then be detected by the device. Thus, a health care worker can ascertain that a particular pathogen is present in a patient, because the pathogen's unique DNA is amplified and detected. Although the original patents covering PCR have expired, there are myriad patents that followed that relate to improvements in PCR techniques. Many of these follow-on PCR patents have also expired and a search of the PCR patent landscape was limited in the present project as outlined below.

The GeneXpert and AlereQ devices are structurally similar. The sample is deposited onto a cartridge, which is inserted into a larger device. Each cartridge comes pre-loaded with the necessary reagents for extracting nucleic acids (*e.g.*, DNA/RNA), amplifying target DNA/RNA, and detecting the presence of the target DNA/RNA in the sample. Once the cartridge is inserted into the larger device, the system runs a program which extracts, amplifies (by PCR), and detects target DNA/RNA, providing a yes/no readout for the presence of target DNA/RNA.

Accordingly, patents and published applications included here are directed to one or more of the following aspects of the GeneXpert and AlereQ devices and cartridges:

1. means for isolating and/or purifying nucleic acids, including a chamber or vessel, reagents, and necessary machinery (*e.g.*, pumps);

2. means for amplifying target DNA/RNA, including a chamber or vessel, reagents, and necessary machinery (*e.g.*, a thermocycler, which is a device that adjusts the temperature of a reaction chamber for specific periods of time); and

3. means for detection of the amplified target DNA/RNA (*e.g.*, reagents for conducting real time PCR, which is a form of PCR that uses fluorescence to detect the amount of a PCR product after each cycle).

B. OraSure OraQuick

The OraSure OraQuick lateral flow device detects the presence of anti-viral antibodies in a patient's blood or saliva, using a method called lateral flow chromatography to separate and identify target antibodies. A patient infected with HIV or HCV, for example, will develop

antibodies against HIV or HCV. The OraSure device acts by detecting the presence of those antibodies in the patient's saliva or blood.

Briefly, a user swabs a subject's mouth with a flat portion of the device (or applies their blood to an applicator attached to the device). The subject then inserts the flat portion into a vial, which is pre-loaded with reagents to allow the subject's proteins (including antibodies) to travel by capillary action up an absorbent paper (*e.g.*, a capillary matrix). Pre-deposited at a set point on the paper are target viral proteins or peptides from, *e.g.*, HIV or HCV. If the subject has been infected with HIV or HCV, the subject will likely have developed antibodies that can bind the deposited viral proteins. As the subject's proteins travel up the absorbent paper, the subject's antibodies directed to those viral proteins, if present, bind and become immobilized at that spot. Detection chemistry (using regents that include Protein A and colloidal gold) allow the deposited antibodies of interest to be visualized by eye as a red mark on the chromatography paper.

Accordingly, patents and published applications included here are directed to one or more of the following aspects of the OraSure device:

1. An absorbent paper (*e.g.*, capillary matrix) having a surface for receiving oral fluid;

2. A lateral flow chromatography strip where the capillary matrix pulls up the oral fluid and delivers the oral fluid to a receiving area of the strip;

3. Means for visual detection of a target on the lateral chromatographic strip; and

4. A housing apparatus that acts as a handle for inserting the paper into a subject's mouth (for sample collection).

III. The Search

Four searches of PCT, US, EP, Chinese, Indian, and Indonesian patents and published applications were performed using the Thomson Innovation database. First, a term-based search directed to the Cepheid GeneXpert and AlereQ molecular devices and their cartridges was performed. This search was directed to terms related to devices, instruments, thermocyclers, cartridges, amplification, the polymerase chain reaction, detection, and quantification, as well as for specific conditions such as hepatitis C, HIV, tuberculosis, and other mycobacterium infections. Select search terms were limited to the claims, and the search was further limited to patents and applications published after 1995. This search attempted to identify patents and publications directed to the Cepheid GeneXpert and AlereQ molecular devices, as well as their respective cartridges. This term search yielded 672 total hits that were reviewed for relevance.

The second search was a term-based search directed to the OraSure system. Terms related to lateral flow immunoassays, nitrocellulose or cellulose membranes, colloidal or colorimetric gold, HIV or HCV, and protein A were searched. The search was limited to patents and applications published after 1995. This term search yielded 367 total hits that were reviewed for relevance.

Targeted searching based on patent assignee was also conducted. The third search was an assignee search directed to any patents or published applications listing Cepheid or Alere as the assignee or applicant. This search yielded 1601 total hits that were reviewed for relevance. It is important to note that this search yielded several patent families in the chart, below, that are not solely assigned to Cepheid or Alere. In some cases, a predecessor company was listed on the published international application. For example, Inverness Medical Switzerland is a predecessor company of Alere Switzerland, and several of the older patent families identified were at one time listed in the name of Inverness Medical Switzerland. It is also interesting to note that several patent families were identified that are relevant to the OraSure OraQuick device that are assigned to Alere or one of its predecessors. Additional research may be warranted to identify any potential coverage Alere may have over the OraSure OraQuick device.

Finally, the fourth search was an assignee search directed to any patents or published applications listing Clondiag, The US Department of Defense, or the University of Medicine and Dentistry of New Jersey as the assignee or applicant. The search was further limited to those publications also having device terms, amplification terms, and detection terms in the claims. This search yielded 90 total hits that were reviewed for relevance.

Following each term search and the assignee search, INPADOC databases available through WIPO and Espacenet were searched to identify additional patents and applications, which are related the patents and publications identified in the term searches, in jurisdictions not available through Thomson Innovation.

Lastly, an online search of product information for the Cepheid GeneXpert, AlereQ, and OraQuick platforms was used to identify patents identified as relevant by the companies that manufacture and market each of the devices.

Relevant patents and published applications are provided in the attached chart.

IV. The Results

The attached chart provides a list of patents and published applications that may cover one or more aspect of the GeneXpert, AlereQ, and/or OraSure devices. The chart is organized to provide the title, the applicant, the international PCT application publication number, the expected expiration date, a brief summary of the technology, the reasons for inclusion, and representative claim(s).

The summaries are based on a brief review of the claims of the patents and publications. Further review of each specification, any issued claims, and any prosecution history will be necessary to draw specific conclusions as to the precise scope of the claims. In addition, the information provided in the chart is based on knowledge of the GeneXpert, AlereQ, and OraQuick technologies obtained through review of the product literature available online. Accordingly, this analysis is limited by the information publically available at the time the attached chart was created.

The representative claims are based on the published PCT application, where available (unless otherwise indicated). The expected expiration date is based on the PCT filing date (unless

otherwise indicated), absent any patent term extension, and subject to the actual issuance of a patent.

Below the bibliographic information, the status of each application in each of the countries of priority concerns for access to point-of-care diagnostics or having potential development and manufacture capacities on these diagnostic systems is listed. As indicated in the chart, several of the countries are not searchable by the databases used here, and there were no related patents or applications identified through the INPADOC searches. Subsequent term searches of various databases may allow us to fill in some of the missing countries.

Applicant and assignee information is based solely on publically available information. In particular, the applicant and assignee information is collected from the published PCT application and/or the United State Patent and Trademark Office (USPTO) assignment database, where available. Assignments made subsequent to the PCT publication or assignments that were not recorded with the USPTO are not included in this analysis, nor are any licensing agreements.

Below is a brief summary of each of the patent families identified through the searches described above. Within each category, the patent families are arranged in order of relevance, with the first patent family considered the most relevant.

A. The GeneXpert and AlereQ Patent Landscape for Devices and their Cartridges

Patent Family 1 is directed to methods of amplifying a target RNA present in a sample obtained directly from a person. These patents/publications are assigned to **Coyote Bioscience Co., LTD.** of China. This family is included because the product literature for the GeneXpert HIV viral load device listed this PCT application, and because sample claims specify that the claimed method includes several elements of the GeneXpert and AlereQ technologies, including (i) a reaction vessel that includes the sample and the necessary reagents for amplifying target RNA and (ii) running the amplification. Because the language of these claims is broad, these claims may cover the methods used in the GeneXpert and AlereQ technologies. This application was filed in China.

Patent Family 2 is directed to a detection device. This patent family is assigned to **Clondiag Gmbh** of Germany. These patents/publications are included because the claimed device may be used in at least the AlereQ device, as Clondiag is a predecessor to Alere. This application was filed in the US, EPO, China, and Brazil. The applications in this family are very similar to the applications in Patent Family 19, below.

Patent Family 3 is directed to a detection device. This patent family is assigned to **Clondiag Gmbh** of Germany. These patents/publications are included because the claimed device may be used in at least the AlereQ device, as Clondiag is a predecessor to Alere. This application was filed in the US, EPO, China, and Brazil. The applications in this family are very similar to the applications in Patent Family 18, above.

Patent Family 4 is directed to a device capable detecting a target nucleic acid in a biological sample. These patents/publications are assigned to **Bioneer Corporation** of Korea, and they are

included because sample claims recite that the device includes several elements of the GeneXpert and AlereQ technologies, including (i) automated purification, (ii) nucleic acid amplification, and (iii) measuring amplified target nucleic acids. Though other elements of the apparatus are listed, it is unclear whether the GeneXpert and AlereQ technologies also include these other features, based on the manufactures' websites, and thus the patents and publications in this family may be relevant. This application was filed in the US, EPO, China, India, and Russia.

Patent Family 5 is directed to a device for detecting a target nucleic acid in a sample. These patents/publications are assigned to **Micronics, Inc.** of the US, and they are included because sample claims recite that the system includes several elements of the GeneXpert and AlereQ technologies, including a sample collection component and a cartridge for receiving the collection component, as well as means for (i) extraction, (ii) amplification, (iii) and detection of amplified target nucleic acids. This application was filed in the US. Micronics, Inc. is also listed as the assignee of WO 2004/065010, WO 2007/106579 A2, and WO 2011/094577 A2, each of which is also included in this chart because they claim similar subject matter

Patent Family 6 is directed to a system for rapid analysis of biological samples. These patents/publications are assigned to **Nanobiosym, Inc.** of the US, and they are included because representative claims recite that the system includes several elements of the GeneXpert and AlereQ technologies, including (i) a mobile device that receives an integrated chip (*e.g.,* a cartridge), where the device controls a fluidic system in the chip; and (ii) where the chip includes elements for nucleic acid extraction, amplification, and detection. This application was filed in the US, EPO, and China.

Patent Family 7 is directed to a method for microfluidic analysis of a fluid sample. These patents/publications are assigned to **Micronics, Inc.** of the US, and they are included because representative claims recite that the method includes several elements of the GeneXpert and AlereQ technologies, including loading a card (*e.g.,* a cartridge) with a sample, extracting components (*e.g.,* nucleic acids) from the sample, amplifying a target (*e.g.,* a nucleic acid), and detecting the amplified target. This application was filed in the US, EPO, and India. Micronics, Inc. is also listed as the assignee of WO 2007/106552 A2, WO 2007/106579 A2, and WO 2011/094577 A2, each of which is also included in this chart.

Patent Family 8 is directed to a method of rapid thermal cycling (*e.g.,* PCR amplification). These patents/publications are assigned to the **University of Utah Research Foundation** of the US. These patents/publications are included because the listed US patents are provided in the product literature for the GeneXpert HIV viral load device, and because representative claims recite a PCR method that could broadly cover the PCR methods used by the GeneXpert and AlereQ technologies. This application was filed in the US and EPO. Notably, all US and EP patents in this family have **expired**; however, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 9 is directed to a method for determining the concentration of a nucleic acid in a sample. This patent family is assigned to **Roche Diagnostics GMBH** of Germany. These patents/publications are included because the listed US patents are provided in the product literature for the GeneXpert HIV viral load device, and because the claims broadly recite a method that includes amplifying a nucleic acid and measuring the amount of the amplified nucleic acid in

real time (*e.g.*, as part of a single process). This method is commonly referred to as real-time PCR (RT-PCR) or quantitative PCR (qPCR); and both the GeneXpert and AlereQ technologies appear to use a form of this method. This application was filed in the US and EPO.

Patent Family 10 is directed to a PCR device. This patent family is assigned to **Applied Biosystems, LLC** of the US. These patents/publications are included because the listed US Patent No. 6,814,934 B1 is provided in the product literature for the GeneXpert HIV viral load device, and because representative claims are directed to an instrument capable of performing real time PCT (RT-PCR). Both the GeneXpert and AlereQ technologies appear to use a form of this method. This application was filed in the US, EPO, South Africa, and Brazil. Notably, all US and EP patents in this family have **likely expired**; however, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 11 is directed to a PCR device that can accept more than one cartridge. This patent family is assigned to **Cepheid** of the US. These patents/publications are included because the GeneXpert device appears to have the ability to accept more than one cartridge simultaneously.This application was filed in the US, EPO, China, and India.

Patent Family 12 is directed to methods of performing a PCR. This patent family is assigned to **Cepheid** of the US. These patents/publications are included because both the GeneXpert and AlereQ technologies rely on PCR, and because this family is assigned to Cepheid it is possible that at least the GeneXpert device uses the recited methods. This application was filed in the US and EPO.

Patent Family 13 is directed to a docking mechanism for receiving a cartridge. This patent family is assigned to Akubio Limited, although the US cases are assigned to **Inverness Medical Switzerland**, which is a predecessor of Alere Switzerland. These patents/publications are included because both the GeneXpert and AlereQ technologies use cartridges inserted into a processing device, and because this family is assigned to a company related to Alere, it is possible that at least the AlereQ device uses the recited docking mechanism. This application was filed in the US and EPO.

Patent Family 14 is directed to methods for preparing a sample for a PCR. This patent family is assigned to **Cepheid** of the US. These patents/publications are included because the method includes use of a device that includes various chambers, including a lysing chamber and a reaction chamber. Because this family is assigned to Cepheid, it is possible that these methods may be used in at least the GeneXpert device. This application was filed in the US, EPO, and China. Notably, all US and EP applications in this family have been abandoned or withdrawn; however, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 15 is directed to a device for detecting a target substance in a liquid sample, wherein the device has multiple connected chambers. This patent family is assigned to **Inverness Medical Switzerland**, which is a predecessor of Alere Switzerland, and the US and EP cases are assigned to Alere Switzerland. These patents/publications are included because the claimed device may be used in at least the AlereQ device. This application was filed in the US, EPO, and China.

Patent Family 16 is directed to a device for detecting a target substance in a liquid sample, wherein the device has multiple connected chambers. This patent family is assigned to **Cepheid** of US. These patents/publications are included because both the Cepheid device and the Alere device include a multi-chambered apparatus, and, because this family is assigned to Cepheid, it is possible that the claimed device may be used in at least the GeneXpert device. This application was filed in the US. Notably, there are no pending US applications in this family; however, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 17 is directed to a loading system for a device, wherein cartridges can be inserted into the device. This patent family is assigned to **Cepheid** of the US. These patents/publications are included because both the GeneXpert and AlereQ technologies use a device that accepts at least one removable cartridge. Because this family is assigned to Cepheid, it is possible that the claimed loading system may be used in at least the GeneXpert device. This application was filed in the US, EPO, China, and India.

Patent Family 18 is directed to a component of a PCR machine, specifically a system for loading a sample into a reaction vessel and for controlling the temperature of the vessel. This patent family is assigned to **Cepheid** of US. These patents are included because both the GeneXpert and AlereQ technologies rely on PCR and include a device for conducting a PCR. Because this family is assigned to Cepheid, it is possible that at least the GeneXpert device uses the claimed component. This application was filed in the US. Notably, there are no pending US applications in this family; however, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 19 is directed to a device that can detect the amount of light reflected by a sample to determine the amount of a target substance in the sample. This patent family is assigned to **Alere Switzerland**. These patents/publications are included because the claimed device may used in at least the AlereQ device. This application was filed in the US, EPO, and China.

Patent Family 20 is directed to a PCR device. This patent family is assigned to **I-STAT Corporation** of the US. These patents/publications are included because sample claims recite that the device includes several elements of the GeneXpert and AlereQ technologies, including means for nucleic acid extraction, amplification, and detection, all contained in a single device. This application was filed in the US and EPO.

Patent Family 21 is directed to a point-of-care device for detecting a target nucleic acid in a sample. This patent family is assigned to **Advanced Theranostics Inc.** of Canada. This published PCT application is included because sample claims recite that the device includes several elements of the GeneXpert and AlereQ technologies, including nucleic acid extraction, amplification, and detection, all contained in a single device. This application was filed in the US, EPO, and China. .

Patent Family 22 is directed to a device that includes a diagnostic card that is capable of running an assay for the rapid detection of one or more pathogens in a sample. This patent family is assigned to **Welch Allyn, Inc.** of the US. These patents/publications are included because sample claims recite that the claimed apparatus includes several elements of the GeneXpert and

AlereQ technologies, including nucleic acid extraction, amplification, and detection, all contained in a single device. This application was filed in the US, EPO, and China.

Patent Family 23 is directed to a cartridge that can be used for the detection of target nucleic acids in a sample. This patent family is assigned to **Micronics Inc.** of the US. These patents/publications are included because sample claims recite that the cartridge includes several elements of the GeneXpert and AlereQ technologies, including extraction, amplification, and detection of target nucleic acids, where all the necessary components are contained in a single unit. The application was filed in the US, EPO, and India. The assignee of this family is also listed as the assignee of WO 2007/106552 A2, WO 2004/065010, and WO 2011/094577 A2, each of which is also included in this chart.

Patent Family 24 is directed to a cartridge for detecting a target in a sample. This patent family is assigned to **Micronics Inc.** of the US. These patents/publications are included because sample claims recite that the cartridge includes several elements, such as fluidic circuits and pumps, which may be used in one or both of the GeneXpert and AlereQ technologies. The assignee of this family is also listed as the assignee of WO 2007/106552 A2, WO 2007/106579 A2, and WO 2004/065010, each of which is also included in this chart. This application was filed in the US, EP, China, and India.

Patent Family 25 is directed to a microchip that can be used to amplify a DNA or RNA target and detect the amplified product . This patent family is assigned to **Clondiag Chip Technologies Gmbh** of Germany. These patents/publications are included because the claimed chip may be used in at least the AlereQ cartridge. This application was filed in the US and EPO; however, there are no application currently pending in either the US or EPO.

Patent Family 26 is directed to a method of detecting and measuring the amount of an amplified DNA or RNA in a sample. This patent family is assigned to **Clondiag Chip Technologies Gmbh** of Germany. These patents/publications are included because the claimed device may be used in at least the AlereQ device, as Clondiag is a predecessor to Alere. This application was filed in the US and EPO; however, there are no application currently pending in either the US or EPO.

Patent Family 27 is directed to a device for purifying DNA from a sample. This patent family is assigned to **Canon U.S. Life Sciences, Inc.** of the US. These patents/publications are included because sample claims recite that the device includes several elements of the GeneXpert and AlereQ technologies, including means for nucleic acid extraction, contained in a single device. The available product literature for the GeneXpert and AlereQ technologies does not provide the specific methods used for extracting and isolating DNA. Thus, it is possible that the claims in this family may broadly cover this aspect of the GeneXpert and AlereQ technologies. This application was filed in the US and EPO.

Patent Family 28 is directed to a device for amplifying target nucleic acids preset in a sample. This patent family is assigned to **Biomerieux** of the US. These patents/publications are included because sample claims recite that the device includes several elements of the GeneXpert and AlereQ technologies, including means for nucleic acid amplification. The available product literature for the GeneXpert and AlereQ technologies does not provide the specific methods used

for DNA amplification. Thus, it is possible that the claims in this family may broadly cover the subject technologies.

Patent Family 29 is directed to a method for detecting the presence of mycoplasma specific nucleic acids. This patent family is assigned to the **University of California** of the US. These patents/publications are included because the listed US Patent No. 5,851,767 is provided in the product literature for the GeneXpert HIV viral load device, and because sample claims recite that the method includes several elements of the GeneXpert and AlereQ technologies (in particular, as the devices are used to detect mycoplasma in a sample), including means for mycoplasma detection in a sample through detection of mycoplasma specific nucleic acids. The available product literature for the GeneXpert and AlereQ technologies does not provide the specific methods used for detection of mycoplasma in a sample. Thus, it is possible that the claims in this family may broadly cover the GeneXpert and AlereQ technologies, in so far as they are directed to detection of mycoplasma in a subject. This application was filed in the US. Notably, the US patents identified in the search described above are expired; however, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 30 is directed to a cartridge for analyzing a sample. This patent family is assigned to **Inverness Medical Switzerland**, which is a predecessor of Alere Switzerland. These patents/publications are included because both the GeneXpert and AlereQ devices use cartridges. Because this family is assigned to a predecessor of Alere, it is possible that the AlereQ cartridges use this technology. This application was filed in the US. EPO, and China. Notably, all identified US and EP applications have been abandoned or withdrawn. However, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 31 is directed to a cartridge for analyzing a fluid sample, wherein the cartridge includes means for analyzing the sample. This patent family is assigned to **Akubio Limited of Great Britain**; however, the US patent in this family is assigned to Inverness Medical Switzerland, which is a predecessor of Alere Switzerland. These patents/publications are included because both the GeneXpert and AlereQ devices use cartridges that are preloaded with various reagents used in the analysis of a sample. Because this family is assigned to a predecessor of Alere, it is possible that the AlereQ cartridges use this technology. This application was filed in the US. EPO, and China. Notably, there are no pending cases in the US or EP; however, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 32 is directed to a cartridge for conducting a chemical reaction, wherein the cartridge has sensors and a reaction vessel. This patent family is assigned to **Cepheid**. These patents/publications are included because both the GeneXpert and AlereQ devices use cartridges similar to those described in this family. Because this family is assigned to Cepheid, it is possible that the GeneXpert cartridges use this technology. This application was filed in the US and EPO.

B. The OraSure OraQuick Patent Landscape

Patent Family 33 is directed to a device for collection and lateral flow chromatography of an oral fluid. This patent family is assigned to **OraSure Technologies** of the US. Based on a

review of the product literature and the PCT claims, this patent family appears to be specifically directed to the OraSure OraQuick lateral flow device. However, further analysis of issued claims in relevant countries is necessary to draw conclusions as to whether any issued patents in this family cover the OraSure OraQuick device. The patents and published applications in this family are directed to a device for collection and lateral flow chromatography of an oral fluid. Sample claims recite that the apparatus includes several elements of the OraQuick technology, including (i) a capillary matrix having a surface for receiving oral fluid; (ii) a lateral flow chromatography strip where the capillary matrix pulls up the oral fluid and delivers the oral fluid to a receiving area of the lateral flow chromatography strip; (iii) means for visual detection of a target on the lateral chromatographic strip; and (iv) a housing apparatus that acts as a handle for inserting the capillary matrix into a subject's mouth (for sample collection); and methods of use thereof for the detection of a target in a sample. This application was filed in the US and EPO.

Patent Family 34 is directed to a chromatography device or kit for detecting human antibodies in a sample. This patent family is assigned to **Genelabs Diagnostics PTE Ltd.** of Singapore. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including (i) a chromatographic element; (ii) a releasable binding partner comprising an antibody or a detectable label; (iii) an immobilized binding partner positioned on the chromatographic element, where the immobilized binding partner can be an HIV or mycobacterium antigen. This application was filed in the US, EPO, and China.

Patent Family 35 is directed to an immunoassay analytical test device. This patent family is assigned to **Clinical Diagnostic Chemicals Limited** of Great Britain. These patents/publications are included because representative claims recite that the apparatus comprises several elements of the subject technology, including (i) a pad for collecting fluid from a subject; (ii) the pad can also be an area that is exposed to a solution that will move the analyte across a membrane; (iii) detection means for permitting detection of the analyte (*e.g.*, use of an antibody). Broadly construed, the published PCT claims may read on the OraQuick technology. This application was filed in the US and EPO.

Patent Family 36 is directed to a rapid test kit for detection of nucleotides (DNA and/or RNA). This patent family is assigned to **Ultrapid Nanodiagnostics Inc.** of the US. These patents/publications are included because sample claims recite that the kit includes several elements of the OraQuick technology, including (i) a membrane; (ii) a genetic probe immobilized on the membrane; (iii) and a stain for visual detection of a target. Broadly construed, the published PCT claims may read on the OraQuick technology. This application was filed in the US, EPO, China, and India. Notably, each US and EPO application is abandoned or withdrawn.

Patent Family 37 is directed to a method for detecting and/or measuring the amount of a target in a liquid sample. This patent family is assigned to **Quantrx Biomedical Corporation** of the US. These patents are included because sample claims recite that the method includes several elements of the OraQuick technology, including (i) a test strip comprising a membrane; (ii) a mobile or mobilizable detectable tracer (*e.g.*, a means of detection); (iii) and a sample application area. Accordingly, the various elements of the claimed method may cover the OraQuick technology. This application was filed in the US.

Patent Family 38 is directed to a device for determining the presence or absence of a target in a fluid sample. This patent family is assigned to **Medmira Inc.** of Canada. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including (i) a test unit comprising a reaction zone in contact with an absorbent zone (*e.g.*, a chromatographic membrane); (ii) an immobilized capture reagent capable of binding with a target; and (iii) an indicator reagent (*e.g.*, a means for visual detection of the target). Accordingly, the various elements of the claimed device may cover the OraQuick technology. This application was filed in the US, EPO, and China.

Patent Family 39 is directed to a diagnostic test strip for detecting a target in a liquid sample. This patent family is assigned to **Advantage Diagnostics Corporation** of the US. These patents/publications are included because sample claims recite that the test strip includes several elements of the OraQuick technology, including (i) an element that binds the target, where the target can be an antibody (*e.g.*, an antibody to HIV or HCV), and where the binding element can include protein A and colloidal gold (for visualization purposes); (ii) a sample application area configured to receive a liquid sample; and a test area including an immobilized binding agent specific for the target. Accordingly, the various elements of the claimed test strip may cover the OraQuick technology. This application was filed in the US, EPO, China, and Brazil.

Patent Family 40 is directed to an assay kit for detecting a target in a sample. This patent family is assigned to **ANP Technologies, Inc.** of the US. These patents/publications are included because sample claims recite that the kit includes several elements of the subject technology, including (i) a detector that specifically binds a target; b) a conjugate; (c) a capture molecule, which specifically binds the target; and (d) a reporter, where the reporter can include colloidal gold (*e.g.*, for visualization purposes). Accordingly, the various elements of the claimed kit may cover the OraQuick technology. This application was filed in the US, EPO, and India.

Patent Family 41 is directed to a test strip for detecting a target in oral fluid. This patent family is assigned to **Beijing Calypte Biomedical Technology Ltd.** of China. These patents/publications are included because the claims recite that the test strip consists of several elements of the OraQuick technology, including (i) a conjugate pad, (ii) a test zone, and (iii) a control zone pad made of at least one matrix material; where the conjugate pad lies downstream of the sample pad, and is striped with a conjugate (for detection); where the test zone is immobilized with a specific binding reagent that specifically binds to the target analyte; and the control zone is immobilized with a capture reagent (for visualization). This application was filed in the US, EPO, China, India, Brazil, Mexico, and Russia. Notably, the only issued patent in this family is in China, and there are no pending US or EP cases. However, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 42 is directed to a device for the detection of a target in a fluid sample using lateral flow techniques. This patent family is assigned to **UNILEVER PLC** of Great Britain. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including (i) a labeled specific binding reagent for a target substance, (ii) which labeled specific binding reagent is mobile within a porous carrier when in the moist state; (iii) an immobilized binding partner positioned on the porous carrier. This application was filed in the US and EPO. Notably, the issued US and EP patents in this family are likely

expired, and there are no pending US or EP applications. However, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 43 is directed to a device for the detection of a target in a fluid sample using lateral flow technology. This patent family is assigned to **Biosite Diagnostics, Inc.** of the US. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including the use of lateral flow to detect a target substance in a liquid sample. This application was filed in the US and EPO. Notably, the issued US and EP patents in this family are likely expired, and there are no pending US or EP applications. However, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 44 is directed to a device for the detection of a target substance in a liquid. This patent family is assigned to **Unipath Ltd.** of Great Britain. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including (i) a test strip, (ii) a first signal that indicates the presence of a target substance, and (iii) a second (control) signal that indicates that the test is complete. This application was filed in the US and EPO. There are no pending applications in the US or EPO. However, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 45 is directed to a device for the detection of a target substance in a liquid. This patent family is assigned to **Inverness Medical Switzerland**, a predecessor of Alere Switzerland. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including that a liquid sample is exposed to a detection region, which indicates the presence of a target substance in the sample. This application was filed in the US, EPO, and China; however, no pending applications were identified in the US, EPO, or China. As noted in this chart, though, the status of related applications in other listed countries is unknown.

Patent Family 46 is directed to assays for detecting a target in a liquid sample using a series of immobilized binding elements. This patent family is assigned to **Inverness Medical Switzerland**, a predecessor of Alere Switzerland. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including various immobilized binding agents used to detect the presence of a target substance in a sample. This application was filed in the US, EPO, and China; however, no pending applications were identified in the US, EPO, or China. As noted in this chart, though, the status of related applications in other listed countries is unknown.

Patent Family 47 is directed to a lateral flow assay for detecting a target in a liquid sample. This patent family is assigned to **Alere Switzerland**. These patents/publications are included because sample claims recite that the device includes several elements they may be incorporated into the OraQuick device, including the use of lateral flow and an immobilized dye, which is used to detect a target substance in a sample. This technology is similar to the OraQuick device, but it is unclear whether the OraQuick device specifically uses the claimed dye element. This application was filed in the US, EPO, and China; however, no pending applications were identified in the US, and our search revealed no pending applications in this family. However, as noted in this chart, the status of related applications in other listed countries is unknown.

Patent Family 48 is directed to a device for detecting a substance in a liquid using lateral flow technology. This patent family is assigned to **Alere Switzerland**. These patents are included because sample claims recite that the device includes several elements they may be incorporated into the OraQuick device, including (i) a matrix that supports the flow of a liquid sample; (ii) an application zone on the matrix for receiving the liquid sample; (iii) one or more reagent zones on the matrix comprising reagents for conducting the assay; (iv) a detection zone on the matrix; and (v) the detection zone comprising an analyte binding area and a positive control area demarcated on the matrix. This application was filed in the US; however, no pending applications were identified in this family. As noted in this chart, though, the status of related applications in other listed countries is unknown.

Patent Family 49 is directed to a device for detecting a substance in a liquid using lateral flow technology. This patent family is assigned to **Oakville Honk Kong Co., Ltd.** of China. These patents are included because sample claims recite that the device includes several elements they may be incorporated into the OraQuick device, including (i) a matrix that supports the flow of a liquid sample; (ii) a sample application zone on the matrix for receiving a liquid sample; and (iii) a detection zone on the matrix. This application was filed in the US, EPO and China; however, no pending applications were identified in this family. As noted in this chart, though, the status of related applications in other listed countries is unknown.

Patent Family 50 is directed to a kit for detecting a substance in a liquid using lateral flow technology, wherein the components necessary for the assay are included in a single kit. This patent family is assigned to **Alere Switzerland**. The patent identified in this family is included because a sample claim recites that the device includes several elements they may be incorporated into the OraQuick device, including (i) a test strip; (ii) a sample receiving end; (iii) a receptacle containing a fluid reagent selected for extracting a specimen from a swab; and (iv) fluid communication between the receptacle and the test strip. Only one patent was identified in this family, in the US, and no pending applications were identified. As noted in this chart, though, the status of related applications in other listed countries is unknown.

Patent Family 51 is directed to an assay for detecting a substance in a liquid sample. This patent family is assigned to **Inverness Medical Switzerland**, a predecessor of Alere Switzerland. These patents/publications are included because sample claims recite that the device includes several elements of the OraQuick technology, including (i) labeling a target substance in provided reagent, and (ii) a detection zone downstream from the reagent. This application was filed in the US and China; however, no pending US applications were identified. As noted in this chart, though, the status of related applications in other listed countries is unknown.

Patent Family 52 is directed to a lateral flow test strip. The lone US patent identified in this family is assigned to **OraSure Technologies, Inc.** of the US. This patent is included because a sample claim recites that the device includes several elements of the OraQuick technology, including (i) a sample receiving area that includes a sample pad, and (ii) two or more analyte capture zones. Because this patent is assigned to OraSure, it is possible that the OraQuick device uses this technology. Although only one US patent was identified in this family, the existence of related applications in other listed countries is unknown.

V. Further Considerations

This landscape document should be considered an initial step in determining the relevant IP landscape for the three devices and their cartridges. There relevancy of any particular patent will depend on where any particular diagnostic device will be made, used, and sold. Further, the relevancy of any patent family will also vary depending on the specific design aspects of any diagnostic device. Additional, more targeted searching should be conducted before an interested party engages in any strategy to make, use, sell, offer for sale, or import any of the devices or their consumable parts.

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All patent data contained in the report were last updated in August 2017.

Patent Landscape for GeneXpert and AlereQ Systems

Patent	Patent Family 1	Patent Family 2	Patent Family 3
Title	METHODS AND SYSTEMS FOR NUCLEIC ACID AMPLIFICATION	ASSAYS	DEVICE AND PROCESS FOR ASSAYS USING BINDING MEMBERS
Applicant	COYOTE BIOSCIENCE CO., LTD. (CN)	CLONDIAG GMBH (DE)	CLONDIAG GMBH (DE)
International PCT Application Publication No.	PCT/CN2013/090425 WO/2015/096063 A1[1] PCT/CN2014/094914 WO/2015/096763 A1[2]	PCT/EP2008/059670 WO/2009/013321	PCT/EP2007/061953 WO/2008/055915
Expected Expiration[1]	[1]Dec. 25, 2033 [2]Dec. 25, 2034	Jul. 23, 2028	Nov. 6, 2027
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to methods of amplifying a target RNA present in a sample obtained directly from a person. The published PCT applications are included because example claims specify that the claimed method includes several key elements of the GeneXpert and AlereQ technologies, including (i) a reaction vessel that includes the sample and the necessary reagents for amplifying target RNA and (ii) running the amplification. Because the language of these claims are broad, these claims may cover the methods used in the GeneXpert and AlereQ technologies.	The published applications in this family are directed to a detection device that may be related to or encompassing the Alere device, as this family is owned by the Alere predecessor, Clondiag. In particular, the claimed devices includes means for releasing DNA or RNA from a cell, means for amplification of the DNA or RNA, and means for detecting the amplified product. This family is very similar to the WO/2008/055915 family, below.	The published applications in this family are directed to a detection device that may be related to or encompassing the Alere device, as this family is owned by the Alere predecessor, Clondiag. In particular, the claimed devices includes means for releasing DNA or RNA from a cell, means for amplification of the DNA or RNA, and means for detecting the amplified product. This family is very similar to the WO/2009/013321 family, above.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A method of amplifying a target ribonucleic acid (RNA) present in a biological sample obtained directly from a subject, comprising: (a) providing a reaction vessel comprising said biological sample and reagents necessary for conducting reverse transcription amplification in parallel with deoxyribonucleic acid (DNA) amplification, said reagents comprising (i) a reverse transcriptase, (ii) a DNA polymerase, and (iii) a primer set for said target RNA, to obtain a reaction	1. A device, comprising (a) a rigid substrate; (b) a flexible cover element at least partially covering the substrate; (c) a first structure formed in the substrate, adapted for accommodating liquids and adapted for releasing contents of one or more cells, spores, or viruses, the contents including target molecules; (d) a second structure formed in the substrate, adapted for accommodating liquids and comprising at least one binding member adapted for capturing the target	1. A device, comprising (a) a rigid substrate; (b) a flexible cover element at least partially covering the substrate; (c) a first structure formed in the substrate, adapted for accommodating liquids and adapted for releasing contents of one or more cells, spores, or viruses, the contents including target molecules; (d) a second structure formed in the substrate, adapted for accommodating liquids and comprising at least one binding member adapted for capturing the target

Patent	Patent Family 1	Patent Family 2	Patent Family 3
	mixture; and (b) subjecting said reaction mixture in said reaction vessel to multiple cycles of a primer extension reaction to generate amplified DNA product that is indicative of the presence of said target RNA, each cycle comprising (i) incubating said reaction mixture at a denaturing temperature for a denaturing duration that is less than or equal to 60 seconds, followed by (ii) incubating said reaction mixture at an elongation temperature for an elongation duration that is less than or equal to 60 seconds, thereby amplifying said target RNA.	molecules and for determining a value indicative for the presence and/or amount of the target molecules; (e) a microfluidic network interconnecting at least the first structure and the second structure; (f) an actuator unit adapted for effecting a fluid flow between the first structure and the second structure by pressing the flexible cover element against the substrate to selectively close a portion of the microfluidic network. 2. A device, comprising (a) a structure adapted for accommodating liquids, wherein the structure comprises at least one binding member and is in fluid communication with a microfluidic network; (b) a control unit adapted for controlling a fluid flow through the microfluidic network in such a manner that target molecules are captured at the at least one binding member, adapted for controlling an amplification of the target molecules in the structure, and adapted for controlling detection of compounds captured at the at least one binding member.	molecules and for determining a value indicative of the presence and/or amount of the target molecules; (e) a microfluidic network interconnecting at least the first structure and the second structure; (f) an actuator unit adapted for effecting a fluid flow between the first structure and the second structure by pressing the flexible cover element against the substrate to selectively close a portion of the microfluidic network. 2. A device, comprising (a) a structure adapted for accommodating liquids, wherein the structure comprises at least one binding member and is in fluid communication with a microfluidic network; (b) a control unit adapted for controlling a fluid flow through the microfluidic network in such a manner that target molecules are captured at the at least one binding member, adapted for controlling an amplification of the target molecules in the structure, and adapted for controlling detection of compounds captured at the at least one binding member.
International Patents and Published Applications (Status)			
United States	US 9,546,389 B2 (Issued Jan. 17, 2017; Expires Dec. 25, 2033) No US cases pending in this family.	US 2010/255473 A1 (Allowed Jun 29, 2017)	US 8,846,313 B2 (Issued Sept. 30, 2014; Expires Apr. 2, 2030, including 878 days of patent term adjustment) US 2015/197822 A1 (Examination in Progress)

Patent	Patent Family 1	Patent Family 2	Patent Family 3
European Patent Office[2]	EP 3087205 A4 (Examination in Progress)	EP 2188054 B1 (Issued Mar. 8, 2017; Likely Expires Jul. 23, 2028) EP 2610007 A1 (Examination in Progress) EP 2612708 A1 (Examination in Progress) EP 2626434 A1 (Examination in Progress) EP 2647432 A1 (Examination in Progress)	EP 2061588 B1 (Issued Jul. 13, 2016; Likely Expires Nov. 6, 2027) EP 2644272 B1 (Issued Apr. 20, 2016; Likely Expires Nov. 6, 2027) EP 2674217 A3 (Examination in Progress)
China	CN 105121663 A (Status Unknown)	CN 101848765 B (Issued Mar. 9, 2016; Likely Expires Jul. 23, 2028) CN 105543084 A (Examination in Progress)	CN 101553306 B (Issued Apr. 4, 2013; Likely Expires Nov. 6, 2027) CN 103173346 B (Issued Apr. 19, 2017; Likely Expires Nov. 6, 2027) CN 103497991 A (Examination in Progress) CN 105925696 A (Examination in Progress)
India	*No Publication Identified*	IN 731/DELNP/2010 (Pending)	IN 3236/DELNP/2009 (Pending)
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	BR PI0814582 A2 (Status Unknown)	BR PI0718561 A2 (Status Unknown)
African Regional Intellectual	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 1	Patent Family 2	Patent Family 3
Property Organization (ARIPO)[3]			
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	MX 2016008447 A (Status Unknown)	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 4	Patent Family 5	Patent Family 6
Title	APPARATUS FOR INTEGRATED REAL-TIME NUCLEIC ACID ANALYSIS AND METHOD FOR DETECTING A TARGET NUCLEIC ACID USING THE SAME	SYSTEM AND METHOD FOR DIAGNOSIS OF INFECTIOUS DISEASES	SYSTEMS AND METHODS FOR MOBILE DEVICE ANALYSIS OF NUCLEIC ACIDS AND PROTEINS
Applicant	BIONEER CORPORATION (KR)	MICRONICS, INC. (US)	NANOBIOSYM, INC. (US)
International PCT Application Publication No.	PCT/KR2010/001530 WO/2010/104345 A2	PCT/US2007/006521 WO/2007/106552 A2	PCT/US2014/029008 WO/2014/144548 A2
Expected Expiration[1]	Mar. 11, 2030	Mar. 14, 2027	Mar. 14, 2034
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a device capable of detecting a target nucleic acid in a biological sample. The published PCT application is included because representative claims recite that the device includes several key elements of the GeneXpert and AlereQ technologies, including (i) automated purification, (ii) nucleic acid amplification, and (iii) measuring amplified target nucleic acids. Though other elements of the apparatus are listed, it is unclear whether the GeneXpert and AlereQ technologies also include these other features, based on the manufactures' websites, and thus the patents and publications in this family may be relevant.	The patents and published applications in this family are directed to a device for detecting a target nucleic acid in a sample. The published PCT application is included because representative claims recite that the system includes several key elements of the GeneXpert and AlereQ technologies, including a sample collection component and a cartridge for receiving the collection component, as well as means for (i) extraction, (ii) amplification, (iii) and detection of amplified target nucleic acids. The assignee of this family is also listed as the assignee of WO 2004/065010, WO 2007/106579 A2, and WO 2011/094577 A2, each of which is also included in this chart.	The patents and published applications in this family are directed to a system for rapid analysis of biological samples. The published PCT application is included because representative claims recite that the system includes several key elements of the GeneXpert and AlereQ technologies, including (i) a mobile device that receives an integrated chip (*e.g.*, a cartridge), wherein the device controls a fluidic system in the chip; and (ii) wherein the chip includes elements for nucleic acid extraction, amplification, and detection.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An apparatus for integrated real-time nucleic acid analysis, for simultaneously performing qualitative analysis or quantitative analysis of target nucleic acids corresponding to various kinds of biological samples, . . . comprising: a plurality of automated purification and dispensation instruments . . . ; a real-time nucleic acid amplifier . . . , and real-time measuring the quantity of different kinds of target nucleic acids obtained by the plurality of automated purification and dispensation instruments 100; a controller assigning multiple wells on the temperature circulation block 210 of the real-time nucleic acid amplifier 200 by the	1. A biosafe system for assaying a target nucleic acid in a biosample, the system comprising: a) A two-piece sample carrier comprising a swab for collecting a sample to be tested . . . ; b) A disposable microfluidic cartridge with external surfaces, with internal works, and with docking means for receiving said two-piece sample carrier, the microfluidic cartridge further comprising a bridging manifold with first fluidic channel in fluidic connection with a sample receiving receptacle, a means for sealingly accepting the tubular nose of said sample carrier in said sample receiving receptacle, a means for fluidically joining said first	1. A system for rapid analysis of biological samples, comprising: a mobile device that receives at least one integrated chip; the mobile device processing the integrated chip to analyze a biological sample loaded thereon; the mobile device and the integrated chip together being configured to perform at least one of manipulation and control of a molecule or a fluidic system on the integrated chip; and wherein the mobile device and integrated chip together are configured to precision control at least one parameter that governs at least one of a plurality of steps of the analysis of the biological sample to within plus or minus 10%, plus

Patent	Patent Family 4	Patent Family 5	Patent Family 6
	column unit, according to kinds of the target nucleic acids, . . . storing information on the biological samples from the automated purification and dispensation instruments 100 correspondingly to the respective wells assigned by the column unit, performing simultaneous amplification under the same condition of the temperature circulation block, and performing integrated management such that amplification results, by which the respective target nucleic acids are qualitatively and quantitatively analyzed, corresponds to the respective biological samples subjected to separation and purification by the automated purification and dispensation instruments 100; and a display unit 300 real-time outputting qualitative or quantitative analysis results from the controller.	fluidic channel to said sample carrier, valve means for introducing and withdrawing lysis reagent to and from said compartment, a means for extracting a target nucleic acid from a sample lysate, a means for eluting a target nucleic acid, an amplification chamber and stirrer means for amplifying a nucleic acid in a sample eluate, a lightpath through said chamber for detecting an amplification product by optical detection means; and, c) A control platform instrument with microprocessing means for sealedly engaging and controlling said internal works of said microfluidic cartridge, . . . , and detection means for reading and displaying an assay result; and further, d) Wherein said means for sealingly accepting the tubular nose of said sample carrier in said sample receiving receptacle . . . are configured to isolate said nasal swab, internal works of said microfluidic cartridge, external surfaces, and instrument, from forward and reverse contamination.	or minus 1%, plus or minus 0.1%, plus or minus 0.01 %, plus or minus 0.001%o or plus or minus 0.0001 %. 2. The system of Claim 1, wherein the mobile device comprises a portable control assembly that receives the at least one compact integrated chip, the integrated chip comprising: an extraction module; optionally a nucleic acid amplification module, in fluid communication with the extraction module; and a biological sample detection module, in fluid communication with the nucleic acid amplification module or extraction module, said portable control assembly processing the integrated chip to analyze a biological sample loaded thereon by employing: an extraction control module; a nucleic acid amplification control module operably connected to the extraction control module; and a biological sample detection control module operably connected with the nucleic acid amplification module and the extraction module.
International Patents and Published Applications (Status)			
United States	US 2012/0135394 A1 (Pending)	US 2009/0061450 A1 (Abandoned)No US cases pending in this family.	US 2014/335527 A1 (Pending) US 2016/0016171 A1 (Pending)
European Patent Office[2]	EP 2407557 A2 (Examination in Progress)	*No Publication Identified*	EP 2969218 A2 (Examination in Progress)
China	CN 102388148 A (Examination in Progress)	*No Publication Identified*	CN 105142789 A (Examination in Progress)
India	1870/MUMNP/2011 (Pending)	*No Publication Identified*	9509/DELNP/2015 (Pending)
South Africa	*No Publication Identified*	*No Publication Identified*	(i) ZA 2015/07527 *(ii)* (Pending)

Patent	Patent Family 4	Patent Family 5	Patent Family 6
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	(iii) MX 2015012031 A (Status Unknown)
Russia	RU 2011141128 A (Status Unknown)	*No Publication Identified*	(iv) RU 2015144109 A (Status Unknown)
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 7	Patent Family 8	Patent Family 9
Title	METHOD AND SYSTEM FOR MICROFLUIDIC MANIPULATION, AMPLIFICATION AND ANALYSIS OF FLUIDS, FOR EXAMPLE, BACTERIA ASSAYS AND ANTIGLOBULIN TESTING	METHOD FOR RAPID THERMAL CYCLING OF BIOLOGICAL SAMPLES	METHOD FOR QUANTIFICATION OF AN ANALYTE
Applicant	MICRONICS INC. (US)	UNIV. OF UTAH RESEARCH FOUNDATION (US) (*Based on Int'l Appl.*)	ROCHE DIAGNOSTICS GMBH (DE) (*Based on EP Publication*)
International PCT Application Publication No.	PCT/US2004/001639 WO/2004/065010 A2	PCT/US1997/009620 WO/97/46707 A2 (Expired) PCT/US1997/009856 WO/97/46712 A2 (Expired) PCT/US1997/010008 WO/97/46714 A1 (Expired)	N/A
Expected Expiration[1]	Jan. 21, 2024	June 4, 2017	N/A
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a method for microfluidic analysis of a fluid sample. The published PCT application is included because representative claims recite that the method includes several key elements of the GeneXpert and AlereQ technologies, including loading a card (*e.g.*, a cartridge) with a sample, extracting components (*e.g.*, nucleic acids) from the sample, amplifying a target (*e.g.*, a nucleic acid), and detecting the amplified target. The assignee of this family is also listed as the assignee of WO 2007/106552 A2, WO 2007/106579 A2, and WO 2011/094577 A2, each of which is also included in this chart.	The patents and published applications in this family are directed to a method of rapid thermal cycling (*e.g.*, PCR amplification). The published US patent is included because representative claims recite a PCR method that could broadly cover the PCR methods used by the GeneXpert and AlereQ technologies. Notably, all US and EP patents in this family have expired; however, as noted in this chart, the status of related applications in other listed countries is unknown.	The patents and published applications in this family are directed to a method for determining the concentration of a nucleic acid in a sample. The published US patent is included because sample claims broadly recite a method that includes amplifying a nucleic acid and measuring the amount of the amplified nucleic acid in real time (e.g., as part of a single process). This method is commonly referred to as real-time PCR (RT-PCR) or quantitative PCR (qPCR); and the GeneXpert and AlereQ technologies appear to use a form of this method.

Patent	Patent Family 7	Patent Family 8	Patent Family 9
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A method for microfluidic analysis of a fluid sample, comprising: loading a microfluidic card with a fluid sample; lysing the fluid sample to separate components of the fluid sample; capturing the separated components on a solid substrate; washing the separated components with wash buffers; amplifying the washed components in an the amplification chamber to an amplification temperature profile; and pumping the amplified components over a lateral flow strip for detection.	1. A method of subjecting a sample to rapid thermal cycling, said method comprising: a) contacting a sample holder containing a sample with heated fluid, thereby raising the temperature of the sample to a first temperature, and holding the sample at about said first temperature for a first predetermined period of time; b) contacting the sample holder with non-heated fluid, thereby lowering the temperature of the sample to a second temperature, an holding the sample at about said second temperature for a second predetermined period of time; c) contacting the sample holder with heated fluid, thereby raising the temperature of the sample to a third temperature, and holding the sample at about said third temperature for a third predetermined period of time; wherein steps a) through c) are completed within a time range of about 30 seconds to 60 seconds and repeated at least one time; and wherein said sample holder has a thermal mass which provides for completing said cycle within said time range. (*US 6,787,338 B1, below*)	1. A method for quantification of the concentration of a nucleic acid in a nucleic acid sample, comprising the steps of: a) contacting said nucleic acid sample with an amplifying agent; b) amplifying at least one predetermined locus of the nucleic acid in said nucleic acid sample by a process comprising the step of subjecting the sample to a number of amplification cycles to create a nucleic acid amplification product; c) determining a value proportional to the amount of the nucleic acid amplification product present at each amplification cycle and using the values to generate a function; d) calculating the first, second or n^{th} order derivative of said function, wherein n is a positive integer; e) determining a fractional cycle number corresponding to a maximum or minimum of said derivative; and f) calculating from said maximum or minimum an initial concentration of the nucleic acid in said nucleic acid sample. (*US 6,503,720 B1, below*)
International Patents and Published Applications (Status)			
United States	US 7,416,892 B2 (Issued Aug. 26, 2008; Expires Feb. 28, 2026) No US cases pending in this family.	US 6,787,338 B1 (Expired) US 6,174,670 B1 (Expired)	US 6,503,720 B2 (Issued Jan. 7, 2003; Expires Mar. 30, 2019) US 6,303,305 B1 (Issued Oct. 16, 2001; Expires Mar. 30, 2019)
European Patent Office[2]	EP 1592505 A2 (Withdrawn) No EP cases pending in this family.	EP 0906449 B1 (Issued Mar. 3, 2004; Likely Expired) EP 0912760 B1 (Likely Expired)	EP 1041158 B1 (Issued Oct. 12, 2005; Likely Expires Mar. 25, 2020) No EP cases pending in this family.

Patent	Patent Family 7	Patent Family 8	Patent Family 9
		EP 0912766 B2 (Likely Expired) EP 1033411 B1 (Likely Expired) EP 1179600 B1 (Likely Expired) EP 1442794 B1 (Likely Expired) EP 1493826 B1 (Likely Expired) EP 1674585 B1 (Likely Expired) EP 1704922 A3 (Withdrawn) EP 2298931 B1 (Likely Expired) No EP cases pending in this family.	
China	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
India	1405/KOLNP/2005 (Withdrawn) No IN cases pending in this family.	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 7	Patent Family 8	Patent Family 9
Organization (ARIPO)[3]			
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 10	Patent Family 11	Patent Family 12
Title	INSTRUMENT FOR MONITORING NUCLEIC ACID AMPLIFICATION	APPARATUS WITH HETEROGENEOUS PROCESSING MODULES	COMPOSITIONS AND METHODS ENABLING A TOTALLY INTERNALLY CONTROLLED AMPLIFICATION REACTION
Applicant	APPLIED BIOSYSTEMS, LLC (US)	CEPHEID (US)	CEPHEID (US)
International PCT Application Publication No.	N/A	PCT/US2013/038210 WO/2013/163424 A1	PCT/US2001/046875 WO/02/052030 A2
Expected Expiration[1]	N/A	Apr. 25, 2033	Dec. 4, 2021
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a PCR device. The U.S. patent is included because representative claims are directed to an instrument capable of performing real time PCT (RT-PCR), and the GeneXpert and AlereQ technologies appear to use a form of this method. Notably, all US and EP patents in this family have likely expired; however, as noted in this chart, the status of related applications in other listed countries is unknown.	The published applications in this family are directed to the modular aspects of the Cepheid device, wherein a single device can accept multiple cartridges.	The patents and published applications in this family, which are assigned to Cepheid, are directed to methods of performing PCR. Because the Cepheid device relies on a PCR, the methods of these patents and applications may be used in the Cepheid device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An instrument for use in monitoring a nucleic acid amplification reaction comprising multiple thermal cycles, comprising: (a) an automated thermal cycler capable of alternately heating and cooling, and adapted to receive, at least one reaction vessel containing an amplification reaction mixture comprising a target nucleic acid, reagents for nucleic acid amplification, and a detectable nucleic acid binding agent; and (b) a detector operable to detect a fluorescence optical signal while the amplification reaction is in progress and without opening the at least one reaction vessel, which fluorescence optical signal is related to the amount of amplified nucleic acid in the reaction vessel. (*US 6,814,934 B1, below*)	1. A biological sample processing apparatus comprising: an enclosure; a plurality of sample processing modules held by the enclosure, each sample processing module configured to hold a removable sample cartridge and to only perform sample processing on a sample within the corresponding removable sample cartridge; each sample processing module configured to perform at least one of a plurality of testing processes on the sample within the removable sample cartridge, wherein at least one module in the apparatus is configured to perform nucleic acid amplification and detection, wherein at least one module in the apparatus is a sample preparation module configured to only perform sample preparation.	1. A method of performing an amplification reaction, comprising: (a) combining in an aqueous solution: (i) a target probe, a first control probe and a second control probe; (ii) a first 5' primer, a first 3 ' primer and a target template, the target template comprising a hybridization site for the first 5' primer, the first 3' primer and the target probe; (iii) a first control template, the first control template comprising a hybridization site for the first 5' primer, the first 3' primer and the first control probe; and (iv) a second 5' primer, a second 3' primer and a second control template, the second control template comprising a hybridization site for the second 5' primer, the second 3' primer, the target probe and a second control probe; (b) performing an amplification reaction to create amplification products; and (c) quantifying binding of

Patent	Patent Family 10	Patent Family 11	Patent Family 12
			the target probe, first control probe and second control probe to the amplification products.
International Patents and Published Applications (Status)			
United States	US 6,814,934 B1 (Expired) US 5,994,056 (Expired) US 6,171,785 B1 (Expired) No US cases pending in this family.	US 2015/0119268 A1 (Examination in Progress)	US 6,312,929 B1 (Issued Nov. 6, 2001; Expires Dec. 22, 2020) US 6,534,645 B2 (Issued Mar. 18, 2003; Expires Dec. 22, 2020) No US cases pending in this family.
European Patent Office[2]	EP 0512334 B1 (Likely Expired) EP 0872562 B2 (Likely Expired) EP 1256631 A1 (Likely Expired) No EP cases pending in this family.	EP 2841600 A1 (Examination in Progress)	EP 1352091 B1 (Likely Expires Dec. 4, 2021) No EP cases pending in this family.
China	*No Publication Identified*	CN104321442 (A) (Pending)	*No Publication Identified*
India	*No Publication Identified*	IN 9340/DELNP/2014 (A) (Pending)	*No Publication Identified*
South Africa	ZA 9202990 A (Likely Expired) No ZA cases pending in this family.	ZA Appl. No. 2014/07770 (Pending)	*No Publication Identified*
Brazil	BR 9201618 A (Likely Expired)	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 10	Patent Family 11	Patent Family 12
	No BR cases pending in this family.		
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	MX 2014012831 A (Status Unknown)	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 13	Patent Family 14	Patent Family 15
Title	DOCKING MECHANISM FOR A SENSOR CARTRIDGE	METHOD AND DEVICE FOR SAMPLE PREPARATION CONTROL	DEVICE FOR DETECTING ANALYTES IN FLUID SAMPLES
Applicant	AKUBIO LIMITED (US cases are assigned to INVERNESS MEDICAL SWITZERLAND GMBH)	CEPHEID (US)	INVERNESS MEDICAL SWITZERLAND GMBH (CH) (US and EP cases are assigned to Alere)
International PCT Application Publication No.	PCT/GB2006/001164 WO/2006/103440 A2	PCT/US2005/013897 WO/2005/106040 A2	PCT/GB2006/003910 WO/2007/049010 A1
Expected Expiration[1]	Mar. 31, 2026	Apr. 22, 2025	Oct. 20, 2026
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a docking mechanism for receiving a cartridge. The cartridge is for use in analyzing a fluid sample. The US assignee, Inverness Switzerland, is a predecessor of Alere Switzerland. Accordingly, it is possible that the claimed docking mechanism is used in the Alere device.	The published applications in this family, which are assigned to Cepheid, are directed to methods for preparing a sample for a PCR, wherein the sample can include cells, microorganisms, and viruses. The method includes use of a device that includes various chambers, including a lysing chamber and a reaction chamber. This method and the device used therein may be a part of the Cepheid device.	The patents and published applications in this family are directed to a device for detecting an analyte in a liquid sample, wherein the device has multiple connected chambers. As this family is assigned to Alere in several countries, it is possible that the claimed device may be a part of the Alere device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A docking mechanism for releasably receiving a cartridge for use in analysing a sample comprising a fluid, the cartridge having a flow cell for the sample and an electrically operated sensor for performing said analysis, the docking mechanism comprising a clamping mechanism for urging fluid connector means against the cartridge to provide a fluid connection between the flow cell inlet and sample delivery means; the docking mechanism also comprising an electrical connector for engaging the sensor to connect the latter to electrical circuitry for operating the sensor, the electrical connector being movable, towards and away from the sensor, relative to the clamping mechanism, so that, in use, the electrical connector exerts on the sensor a force which is sufficient to maintain the necessary electrical connection, whilst not being so great as to have a	1. A method for preparing a sample for a nucleic acid amplification reaction and for verifying the effectiveness of the sample preparation, the sample being suspected of containing target entities selected from the group consisting of cells, spores, microorganisms, and viruses, the target entities comprising at least one target nucleic acid sequence, the method comprising the steps of: (a) introducing the sample into a device having: (i) a mixing chamber for mixing the sample with sample preparation controls, the sample preparation controls being selected from the group consisting of cells, spores, microorganisms, and viruses, and the sample preparation controls comprising a marker nucleic acid sequence; (ii) a lysing chamber; and (iii) a reaction chamber; (b) mixing the sample with the sample preparation controls in the mixing chamber; (c) subjecting the sample preparation controls and the	1. A device for detecting the presence of an analyte in a liquid sample, comprising: an opening for introducing the liquid sample into a first chamber for collecting the liquid sample; a second chamber connected to the first chamber by a passageway and containing a test element; a third chamber connected to the second chamber by a channel and containing a movable member having first and second positions, the third chamber being divided by the movable member into first and second zones and the first zone comprising a vent hole; the movable member in contact with at least one wall of the third chamber to prevent gas communication between the first and second zones.

Patent	Patent Family 13	Patent Family 14	Patent Family 15
	substantial detrimental effect on the accuracy of the sensor.	target entities, if present in the sample, to a lysis treatment in the lysing chamber; (d) subjecting nucleic acid released in the lysing chamber to nucleic acid amplification conditions in the reaction chamber; and (e) detecting the presence or absence of the target nucleic acid sequence and of the marker nucleic acid sequence; whereby detection of the marker nucleic acid sequence indicates satisfactory sample preparation.	
International Patents and Published Applications (Status)			
United States	US 7,980,149 B2 (Issued Jul. 19, 2011; Expires Mar. 5, 2028) No US cases pending in this family.	US 2005/244837 A1 (Abandoned) US 2010/129827 A1 (Abandoned) No US cases pending in this family.	US 9,011,770 B2 (Issued Apr. 21, 2015; Expires Aug. 24, 2030) US 2009/308185 (A1) (Abandoned) No US cases pending in this family.
European Patent Office[2]	EP 1864120 B1 (Issued Nov. 30, 2011; Expires Mar. 31, 2026) No EP cases pending in this family.	EP 1740720 A2 (Withdrawn) No EP cases pending in this family.	EP 1963855 A1 (Examination in Progress)
China	*No Publication Identified*	CN 101124334 A (Withdrawn) No CN cases pending in this family.	CN 100478671 C (Issued Apr. 15, 2009; Likely Expires Oct. 20, 2026) No CN cases pending in this family.
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 13	Patent Family 14	Patent Family 15
Organization (ARIPO)[3]			
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 16	Patent Family 17	Patent Family 18
Title	REAGENT RESERVOIR SYSTEM FOR ANALYTICAL INSTRUMENTS	UNIVERSAL DOCKING BAY AND DATA DOOR IN A FLUIDIC ANALYSIS SYSTEM	REACTION VESSEL AND TEMPERATURE CONTROL SYSTEM
Applicant	CEPHEID (US)	CEPHEID (US)	CEPHEID (US)
International PCT Application Publication No.	N/A	PCT/US2013/058300 WO/2014/039703 A1	PCT/US2001/003310 WO/01/57253 A1
Expected Expiration[1]	N/A	Sept. 5, 2033	Jan. 31, 2021
Brief Summary and Reasons for Inclusion	The patents in this family are directed to a system for storing and then activating a dried reagent. Because this technology could be used in a PCR device, and because this family is assigned to Cepheid, it is possible that the claimed system is used in the Cepheid device.	The published applications in this family are directed to a loading system for a device, wherein cartridges can be inserted into the device. This technology appears to be related to the modular version of the Cepheid device, wherein a single device can accept multiple cartridges.	The patents and published applications in this family are directed to a component of a PCR device that may be a part of the Cepheid device. In particular, the claimed reaction vessel has various chambers and means for transporting fluid between the chambers; and, because the family is assigned to Cepheid, it is possible that this technology is included in the Cepheid device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A reagent reservoir system for storing and activating a dried reagent, the system comprising: a) a chamber, which has a longitudinal axis, a fluid port, an exhaust port, and a retaining member; and b) the dried reagent, which is disposed in a reagent holding end of the chamber, wherein, the fluid port is disposed at the reagent holding end of the chamber, the retaining member is movably disposed in the chamber between the exhaust port and the dried reagent and is sized such that space between the interior of the chamber and the retaining member is smaller than the dried reagent, obstructing passage of the dried reagent from the reagent holding end toward the opposite end of the chamber. (*US 8,187,557 B2, below*)	1. An analytic system, comprising: a bay having an opening on one side, the bay of a size and shape to enclose a cartridge carrying sample material to be analyzed; one or more mechanisms within the bay through which the cartridge and or material within the cartridge can be influenced; a door of a size to cover the opening; a latch mechanism associated with the bay and the door, by which the door is latched when closed; and an imaging device incorporated in the door positioned and directed such that, with the door in an open position, the imaging device is capable of imaging presence or absence of a cartridge and a visible indicia affixed on a surface of a cartridge in place in the bay.	1. A system for loading a sample into a reaction vessel and for controlling the temperature of the sample in the vessel, wherein the vessel includes a reaction chamber, a loading reservoir in fluid communication with the chamber, and an aspiration port in fluid communication with the chamber, the system comprising: (a) an aspiration and dispensing device for dispensing the sample into the loading reservoir, for establishing a seal with the aspiration port, and for drawing the sample from the loading reservoir into the chamber; (b) at least one thermal surface for contacting a wall of the chamber; (c) means for increasing the pressure in the chamber, wherein the pressure increase in the chamber is sufficient to force the wall to conform to the thermal surface; and (d) at least one thermal element for heating or cooling the surface to induce a temperature change within the chamber.

Patent	Patent Family 16	Patent Family 17	Patent Family 18
International Patents and Published Applications (Status)			
United States	US 8,187,557 B2 (Issued May 29, 2012; Expires Jan. 5, 2029) US 8,758,701 B2 (Issued June 24, 2014; Expires Jul. 13, 2026) US 9,057,674 B2 (Issued June 16, 2015; Expires Jul. 13, 2026) No US cases pending in this family.	US 2014/0098252 A1 (Pending)	US 6,403,037 B1 (Issued June 11, 2002; Expires Feb. 4, 2020) US 7,101,509 B2 (Issued Sept. 5, 2006; Expires Feb. 4, 2020) No US cases pending in this family.
European Patent Office[2]	*No Publication Identified*	EP 2893356 A1 (Examination in Progress)	*No Publication Identified*
China	*No Publication Identified*	CN 104737024 A (Examination in Progress)	*No Publication Identified*
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 16	Patent Family 17	Patent Family 18
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 19
Title	IMPROVEMENTS IN OR RELATING TO READING OF ASSAYS
Applicant	ALERE SWITZERLAND GMBH (CH)
International PCT Application Publication No.	PCT/GB2012/052430 WO/2013/061026 A1
Expected Expiration[1]	Oct. 2, 2032
Brief Summary and Reasons for Inclusion	The published applications in this family are directed to a component of a detection device that may be a part of the Alere device. In particular, the claimed apparatus comprises a unit that detects the amount of light reflected by a substance to determine the amount of a target in the substance. Because the family is assigned to Alere, it is possible that this technology is included in the Alere device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An assay result reading apparatus for use with an assay in which a detectable substance tends to accumulate within a detection zone of the assay, the reading apparatus comprising: a housing or baffle, having a window therein; a light source which emits light through the window so as to illuminate the detection zone of the assay; and a light detector to detect the amount of light reflected and/or transmitted by the detection zone, which amount is at least partly dependent on the amount of detectable substance accumulated in the detection zone; wherein the shape of the window is adapted to render the reading apparatus less sensitive, preferably insensitive, to minor mis-positioning of the detection zone, relative to one or more of the window, the light source and the light detector.
International Patents and Published Applications (Status)	

Patent	Patent Family 19
United States	US 9,719,934 B2 (Issued Aug. 1, 2017; Expires May 18, 2033) No US cases pending in this family.
European Patent Office[2]	EP 2771674 A1 (Examination in Progress)
China	CN 103857998 B (Issued May 17, 2017; Likely Expires Oct. 2, 2032) No CN cases pending in this family.
India	*No Publication Identified*
South Africa	*No Publication Identified*
Brazil	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*
Mexico	*No Publication Identified*
Russia	*No Publication Identified*
Indonesia	*No Publication Identified*
Nigeria	*No Publication Identified*

Patent Landscape for GeneXpert and AlereQ Cartridges

Patent	Patent Family 20	Patent Family 21	Patent Family 22
Title	MOLECULAR DIAGNOSTICS SYSTEM AND METHODS	POINT OF CARE POLYMERASE CHAIN REACTION DEVICE FOR DISEASE DETECTION	ROTARY CAM VALVE
Applicant	I-STAT CORPORATION (US)	ADVANCED THERANOSTICS INC. (CA)	WELCH ALLYN, INC. (US)
International PCT Application Publication No.	PCT/US2005/046772 WO/2006/071770 A8	PCT/CA2015/050648 WO/2016/004539 A1	PCT/US2005/039786 WO/2006/052652 A2
Expected Expiration[1]	Dec. 21, 2025	Jul. 10, 2035	Nov. 4, 2025
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a PCR device. The published PCT application is included because sample claims recite that the device includes several key elements of the GeneXpert and AlereQ technologies, including means for nucleic acid extraction, amplification, and detection, all contained in a single device.	The patents and published applications in this family are directed to a point-of-care device for detecting a target nucleic acid. The published PCT application is included because sample claims recite that the device includes several key elements of the GeneXpert and AlereQ technologies, including nucleic acid extraction, amplification, and detection, all contained in a single device.	The patents and published applications in this family are directed to a device that includes a diagnostic card that is capable of running an assay for the rapid detection of one or more pathogens in a sample. The published PCT application is included because sample claims recite that the apparatus includes several key elements of the GeneXpert and AlereQ technologies, including nucleic acid extraction, amplification, and detection, all contained in a single device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An integrated single-use device for performing a nucleic acid analysis, comprising: a housing, an entry port for accepting a sample suspected of containing a target nucleic acid, a first chamber operably connected to the entry port containing a reagent for extracting the target nucleic acid, a first conduit permitting passage of extracted nucleic acid into an amplification chamber, said housing containing an amplification reagent that is capable of incorporating a detectable label into an amplified nucleic acid target, the amplification chamber having a heating means and a temperature sensing means for controlling amplification conditions, the amplification chamber being operably linked to a second conduit containing a sensing region with an immobilized capture oligonucleotide, said housing containing a means for	1. A point-of-care device for detecting a target nucleic acid comprising: an extraction chamber adapted to receive a biological sample, wherein said extraction chamber comprises means to extract and lyse the sample to release nucleic acid; a first amplification chamber in communication with the extraction chamber, wherein said amplification chamber comprises means to trigger nucleic acid amplification of a target nucleic acid sequence to occur; and a detection chamber in communication with the amplification chamber, wherein said detection chamber comprises means to detectably label the target nucleic acid and means to detect a signal associated with labeled target nucleic acid.	1. An apparatus comprising: a diagnostic card configured to enable at least one nucleic acid diagnostic assay for rapidly detecting the presence or absence of multiple pathogens at the point-of-care. 6. The apparatus of claim 1 wherein said nucleic acid assays include an amplification phase. 7. The apparatus of claim 6 wherein said amplification phase comprises polymerase chain reaction. 14. The apparatus of claim 1 wherein at least one reagent for said assays is contained on board said card.

Patent	Patent Family 20	Patent Family 21	Patent Family 22
	moving the amplified target to the sensing region to permit binding of said amplified target to said capture oligonucleotide, said second conduit operably attached to a holding chamber containing a fluid able to substantially displace uncaptured amplified target from the sensing region and permitting sensing of said detectable label retained in said sensing region.		15. The apparatus of claim 14 wherein said at least one reagent is selected from the group consisting of a lysis reagent, an elution reagent, a rehydrating fluid, a pumping fluid, drying reagents, and polymerase chain reaction reagents.
International Patents and Published Applications (Status)			
United States	US 2015/0064707 A1 (Pending; pending claims directed to a device require magnetic beads)	US 2017/0173585 A1 (Pending)	US 2006/094028 A1 (Abandoned) US 2006/0178568 A1 (Abandoned)No US cases pending in this family.
European Patent Office[2]	EP 1871527 A2 (Allowed; pending claims require magnetic beads)	EP 3167045 A1 (Pending)	EP 1807541 A2 (Withdrawn) No EP cases pending in this family.
China	*No Publication Identified*	CN106715673 A (Status Unknown)	CN 101374959 A (Withdrawn) No CN cases pending in this family.
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 20	Patent Family 21	Patent Family 22
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 23	Patent Family 24	Patent Family 25
Title	INTEGRATED NUCLEIC ACID ASSAYS	SAMPLE-TO-ANSWER MICROFLUIDIC CARTRIDGE	MICROCHIP MATRIX DEVICE FOR DUPLICATING AND CHARACTERIZING NUCLEIC ACIDS
Applicant	MICRONICS INC. (US)	MICRONICS, INC. (US)	CLONDIAG CHIP TECHNOLOGIES GMBH (DE)
International PCT Application Publication No.	PCT/US2007/006584 WO/2007/106579 A2	PCT/US2011/022973 WO/2011/094577 A2	PCT/EP2000/006103 WO/2001/002094 A1
Expected Expiration[1]	Mar. 15, 2027	Jan. 28, 2011	June 30, 2020
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a cartridge that can be used for the detection of target nucleic acids in a sample. The published PCT application is included because sample claims recite that the cartridge includes several key elements of the GeneXpert and AlereQ technologies, including extraction, amplification, and detection of target nucleic acids, wherein all the necessary components are contained in a single unit. The assignee of this family is also listed as the assignee of WO 2007/106552 A2, WO 2004/065010, and WO 2011/094577 A2, each of which is also included in this chart.	The patents and published applications in this family are directed to a cartridge for detecting a target in a sample. The published PCT application is included because sample claims recite that the cartridge includes several elements, such as fluidic circuits and pumps, which may be used in one or both of the GeneXpert and AlereQ technologies. The assignee of this family is also listed as the assignee of WO 2007/106552 A2, WO 2007/106579 A2, and WO 2004/065010, each of which is also included in this chart.	The published applications in this family are directed to microchip that can be used to amplify a DNA or RNA target and detect the amplified product. This technology may be a part of the Alere device, specifically an Alere cartridge, as this family is owned by the Alere predecessor, Clondiag.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A microfluidic cartridge for performing a bioassay, comprising: a. A fluidic subcircuit for extracting nucleic acids from a biosample; b. a fluidic subcircuit for synthesizing amplicons; c. a fluidic subcircuit with means for detecting amplicons; and, wherein said fluidic subcircuits are formed in a single integrated member.	1. A microfluidic cartridge for assay of a target analyte or analytes in a biological sample, which comprises: a) a plastic, thermally insulative cartridge body enclosing: i) a hydraulic works . . . , one or more on-board liquid or dry reagents for an assay, and a wettable downstream microfluidic subcircuit . . . ; and ii) a pneumatic works . . . ; and b) at least one pneumohydraulic diaphragm . . . ; characterized in that said pneumohydraulic diaphragm is selected from: A) an elastic, energy-storing pneumohydraulic diaphragm configured for passively storing a liquid volume under a hydraulic pressure and releasing said liquid volume during wetout of a downstream channel or chamber of	1. Device for duplicating and characterizing nucleic acids in a reaction chamber, characterized in that a chamber body (1) containing an optically permeable chip (2) having a detection area (12), and being optically permeable at least in the zone of detection area (12) of the chip (2), is sealingly placed on an optically permeable chamber support (5), so that a sample chamber (3) having a capillary gap (7) is formed between the chamber support (5) and the detection area (12) of the chip (2), which is temperature adjustable and flow-controllable. (*As-filed US 7,888,074 claim 1; PCT Publication is in German*)

Patent	Patent Family 23	Patent Family 24	Patent Family 25
		said wettable microfluidic subcircuit; B) a duplexedly layered pneumohydraulic diaphragm having a liquid center for storing and releasing a liquid reagent; C) a pneumohydraulic diaphragm configured for eliminating headspace from a hydraulic chamber during wetout; or D) a pair of pneumohydraulic diaphragms comprising a first pneumohydraulic diaphragm interfacing a first hydraulic chamber with valved inlet and a second pneumohydraulic diaphragm interfacing a second hydraulic chamber with valved outlet, and an elevated intercommunicating channel between said first and second hydraulic chambers, wherein said pair is configured for reciprocally exchanging fluid through said channel . . . ; and wherein said hydraulic chambers and diaphragms are configured for preventing or reducing bubble entrainment or reagent washout during wetout, fill, pumping or rehydration steps of an assay.	
International Patents and Published Applications (Status)			
United States	US 8,222,023 B2 (Issued Jul. 17, 2012; Expires Oct. 3, 2027) No US cases pending in this family.	US 9,132,423 B2 (Issued Sep. 15, 2015; Expires Sep. 24, 2031) US 2016/0193603 A1 (Pending)	US 7,888,074 B2 (Issued Feb. 15, 2011; Expires June 30, 2020) No US cases pending in this family..
European Patent Office[2]	EP 2007905 B1 (Issued Aug. 22, 2012; Likely Expires Mar. 15, 2027) No EP cases pending in this family.	EP 2528687 A2 (Pending)	EP 1192007 B1 (Issued Apr. 21, 2004; Likely Expires June 30, 2020) No EP cases pending in this family.

Patent	Patent Family 23	Patent Family 24	Patent Family 25
China	*No Publication Identified*	CN 102740976 B (Issued Apr. 20, 2016; Likely Expires Jan. 28, 2031)	*No Publication Identified*
India	IN Appl. No. 3786/KOLNP/2008 (Withdrawn) No IN cases pending in this family.	IN Appl. No. 6226/CHENP/2012 (Pending)	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 26	Patent Family 27	Patent Family 28
Title	METHOD FOR IDENTIFYING NUCLEIC ACID MOLECULES AMPLIFIED IN A POLYMERASE CHAIN REACTION	METHODS AND SYSTEMS FOR MICROFLUIDIC DNA SAMPLE PREPARATION	SIMPLIFIED DEVICE FOR NUCLEIC ACID AMPLIFICATION AND METHOD FOR USING SAME
Applicant	(ii) CLONDIAG CHIP TECHNOLOGIES GMBH (DE)	CANON U.S. LIFE SCIENCES, INC. (US)	BIOMERIEUX (FR)

Patent	Patent Family 26	Patent Family 27	Patent Family 28
International PCT Application Publication No.	PCT/EP2002/007539 WO/2003/004699	PCT/US2009/051021 WO/2010/009415 A1	PCT/FR2010/051936 WO/2011/033231 A1
Expected Expiration[1]	Jul. 5, 2022	Jul. 17, 2029	Sept. 17, 2030
Brief Summary and Reasons for Inclusion	The published applications in this family are directed to methods of detecting and measuring the amount of an amplified DNA or RNA in a sample. This technology may be a part of the Alere device, specifically an Alere cartridge, as this family is owned by the Alere predecessor, Clondiag.	The patents and published applications in this family are directed to a device for purifying DNA from a sample. The published PCT application is included because sample claims recite that the device includes several key elements of the GeneXpert and AlereQ technologies, including means for nucleic acid extraction, contained in a single device. The available product literature for the GeneXpert and AlereQ technologies does not provide the specific methods used for extracting and isolating DNA. Thus, it is possible that the claims in this family may broadly cover this aspect of the GeneXpert and AlereQ technologies.	The patents and published applications in this family are directed to a device for amplifying target nucleic acids preset in a sample. The published PCT application is included because sample claims recite that the device includes several key elements of the GeneXpert and AlereQ technologies, including means for nucleic acid amplification. The available product literature for the GeneXpert and AlereQ technologies does not provide the specific methods used for DNA amplification. Thus, it is possible that the claims in this family may broadly cover the subject technologies.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A method for qualitative and/or quantitative detection of nucleic acid molecules amplified in an amplification reaction, comprising determining a change in mass of oligonucleotides comprising target DNA, wherein said determining is conducted during the amplification reaction. (*As-filed US 2004/197807 A1 claim 1; PCT Publication is in German*)	11. A microfluidic device for purifying DNA from a sample comprising: (a) a sample port and lysis buffer port in fluid communication with a mixing region of the micro fluidic device, said mixing region being configured to permit mixing of a sample from the sample port and lysis buffer from the lysis buffer port mix; (b) a cell lysis region in fluid communication with the mixing region, said cell lysis region being configured to permit the lysis buffer to selectively lyse cellular membranes of cells in the sample without lysing nuclear membranes of the cells to produce intact nuclei from the cells in the sample; (c) a nuclei trapping region wherein intact nuclei from the sample are trapped by a filter while other components of the sample flow through the filter and into a waste collection region of the microfluidic device, said nuclei trapping region being in fluid communication with said cell lysis region; (d) a nuclei lysis region in	1. A disposable device (1) for amplifying at least one target nucleic acid present in a liquid and biological sample of interest (6), which consists of a solid body (2), at least one fluid channel (3) connecting an inlet (4), via which all or part of the sample of interest (6) can be drawn up and/or discharged, and an outlet (5), which is itself connected to a device (7) for the drawing up and/or discharging of the said sample of interest, the fluid channel (3) further comprising from the inlet (4) to the outlet (5): a first compartment (8) containing all or part of thermostable constituents (12) required for producing the amplification, a means (15) for mixing the thermostable constituents (12), optionally combined with non-thermostable constituents (13), with the sample of interest (6), a second compartment (9) containing all or part of the non-thermostable constituents (13) required for producing the amplification, and in addition, at least

Patent	Patent Family 26	Patent Family 27	Patent Family 28
		which the nuclear membranes of the intact nuclei are lysed to release the DNA; and (e) a DNA collection region in said microfluidic device wherein DNA released from the trapped intact nuclei is collected.	one zone intended for heating (11) the said sample of interest (6) mixed with the said thermostable and non-thermostable amplification constituents (12 combined with 13), in order to allow the amplification of the target nucleic acid. (*English translation as published in US case, see below*)
International Patents and Published Applications (Status)			
United States	US 2004/197807 A1 (Abandoned) No US cases pending in this family.	US 8,304,185 B2 (Issued Nov. 6, 2012; Expires May 20, 2030) US 8,313,906 B2 (Issued Nov. 20, 2012; Expires May 23, 2030) US 9,116,088 B2 (Issued Aug. 25, 2015; Expires Aug. 21, 2029) US 9,513,196 B2 (Issued Dec. 6, 2016; Expires Jul. 17, 2029) US 2016/0145601 A1 (Pending)	US 9,707,554 B2 (Issued Jul. 18, 2017; Expires June 15, 2032) No US cases pending in this family.
European Patent Office[2]	EP 1404880 B1 (Issued Jan. 20, 2010; Likely Expires Jul. 5, 2022) No EP cases pending in this family.	EP 2315848 B1 (Issued Dec. 10, 2014; Likely Expires Jul. 17, 2029 No EP cases pending in this family.	EP 2477745 A1 (Pending)
China	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 26	Patent Family 27	Patent Family 28
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 29	Patent Family 30	Patent Family 31
Title	DETECTION OF PROKARYOTIC ORGANISM BY DNA HYBRIDIZATION	CARTRIDGE FOR A FLUID SAMPLE ANALYSER	CARTRIDGE FOR A FLUID SAMPLE ANALYSER
Applicant	UNIV CALIFORNIA (US) (*According to Espacenet*)	INVERNESS MEDICAL SWITZERLAND GMBH	AKUBIO LIMITED (GB) (US Patent Assigned to INVERNESS MEDICAL)
International PCT Application Publication No.	N/A	PCT/GB2007/003659 WO/2008/037989 A2	PCT/GB2006/001162 WO/2006/103439 A2
Expected Expiration[1]	N/A	Sept. 26, 2027	Mar. 31, 2026
Brief Summary and Reasons for Inclusion	The patents in this family are directed to a method for detecting the presence of mycoplasma specific nucleic acids. The US patents are included because sample claims recite that the method includes several key elements of the GeneXpert and AlereQ technologies (in particular, as the devices are used to detect mycoplasma in a sample), including means for mycoplasma detection in a sample through detection of mycoplasma specific nucleic acids. The available product literature for the GeneXpert and AlereQ technologies does not provide the specific methods used for detection of mycoplasma in a sample. Thus, it is possible that the claims in this family may broadly cover the GeneXpert and AlereQ technologies, in so far as they are directed to detection of mycoplasma in a subject. Notably, the US patents identified in the search described above are expired; however, as noted in this chart, the status of related applications in other listed countries is unknown.	The published applications in this family, which are owned by a predecessor to Alere, are directed to a cartridge that may be used in the Alere device.	The patents and published applications in this family, some of which are assigned to Alere or Inverness Medical, are directed to a cartridge for analyzing a fluid sample, wherein the cartridge contains means for analyzing the sample. Because this technology is assigned to Alere, it is possible that this technology is part of the Alere system.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A method for detecting the presence of mycoplasma specific nucleic acids, which comprises: contacting a medium, which may contain a nucleic acid or nucleic acid fragment from said mycoplasma having said particular nucleotide sequence, with an oligonucleotide, said oligonucleotide comprising a nucleotide sequence complementary to said particular nucleotide sequence, whereby said oligonucleotide	1. A cartridge for apparatus for analysing a sample comprising a fluid, the cartridge comprising a housing having at least two parts and a sample receiving cell comprising a surface, on one of said parts, a sensor comprising an electrical- mechanical transducer spaced from said surface, and an adhesive membrane attaching the sensor to one of the housing parts,	1. A cartridge for apparatus for analyzing a sample comprising a fluid, the cartridge comprising a flow cell formed from a substantially rigid support surface, a sensor comprising electrical-mechanical transducer for performing said analysis; an adhesive means attaching the sensor to the support surface, and a membrane spacing the sensor from the support to define the flow cell between the support surface and

Patent	Patent Family 29	Patent Family 30	Patent Family 31
	hybridizes with any nucleic acid or nucleic acid fragment from said mycoplasma which may be present in said medium; and detecting the presence of any nucleic acid or nucleic acid fragment hybridized with said oligonucleotide; wherein said particular nucleotide sequence includes at least one of the following mycoplasma-specific sequence regions or a sequence region, of at least nine nucleotides, complementary to at least one of the following sequences: . . . ; wherein said oligonucleotide hybridizes with the nucleic acid or nucleic acid fragment from mycoplasma but not nucleic acids from eukaryotic or from other prokaryotic organisms, and wherein said oligonucleotide comprises at least nine nucleotides but is less than the length of mycoplasma rRNA or the nucleic acid sequence encoding mycoplasma rRNA. (*US 5,851,767 B1, below*)	wherein the membrane is attached only to one of said parts of the housing.	the sensor, the flow cell also having an opening through which, in use, the sample passes.
International Patents and Published Applications (Status)			
United States	US 5,851,767 (Expired) US 6,245,509 B1 (Expired) No US cases pending in this family.	US 2010/0233032 A1 (Abandoned) No US cases pending in this family.	US 7,963,151 B2 (Issued June 21, 2011; Expires Nov. 12, 2027) No US cases pending in this family.
European Patent Office[2]	*No Publication Identified*	EP2076762 (Abandoned) No EP cases pending in this family.	EP 1864119 A2 (Withdrawn) No EP cases pending in this family.
China	*No Publication Identified*	CN 101680851 A (Withdrawn) No CN cases pending in this family.	CN 101258402 A (Withdrawn) No CN cases pending in this family.
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 29	Patent Family 30	Patent Family 31
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 32
Title	CARTRIDGE FOR CONDUCTING A CHEMICAL REACTION
Applicant	CEPHEID (US)
International PCT Application Publication No.	PCT/US1998/016870 WO/99/09042 A2 PCT/US1998/027632 WO/99/33559 A1 PCT/US2000/014739 WO/00/72970 A1 PCT/US2000/014740 WO/00/73413 A2
Expected Expiration[1]	Aug. 13, 2018
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a cartridge for conducting a chemical reaction, wherein the cartridge has sensors and a reaction vessel. Because this family is assigned to Cepheid, it is possible that the claimed cartridge is incorporated into the Cepheid device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A cartridge for conducting a chemical reaction, the cartridge comprising: a) a body having (1) a plurality of sensor chambers having optical sensors positioned to detect liquid in the sensor chamber and (2) at least one flow path formed therein; and b) a reaction vessel extending from the body, the vessel comprising: i) a rigid frame defining a plurality of side walls of a reaction chamber, wherein the frame includes at least one channel connecting the flow path to the chamber; and ii) at least one sheet attached to the rigid frame to form a major wall of the chamber, wherein the major wall is sufficiently flexible to conform to a surface that comes into contact with the major wall. *See US 9,322,052 B2 below.*

International Patents and Published Applications (Status)	
United States	US 6,368,871 B1 (Issued Apr. 9, 2002; Expires Mar. 2, 2018) US 6,391,541 B1 (Issued May 21, 2002; Expires May 30, 2020) US 6,431,476 B1 (Issued Aug. 13, 2002; Expires Dec. 21, 2019) US 6,440,725 B1 (Issued Aug. 27, 2002; Expires Dec. 24, 2018) US 6,664,104 B2 (Issued Dec. 16, 2003; Expires Dec. 24, 2018) US 6,783,736 B1 (Issued Aug. 31, 2004; Expires June 13, 2021) US 6,818,185 B1 (Issued Nov. 16, 2004; Expires Mar. 2, 2018) US 6,878,540 B2 (Issued Apr. 12, 2005; Expires Dec. 24, 2018) US 6,881,541 B2 (Issued Apr. 19, 2005; Expires Aug. 13, 2017)

	US 6,887,693 B2 (Issued May 3, 2005; Expires Dec. 21, 2019) US 6,893,879 B2 (Issued May 17, 2005; Expires Aug. 13, 2017) US 6,987,018 B2 (Issued Jan. 17, 2006; Expires Nov. 2, 2019) US 7,135,144 B2 (Issued Nov. 14, 2006; Expires Sept. 16, 2019) US 7,569,346 B2 (Issued Aug. 4, 2009; Expires Dec. 31, 2018) US 7,914,994 B2 (Issued Mar. 29, 2011; Expires Dec. 24, 2018) US 8,168,442 B2 (Issued May 1, 2012; Expires June 12, 2022) US 8,247,176 B2 (Issued Aug. 21, 2012; Expires Dec. 24, 2018) US 8,268,603 B2 (Issued Sept. 18, 2012; Expires Aug. 13, 2017)

	US 8,580,559 B2 (Issued Nov. 12, 2013; Expires Dec. 24, 2018) US 8,592,157 B2 (Issued Nov. 26, 2013; Expires Dec. 24, 2018) US 8,709,363 B2 (Issued Apr. 29, 2014; Expires Mar. 2, 2018) US 9,156,032 B2 (Issued Oct. 13, 2015; Expires Oct. 16, 2019) US 9,322,052 B2 (Issued Apr. 26, 2016; Expires Mar. 2, 2018) US 2002/0019060 A1 (Abandoned) US 2004/0200909 A1 (Abandoned) US 2008/0057572 A1 (Pending) US 2013/0236907 A1 (Abandoned) US 2013/0220931 A1 (Abandoned)

	US 2014/0141424 A1 (Abandoned) US 2016/0367991 A1 (Pending)
European Patent Office[2]	EP 1179585 B1 (Issued Jul. 9, 2008; Likely Expires Dec. 24, 2018) EP 1180135 B1 (Issued Aug. 17, 2005; Likely Expires May 30, 2020) EP 1181098 B2 (Issued on Jul. 26, 2006; Likely Expires May 30, 2020) EP 1208189 B1 (Issued on Oct. 6, 2004; Likely Expires May 30, 2020) EP 1003759 A2 (Withdrawn) EP 1042061 A1 (Pending)
China	*No Publication Identified*
India	*No Publication Identified*
South Africa	*No Publication Identified*
Brazil	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*

Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*
Mexico	MX 2012004397 A (Issued Nov. 22, 2013; Likely to Expire Oct. 13, 2030
Russia	*No Publication Identified*
Indonesia	*No Publication Identified*
Nigeria	*No Publication Identified*

Patent Landscape for OraSure OraQuick Lateral Flow Device

Patent	Patent Family 33	Patent Family 34	Patent Family 35
Title	DEVICE FOR COLLECTION AND ASSAY OF ORAL FLUIDS	IMMUNOCHROMATOGRAPHIC ASSAY DEVICES WITH SEPARATORS	IMMUNOASSAY APPARATUS FOR DIAGNOSIS
Applicant	EPITOPE, INC. (US) *Now* ORASURE TECHNOLOGIES (US)	GENELABS DIAGNOSTICS PTE LTD. (SG)	CLINICAL DIAGNOSTIC CHEMICALS LIMITED (GB)
International PCT Application Publication No.	PCT/US1999/007124 WO/1999/050656 A1	PCT/US2001/002554 WO/2001/055723 A1	PCT/GB1998/001412 WO/1998/052044 A1
Expected Expiration[1]	Mar. 29, 2019	Jan. 25, 2021	May 15, 2018
Brief Summary and Reasons for Inclusion	Based on our review of the product literature and the PCT claims, this patent family appears to be specifically directed to the OraSure OraQuick lateral flow device. However, further analysis of issued claims in relevant countries is necessary to draw conclusions as to whether any issued patents in this family cover the OraSure OraQuick device. The patents and published applications in this family are directed to a device for collection and lateral flow chromatography of an oral fluid. Sample claims recite that the apparatus includes several key elements of the OraQuick technology, including (i) a capillary matrix having a surface for receiving oral fluid; (ii) a lateral flow chromatography strip wherein the capillary matrix pulls up the oral fluid and delivers the oral fluid to a receiving area of the lateral flow chromatography strip; (iii) means for visual detection of a target on the lateral chromatographic strip; and (iv) a housing apparatus that acts as a handle for inserting the capillary matrix into a subject's mouth (for sample collection); and methods of use thereof for the detection of a target in a sample.	The patents and published applications in this family are directed to a chromatography device or kit for detecting human antibodies in a sample. The published PCT application is included because sample claims recite that the device includes several key elements of the OraQuick technology, including (i) a chromatographic element; (ii) a releasable binding partner comprising an antibody or a detectable label; (iii) an immobilized binding partner positioned on the chromatographic element, wherein the immobilized binding partner can be an HIV or mycobacterium antigen.	The patents and published applications in this family are directed to an immunoassay analytical test device. The published PCT application is included because representative claims recite that the apparatus comprises several key elements of the subject technology, including (i) a pad for collecting fluid from a subject; (ii) the pad can also be an area that is exposed to a solution that will move the analyte across a membrane; (iii) detection means for permitting detection of the analyte (e.g., use of an antibody). Broadly construed, the published PCT claims may read on the OraQuick technology.

Patent	Patent Family 33	Patent Family 34	Patent Family 35
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An apparatus for collection and lateral flow chromatography of an oral fluid, said apparatus comprising: a capillary matrix having exposed a surface for receiving oral fluid; and a lateral flow chromatography strip where said lateral flow chromatography strip is in communication with said capillary matrix such that when said capillary matrix receives oral fluid, said capillary matrix wicks up said oral fluid and delivers said oral fluid to a receiving area of said lateral flow chromatography strip. 19. The apparatus of claim 1, further comprising: a housing having a cavity, wherein said lateral flow chromate-graphy strip extends into the cavity along the housing to an inspection site on the housing; and at least one inspection site from an exterior of the housing to the lateral chromatographic strip to enable visual inspection of reagents at selected sites on the lateral chromatographic strip. 20. The apparatus of claim 19, wherein said housing acts as a handle for inserting said capillary matrix into said oral cavity. 21. A method of detection or quantifying one or more analytes in an oral fluid, said method comprising the steps of: i) inserting into the oral cavity of a mammal an apparatus comprising a capillary matrix attached to a lateral flow chromatography strip, such that said capillary matrix is contacted with an oral mucosal surface whereby said capillary matrix wicks up oral fluid and delivers said oral fluid to a receiving area of said lateral flow chromatography strip; and ii) reading a signal on said lateral flow chromatography strip that	1. An assay device or kit comprising: a) a chromatographic element comprising a sample receiving end, a reagent releasing end, and a reaction zone; b) an absorbent pad; and c) a separator positioned between the chromatographic element and the absorbent pad. 2. The assay or kit device of claim 1 , wherein the reagent releasing end comprises a releasable binding partner. 3. The assay device or kit of claim 2, wherein the releasable binding partner comprises one or more antibodies directed against one or more conserved regions of a human antibody. 4. The assay device or kit of claim 2, wherein the releasable binding partner comprises a detectable label. 6. The assay device or kit of claim 1 , wherein the reaction zone comprises an immobilized binding partner for a specific analyte. 7. The assay device or kit of claim 6, wherein the immobilized binding partner comprises one or more antigens selected from the group consisting of a recombinant HIV 1 antigen, a recombinant HIV 2 antigen, a Helicobacter pylori-derived antigen, and a Mycobacterium tuberculosis-derived antigen.	1. Immunoassay analytical test apparatus, which apparatus comprises: (a) a zone for receiving a sample containing an analyte; (b) a zone for receiving a mobile phase, which zone may be the same as the sample receiving zone, or different thereto; (c) detection means for permitting detection of said analyte by immunoreaction; (d) a first flow path for flow of said analyte in said mobile phase from said sample receiving zone to said detection means; and (e) a second flow path permitting flow of said mobile phase to said detection means. 2. Apparatus according to claim 1, wherein said second flow path includes labeled immunoactive material.

Patent	Patent Family 33	Patent Family 34	Patent Family 35
	indicates the presence absence or quantity of said one or more analytes.		
International Patents and Published Applications (Status)			
United States	US 8,062,908 B2 (Issued Nov. 22, 2011; Expires Jul. 18, 2019) US 7,541,194 B2 (Issued June 2, 2009; Expires Jul. 18, 2019) US 7,192,555 B2 (Issued Mar. 20, 2007; Expires Mar. 29, 2019) US 6,303,081 B1 (Issued Oct. 16, 2001; Expires Mar. 29, 2019) US 2002/0192839 A1 (Abandoned) US 2010/0239458 A1 (Abandoned) US 2012/0149124 A1 (Abandoned) No US cases pending in this family.	US 6,316,205 B1 (Issued Nov. 13, 2001; Expires Jan. 28, 2020) US 6,617,116 B2 (Issued Sept. 9, 2003; Expires Jan. 28, 2020) US 6,849,414 B2 (Issued Feb. 1, 2005; Expires Jan. 28, 2020) No US cases pending in this family.	US 6,689,317 B1 (Issued Feb. 10, 2004; Expires May 15, 2018) US 2004/0115795 A1 (Abandoned) No US cases pending in this family.

Patent	Patent Family 33	Patent Family 34	Patent Family 35
European Patent Office[2]	EP 1696236 B1 (Issued Jul. 16, 2014; Likely Expires Mar. 29, 2019) EP 1086372 B1 (Issued May 31, 2006; Likely Expires Mar. 29, 2019)	EP 1250598 B1 (Issued Oct. 19, 2005; Likely Expires Jan. 25, 2021)	EP 981751 B1 (Issued Jan. 21, 2004; Likely Expires May 15, 2018)
China	*No Publication Identified*	CN 1168985 C (Issued Feb. 12, 2003; Likely Expires Jan. 25, 2021) No CN cases pending in this family.	*No Publication Identified*
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 36	Patent Family 37	Patent Family 38
Title	RAPID TEST INCLUDING GENETIC SEQUENCE PROBE	POSITIVE DETECTION LATERAL-FLOW APPARATUS AND METHOD FOR SMALL AND LARGE ANALYTES	RAPID DIAGNOSTIC DEVICE, ASSAY AND MULTIFUNCTIONAL BUFFER
Applicant	ULTRAPID NANODIAGNOSTICS INC. (US)	QUANTRX BIOMEDICAL CORPORATION (US) *(Assignee)*	MEDMIRA INC. (CA)
International PCT Application Publication No.	PCT/US2009/031011 WO/2009/128960 A2	N/A	PCT/CA2002/001210 WO/2003/012443 A2
Expected Expiration[1]	Jan. 14, 2029	N/A	Aug. 2, 2022
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a rapid test kit for detection of nucleotides (DNA and/or RNA). The published PCT application is included because sample claims recite that the kit includes several key elements of the OraQuick technology, including (i) a membrane; (ii) a genetic probe immobilized on the membrane; (iii) and a stain for visual detection of a target. Broadly construed, the published PCT claims may read on the OraQuick technology.	The patents and published applications in this family are directed to a method for detecting and/or measuring the amount of a target in a liquid sample. The US patent is included because sample claims recite that the method includes several key elements of the OraQuick technology, including (i) a test strip comprising a membrane; (ii) a mobile or mobilizable detectable tracer (e.g., a means of detection); (iii) and a sample application area. Accordingly, the various elements of the claimed method may cover the OraQuick technology.	The patents and published applications in this family are directed to a device for determining the presence or absence of a target in a fluid sample. The published PCT application is included because sample claims recite that the device includes several key elements of the OraQuick technology, including (i) a test unit comprising a reaction zone in contact with an absorbent zone (e.g., a chromatographic membrane); (ii) an immobilized capture reagent capable of binding with a target; and (iii) an indicator reagent (e.g., a means for visual detection of the target). Accordingly, the various elements of the claimed device may cover the OraQuick technology.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A rapid test kit for detection of a DNA, an RNA or a fragment of a DNA or an RNA, the kit comprising: a membrane; at least one genetic probe immobilized on a test portion of the membrane such that, when a fluid containing the DNA, RNA or the fragment of the DNA or the RNA is directly filtered through the membrane, the at least one genetic probe immobilizes the DNA, RNA or the fragment of the DNA or the RNA; and a staining agent selected such that, if the DNA, RNA or the fragment of the DNA or the RNA is present at a detectable level, the staining agent is immobilized preferentially on the test portion of the	US 6,699,722 B2: 1. A method for detecting and/or quantitating an analyte in a liquid sample, comprising: (a) providing a test strip comprising a mobilization zone; a mobile or mobilizable detectable tracer in the mobilization zone; a sample application area; a primary capture area comprising a first immobilized binding partner having a binding affinity for the analyte and a binding affinity for the detectable tracer; and a secondary capture area comprising a second immobilized binding partner having a binding affinity for the detectable tracer;	1. A device (1) for determining the presence or absence of a target analyte (10) in a fluid test sample (9), comprising: a test unit (2) comprising a reaction zone (5) in vertical communication with an absorbent zone (4), wherein the reaction zone (5) contains immobilized capture reagent (6) capable of binding with a target analyte (10) of interest to form a two-membered complex of a specific binding interaction; and a post-filter unit (3) comprising a label zone (7) containing a dried indicator reagent (8), wherein the indicator reagent (8) is capable of binding to a member of the specific binding interaction to produce

Patent	Patent Family 36	Patent Family 37	Patent Family 38
	membrane such that a contrast is observable between the test portion and a background portion of the membrane. 6. The rapid test kit of claim 1, wherein the staining agent comprises an oligonucleotide- functionalized nanoparticle or nanotube having an oligonucleotide capable of hybridizing at room temperature with the DNA, RNA or the fragment of the DNA or the RNA to be detected by the rapid test kit. 7. The rapid test kit of claim 6, wherein the at least one genetic probe includes a complimentary oligonucleotide for hybridization with a specific region of the DNA, RNA or the fragment of the DNA or the RNA. 8. The rapid test kit of claim 7, wherein the complimentary oligonucleotide is conjugated with a chitosan or a chitosan derivative such that the complimentary oligonucleotide is immobilized on the membrane. 9. The rapid test kit of claim 8, wherein the oligonucleotide-functionalized nanoparticle or nanotube comprises a gold nanoparticle functionalized by a thiolated oligonucleotide complementary to a different portion of the DNA, the RNA or the fragment of the DNA or the RNA than the portion of the DNA, the RNA or the fragment of the DNA or the RNA hybridized by the complimentary oligonucleotide immobilized on the membrane.	wherein the sample application area, mobilization zone, primary capture area and secondary capture area are in a path of liquid flow from the sample application area distally through the mobilization zone to the primary capture area and then to the secondary capture area, wherein a distal flow of analyte reaches the primary capture area before a distal flow of tracer reaches the primary capture area; (b) contacting the liquid sample with the sample application area of the test strip, and allowing the liquid sample to mobilize the detectable tracer such that the detectable tracer migrates with the liquid sample, wherein the detectable tracer has a weight greater than the analyte to permit analyte flow to move at a faster rate than the tracer flow along the path of liquid flow, such that the tracer flow reaches the primary capture zone after analyte flow in the liquid sample reaches the primary capture area; wherein the analyte flow that reaches the primary capture zone occupies first immobilized binding partner such that subsequent binding of detectable tracer to first immobilized binding partner is inhibited, whereby unbound detectable tracer continues along the path of liquid flow distally to bind to second immobilized binding partner and provide a signal from the secondary capture area that indicates the presence of the analyte in the liquid sample. 11. The method of claim 1, wherein the detectable tracer comprises a detectable tracer for an analyte selected from the group consisting of an antigen of an infectious disease, an antigen to an antibody of an infectious disease, a hormone, a growth factor, a therapeutic drug, a drug of abuse, a product of the metabolism of a drug of abuse, and a hapten.	a visually detectable signal following resolubilization thereof by buffer reagent (12); and characterized in that the reaction zone (5) of the test unit and the label zone (7) of the post-filter unit (3) are capable of being disposed in transient fluid communication with each other so as to allow direct passage of resolubilized indicator reagent (8) from the label zone (7) to the reaction zone (5) following application of buffer reagent (12) to the label zone (7). 2. The device (1) according to claim 1 , characterized in that the specific binding interaction is an antibody-antigen interaction. 21. The device (1) according to claim 1, characterized in that the indicator reagent (8) comprises a direct label. 22. The device (1) according to claim 21, characterized in that the direct label is colloidal gold.

Patent	Patent Family 36	Patent Family 37	Patent Family 38
	10. The rapid test kit of claim 9, wherein the thiolated oligonucleotide is a primer selected to hybridize a viral RNA selected from the group consisting of an HIV virus, a Hepatitis B virus, a Hepatitis C virus, a SARS virus and combinations thereof. 11. The rapid test kit of claim 10, wherein the primer is selected to hybridize the viral RNA of the HIV virus.	12. The method of claim 11, wherein the detectable tracer comprises a detectable tracer for an analyte comprising an antibody selected from the group consisting of an antibody to Human Immunodeficiency Virus (HIV), an antibody to Human T-Cell Lymphotropic Virus (HTLV), an antibody to Helicobacter pylori, an antibody to hepatitis, an antibody to measles, an antibody to mumps, and an antibody to rubella.	
International Patents and Published Applications (Status)			
United States	US 2009/0181361 A1 (Abandoned) US 2010/0105024 A1 (Abandoned) US 2013/0022960 A1 (Abandoned) No US cases pending in this family.	US 6,699,722 B2 (Issued Mar. 2, 2014; Expires Apr. 13, 2021) US 7,517,699 B2 (Issued Apr. 14, 2009; Expires Apr. 13, 2021) US 2009/253219 A1 (Abandoned) No US cases pending in this family.	US 7,531,362 B2 (Issued May 12, 2009; Expires May 5, 2023) US 8,025,850 B2 (Issued Sept. 27, 2011; Expires June 6, 2022) US 8,287,817 B2 (Issued Oct. 16, 2012; Expires June 6, 2022) US 8,586,375 B2 (Issued Nov. 19, 2013; Expires June 6, 2022) US 9,164,087 B2 (Issued Oct. 20, 2015; Expires June 6, 2022) No US cases pending in this family.
European Patent Office[2]	EP 2245186 A2 (Withdrawn)	*No Publication Identified*	EP 1417489 B1 (Issued May 12, 2004;

Patent	Patent Family 36	Patent Family 37	Patent Family 38
	No EP cases pending in this family.		Expires Aug. 2, 2022) No EP cases pending in this family.
China	CN 101978072 A (Withdrawn) No CN cases pending in this family.	*No Publication Identified*	CN 100427950 C (Issued Oct. 22, 2008; Likely Expires Aug. 8, 2022)
India	IN 2990/KOLNP/2010 (Examination in Progress)	*No Publication Identified*	*No Publication Identified*
South Africa	(i) ZA 2010/05791 B (Issued Oct. 26, 2011; Likely Expires Jan. 14, 2009)	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 39	Patent Family 40	Patent Family 41
Title	DIAGNOSTIC TEST FOR ANALYTES IN A SAMPLE	POLYMER CONJUGATE ENHANCED BIOASSAYS	ORAL FLUID RAPID IMMUNOCHROMATOGRAPHY TEST
Applicant	ADVANTAGE DIAGNOSTICS CORPORATION (US)	ANP TECHNOLOGIES, INC. (US)	BEIJING CALYPTE BIOMEDICAL TECHNOLOGY LTD. (CN)
International PCT Application Publication No.	PCT/US2004/008355 WO/2005/003732 A2	PCT/US2006/016580 WO/2006/119160 A2	PCT/CN2005/000701 WO/2006/122450 A1
Expected Expiration[1]	Mar. 19, 2024	May 2, 2026	May 20, 2025
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to a diagnostic test strip for detecting a target in a liquid sample. The published PCT application is included because sample claims recite that the test strip includes several key elements of the OraQuick technology, including (i) an element that binds the target, wherein the target can be an antibody (e.g., an antibody to HIV or HCV), and wherein the binding element can include protein A and colloidal gold (for visualization purposes); (ii) a sample application area configured to receive a liquid sample; and a test area including an immobilized binding agent specific for the target. Accordingly, the various elements of the claimed test strip may cover the OraQuick technology.	The patents and published applications in this family are directed to an assay kit for detecting a target in a sample. The US patent is included because sample claims recite that the kit includes several key elements of the subject technology, including (i) a detector that specifically binds a target; b) a conjugate; (c) a capture molecule, which specifically binds the target; and (d) a reporter, wherein the reporter can include colloidal gold (e.g., for visualization purposes). Accordingly, the various elements of the claimed kit may cover the OraQuick technology.	The patents and published applications in this family are directed to a test strip for detecting a target in oral fluid. The published PCT application is included because the claims recite that the test strip consists of several key elements of the OraQuick technology, including (i) a conjugate pad, (ii) a test zone, and (iii) a control zone pad made of at least one matrix material; wherein the conjugate pad lies downstream of the sample pad, and is striped with a conjugate (for detection); wherein the test zone is immobilized with a specific binding reagent that specifically binds to the target analyte; and the control zone is immobilized with a capture reagent (for visualization). Notably, the only issued patent in this family is in China, and there are no pending US or EP cases. However, as noted in this chart, the status of related applications in other listed countries is unknown.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A diagnostic test strip for detecting an analyte of interest in a liquid sample, the test strip comprising: a conjugate source area, comprising a conjugate configured to bind the analyte of interest; a sample application area located downstream of said conjugate source area and configured to receive said liquid sample; and a test area located downstream of said	US 8,563,329 B2: 1. An assay kit for detecting a target in a sample, comprising: a) a detector that specifically binds said target of said sample, said detector tagged with a plurality of a first member of a first binding pair; b) a conjugate comprising a modified dendritic polymer and a second member of said first binding pair; (c) a capture molecule comprising a member of a second	1. A lateral flow immunochromato-graphy test strip for detecting an analyte in oral fluid, consisting essentially of a sample pad, a conjugate pad, a test zone and control zone pad made of at least one matrix material, wherein the conjugate pad lies downstream of the sample pad, and is striped with a conjugate; the test zone and control zone pad lies downstream of the conjugate pad, and contains the test zone and control zone, wherein the test zone is immobilized with an

Patent	Patent Family 39	Patent Family 40	Patent Family 41
	conjugate source area and comprising immobilized binding agent specific for the analyte of interest. 3. The test strip of Claim 1, wherein the analyte of interest is an antibody. 4. The test strip of Claim 3, wherein the analyte of interest is an antibody to human immunodeficiency virus (HIV). 5. The test strip of Claim 3, wherein the analyte of interest is an antibody to hepatitis C virus (HCV). 14. The test strip of Claim 1, wherein the conjugate comprises a binding component and a label. 15. The test strip of Claim 14, wherein the binding component is protein A. 16. The test strip of Claim 14, wherein the label is selected from the group consisting of colloidal gold, colloidal silver, colloidal black and dyed latex particles.	binding pair which specifically binds said target; and (d) a reporter. 3. The kit of claim 1, wherein said reporter comprises a colored, luminescent or fluorescent particulate or moiety, an enzyme, or a combination thereof. 5. The kit of claim 3, wherein said colored particulate comprises colloidal metals, comprising gold or silver, colored latex beads or colored dyes.	specific binding reagent that specifically binding to the target analyte; and the control zone is immobilized with a second capture reagent. 2. The test strip according to claim 1, wherein the analyte to be tested is selected from antibodies against antigens of infectious disease, hormones, growth factors, therapeutic drugs, drugs of abuse and products of the metabolism of drugs of abuse. 7. The test strip according to claim 1, wherein the conjugate comprises a label conjugated to a first capture reagent that captures antibodies endogenous to the oral fluid. 8. The test strip according to claim 7, wherein the label is selected from colloidal gold particles; elemental or metal sol particles including selenium, silver, ferrite or carbon; other bead particles including colored latex, liposomes, and dye particles. 9. The test strip according to claim 7 or 8, wherein the label is colloidal gold particles.
International Patents and Published Applications (Status)			
United States	US 7,393,697 B2 (Issued Jul. 1, 2008; Expires Feb. 19, 2025) No US cases pending in this family.	US 8,563,329 B2 (Issued Oct. 22, 2013; Expires May 2, 2026) US 9,176,142 B2 (Issued Nov. 3, 2015; Expires May 2, 2026) US 9,360,477 B2 (Issued June 7, 2016;	US 2011/0003310 A1 (Abandoned) No US cases pending in this family.

Patent	Patent Family 39	Patent Family 40	Patent Family 41
		Expires May 2, 2026) No US cases pending in this family.	
European Patent Office[2]	EP 1658483 B1 (Issued Dec. 22, 2010; Likely Expires Mar. 19, 2024) No EP cases pending in this family.	EP 1877553 B1 (Issued Jan. 19, 2011; Likely Expires May 2, 2026) EP 2208998 A2 (Pending; Refused Feb. 2015; Appealed Apr. 2015)	EP 1882184 A1 (Withdrawn) No EP cases pending in this family.
China	CN 1902489 B (Issued Jul. 4, 2012; Likely Expires Mar. 19, 2024XXX) No CN cases pending in this family.	*No Publication Identified*	CN 01495865 B (XXX) No CN cases pending in this family.
India	*No Publication Identified*	IN 9150/DELNP/2007 (Abandoned)	IN 200704430P2 (Appl. No. 4430/KOLNP/2007) (Abandoned)
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	BR PI0411059 B1 (Issued Aug. 23, 2016; Likely to Expire Mar. 19, 2024) No BR cases pending in this family.	*No Publication Identified*	BR PI0520182 A2 (Abandoned) No BR cases pending in this family.
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 39	Patent Family 40	Patent Family 41
Mexico	*No Publication Identified*	*No Publication Identified*	MX 2007014476 A (Abandoned) No MX cases pending in this family.
Russia	*No Publication Identified*	National Phase Entered; Application Subsequently Withdrawn	RU App. No. 2007142142 (Status Unknown)
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 42	Patent Family 43	Patent Family 44
Title	IMMUNOASSAYS AND DEVICES THEREFOR	BIOASSAY DEVICE WITH NON-ABSORBENT TEXTURED CAPILLARY SURFACE	REAGENT TEST STRIP COMPRISING CONTROL MEANS AND TIMER MEANS
Applicant	UNILEVER PLC (GB)	BIOSITE DIAGNOSTICS, INC. (US)	UNIPATH LTD (GB)
International PCT Application Publication No.	PCT/GB1988/000322 WO/88/08534 A1	PCT/US1991/001349 WO/91/13998 A1	PCT/EP2003/000274 WO/03/058243 A2
Expected Expiration[1]	Apr. 26, 2008	Feb. 26, 2011	Jan. 9, 2023
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are directed to an analytical device that is similar to the OraSure device. In particular, the claimed device includes detection of a target in a fluid sample using lateral flow of the sample, and labeling of the sample.	The patents and published applications in this family are directed to an analytical device that uses technology that is similar to the OraSure device. In particular, the claimed device includes means for detection of a target in a fluid sample using lateral flow.	The patents and published applications in this family are directed to an analytical device that uses technology that is similar to the OraSure device. In particular, the claimed device uses a test strip that indicates the presence of a substance in a liquid by use of a first signal and indicates that the test is complete by use of a second (control) signal.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An analytical test device comprising a hollow casing constructed of moisture impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device also	1. A device for assaying a sample suspected of containing at least one target ligand comprising: a porous member having an upper and a lower surface, said sample being applied to said upper surface; and a non-absorbent member having a textured surface with channels capable of forming a network of capillary	1. An assay device to determine the presence of at least one analayte of interest in a liquid sample, the device comprising means for generating a first signal, or "test" signal, which indicates the presence and/or amount of analyte of interest in the sample; and means for generating a second signal, the generation of

Patent	Patent Family 42	Patent Family 43	Patent Family 44
	containing a labelled specific binding reagent for an analyte which labelled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabelled specific binding reagent for the same analyte which unlabelled reagent is permanently immobilised in a detection zone on the carrier material and is therefore not mobile in the moist state, the relative positioning of the labelled reagent and detection zone being such that liquid sample applied to the device can pick up labelled reagent and. thereafter permeate into the detection zone, and the device incorporating means enabling the extent (if any) to which the labelled reagent becomes bound in the detection zone to be observed.	channels when placed in communication beneath or around said porous member, said capillary network substantially parallel to the lower surface of said porous member; whereby sample, alone or in combination with other fluids is drawn through said porous member to said capillary network formed between said porous member and said non-absorbent member when substantially all the void volume of said porous member is filled with said sample and/or fluids and when contact is made between said porous member and said non-absorbent member.	which second signal indicates both (a) the test has been successfully conducted, and that (b) sufficient time has elapsed following contact of the assay device with the liquid sample for the test to be read and for the first signal to have been properly generated.
International Patents and Published Applications (Status)			

Patent	Patent Family 42	Patent Family 43	Patent Family 44
United States	US 6,228,660 B1 (Expired) US 5,602,040 (Expired) US 5,622,871 (Expired) US 5,656,503 (Expired) US 6,187,598 B1 (Expired) US 6,818,455 B2 (Expired) US 7,109,042 B2 (Expired) US 2005/0244986 A1 (Abandoned) (ii) US 6,228,660 B1 (Expired) (iii) No US cases pending in this family.	US 5,922,615 (Expired) US 6,297,060 B1 (Expired) No US cases pending in this family.	US 7,718,443 B2 (Issued May 18, 2010; Expires Oct. 4, 2025) US 9,052,311 B2 (Issued June 9, 2015; Expires Sept. 14, 2024) No US cases pending in this family.
European Patent Office[2]	EP 0291194 B8 (Likely Expired) EP 0560410 B1 (Likely Expired) EP 0560411 B1	EP 0447154 B1 (Likely Expired) No EP cases pending in this family.	EP 1327884 B1 (Expires Jan. 9, 2022) No EP cases pending in this family.

Patent	Patent Family 42	Patent Family 43	Patent Family 44
	(Likely Expired) EP 1248112 A2 (Withdrawn) EP 1555529 A2 (Withdrawn) No EP cases pending in this family.		
China	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 45	Patent Family 46	Patent Family 47
Title	ASSAY DEVICE FOR LIQUID SAMPLE	ASSAY	LATERAL FLOW IMMUNOASSAY CONTROLS
Applicant	INVERNESS MEDICAL SWITZERLAND GMBH (CH)	INVERNESS MEDICAL SWITZERLAND GMBH (CH)	ALERE SWITZERLAND GMBH (CH)
International PCT Application Publication No.	PCT/GB2003/002765 WO/2004/003559 A1	PCT/GB2004/005146 WO/2005/059547 A2	N/A
Expected Expiration[1]	June 26, 2023	Dec. 10, 2024	Feb. 10, 2024
Brief Summary and Reasons for Inclusion	The patents and published applications in this family are generally directed an assay that is similar to the OraSure device. In particular, the claimed device takes up a liquid and generates a signal to indicate the presence of a particular substance in the liquid. This family is assigned to Inverness Medical Switzerland, which is a predecessor to Alere.	The patents and published applications in this family are directed to assays for detecting a target in a liquid sample using a series of immobilized binding elements. This technology is similar to the underlying technology used in the OraSure device. In particular the OraSure device uses immobilized binding elements positioned on the test strip to capture and detect a target substance is a sample. This family is assigned to Inverness Medical Switzerland, which is a predecessor to Alere.	The patents and published applications in this family are directed to a lateral flow test strip that uses an immobilized dye hidden beneath a barrier as an indicator of the presence of a target in the sample liquid. This technology is similar to the OraSure device, but it is unclear whether the OraSure device specifically uses this barrier-hidden dye element.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An assay device comprising liquid transport means adapted to take up a liquid sample and conduct the liquid to an analyte detection region operable to provide a test signal indicative of the presence and/or amount of an analyte in the liquid sample; characterized in that the assay device further comprises a sample presence signal generation means.	1. An assay kit for detecting an analyte of interest in a sample, comprising: a) a reporter species; b) a labeled species having first and second binding regions, wherein the first binding region is capable of binding to the analyte of interest and the second binding region is capable of binding to the reporter species; c) an immobilized species capable of binding to the first binding region of the labeled species; and d) immobilized capture reagent capable of binding to the reporter species, the arrangement being such that the sample is contacted with the labeled species, is then contacted with the immobilized species and is subsequently contacted with the immobilized capture reagent, the reporter species being added prior to exposure of the sample to the immobilized capture reagent, wherein if no analyte is present in the sample, the labeled species becomes bound to the immobilized species and is therefore unable to bind to the	1. An analytical test device for detecting an analyte suspected of being present in a liquid sample applied to the device, the device comprising a test strip, the test strip comprising a sample application area; a mobilisable labeled specific binding reagent which binds the analyte if present in the liquid sample; a test result zone located downstream of the sample application area, the test result zone comprising an immobilized specific binding reagent which binds the analyte; and a control zone located downstream of the test result zone, the control zone comprising a visible barrier and mobilisable control dye, wherein the mobilisable control dye is covered by the visible barrier and not visible to a user when the test strip is in a dry state, and wherein the mobilisable control dye becomes visible to a user when the liquid sample contacts the control zone and the mobilisable control

Patent	Patent Family 45	Patent Family 46	Patent Family 47
		immobilized capture reagent, and wherein, if analyte is present in the sample, the analyte binds to the labeled species such that the labeled species is unable to bind to the immobilized species but can bind to the immobilized capture reagent via the reporter species, the presence of the analyte thus being determined by the presence of labeled species bound to the immobilized capture reagent via the reporter species.	dye is mobilized and moves downstream of the visible barrier. (*US 8,193,002 B2, below*)
International Patents and Published Applications (Status)			
United States	US 8,454,903 B2 (Issued June 4, 2013; Expires Feb. 24, 2025) US 8,992,854 B2 (Issued Mar. 31, 2015; Expires June 26, 2023) No US cases pending in this family.	US 7,901,949 B2 (Issued Mar. 8, 2011; Expires Jan. 12, 2025) US 2011/223690 A1 (Abandoned) No US cases pending in this family.	US 7,459,314 B2 (Issued Dec. 2, 2008; Expires Jul. 4, 2025) US 8,193,002 B2 (Issued June 5, 2012; Expires Aug. 6, 2024) US 8,828,739 B2 (Issued Sept. 9, 2014; Expires Feb. 10, 2024) No US cases pending in this family.
European Patent Office[2]	EP 1376131 A1 (Withdrawn) EP 1521965 A1 (Withdrawn) No EP cases pending in this family.	EP 1706743 B1 (Issued Nov. 18, 2009; Likely Expires Dec. 10, 2024) No EP cases pending in this family.	*No Publication Identified*
China	CN 1682114 B (Issued May 26, 2010; Likely Expires June 26, 2023) No CN cases pending in this family.	CN 1894585 B (Issued June 15, 2011; Likely Expires Dec. 10, 2024) No CN cases pending in this family.	*No Publication Identified*

Patent	Patent Family 45	Patent Family 46	Patent Family 47
India	*No Publication Identified*	IN 3347/DELNP/2006 (Abandoned) No IN cases pending in this family.	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 48	Patent Family 49	Patent Family 50
Title	DEVICES FOR ANALYTE ASSAYS WITH BUILT-IN RESULT REPORTING USING RECOGNIZABLE SYMBOLS	DEVICES AND METHODS FOR ANALYTE ASSAYS WITH BUILT-IN RESULT REPORTING USING RECOGNIZABLE SYMBOLS	DIAGNOSTIC KIT
Applicant	ALERE SWITZERLAND GMBH (CH)	OAKVILLE HONG KONG CO., LIMITED (CN)	ALERE SWITZERLAND GMBH
International PCT Application Publication No.	N/A	PCT/CN2006/000310 WO/2006/092103 A1	N/A
Expected Expiration[1]	Jan. 11, 2026	Mar. 2, 2026	Feb. 17, 2029

Patent	Patent Family 48	Patent Family 49	Patent Family 50
Brief Summary and Reasons for Inclusion	The patents in this family are directed to a device for detecting a substance in a liquid using lateral flow technology, including visual indicators for the presence of the target.	The patents and published applications in this family are directed a device for detecting a substance in a liquid using lateral flow technology, including visual indications for the presence of the target.	This patent is directed to a kit for detecting a substance in a liquid using lateral flow technology, wherein the components necessary for the assay are included in the kit. The description of the claimed device is similar to the OraSure device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. A device for performing an assay to detect the presence or absence of an analyte in a sample comprising: a matrix that supports the flow of a liquid sample; an application zone on the matrix for receiving the liquid sample; one or more reagent zones on the matrix comprising reagents for conducting the assay; a detection zone on the matrix, the detection zone comprising an analyte binding area and a positive control area demarcated on the matrix; wherein the analyte binding area and the positive control area interact to form recognizable symbols indicative of the presence or absence of analyte in the sample, and wherein at least a portion of detection zone is covered by an opaque, water-soluble dye. (*US 7,803,636 B2, below*)	1. A device for detecting the presence or absence of an analyte in a sample comprising: a matrix that supports the flow of a liquid sample; a sample application zone on the matrix for receiving a liquid sample; a detection zone on the matrix having a positive control area comprising one or more components that exhibit a first color when dry and a second color when wet, and an analyte binding area comprising a specific binding molecule; and one or more reagent zones on the matrix comprising reagents for conducting the assay.	1. A self contained diagnostic kit for performing analysis of a specimen comprising: a tubular housing having a bottom end and an upper end; a sampling unit removably stored within the housing, the sampling unit comprising a swab mounted at one end of a rod for collecting said specimen; at least one test strip positioned substantially along a wall of the tubular housing, the test strip having a sample receiving end; at least one receptacle positioned at the bottom end of said tubular body, the at least one receptacle containing a fluid reagent selected for extracting said specimen from said swab, the receptacle having an upper opening sealed by a rupturable foil; a longitudinal passage extending between said upper end of the tubular housing and said upper opening of said receptacle; a flexible elongated wick having one end in fluid communication or integrally formed with the sampling receiving end of said at least one test strip and a second end bent above and adjacent to said rupturable foil, intersecting said longitudinal passage, such that when the sampling unit is inserted into said receptacle through said passage, said second end of the wick is pushed down into the receptacle, thereby forming a fluid communication between said at least one receptacle and said at least one test strip. (*US 8,038,965 B2, below*)
International Patents and Published Applications (Status)			

Patent	Patent Family 48	Patent Family 49	Patent Family 50
United States	US 7,297,502 B2 (Issued Nov. 20, 2007; Expires Feb. 2, 2025) US 7,803,636 B2 (Issued Sept. 28, 2010; Expires Jan. 11, 2026) No US cases pending in this family.	US 7,704,753 B2 (Issued Apr. 27, 2010; Expires Feb. 2, 2025) No US cases pending in this family.	US 8,038,965 B2 (Issued Oct. 18, 2011; Expires Feb. 17, 2029) No US cases pending in this family.
European Patent Office[2]	*No Publication Identified*	EP 1861706 B1 (Issued March 2, 2016; Likely Expires Mar. 2, 2026) No EP cases pending in this family.	*No Publication Identified*
China	*No Publication Identified*	CN 1828301 B (Issued Oct. 6, 2010; Likely Expires Mar. 2, 2026) No CN cases pending in this family.	*No Publication Identified*
India	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 48	Patent Family 49	Patent Family 50
Indonesia	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 51	Patent Family 52
Title	ASSAY DEVICE	LATERAL FLOW ASSAY DEVICE WITH MULTIPLE EQUIDISTANT CAPTURE ZONES
Applicant	INVERNESS MEDICAL SWITZERLAND (CH)	ORASURE TECHNOLOGIES, INC. (US)
International PCT Application Publication No.	PCT/GB2008/003368 WO/2009/044167 (A1)	N/A
Expected Expiration[1]	Oct. 3, 2028	Oct. 25, 2031
Brief Summary and Reasons for Inclusion	The published applications in this family are directed to an assay for detecting a substance in a liquid sample. The claimed assay includes several elements that may be a part of the OraSure device, including labeling the target substance, a detection zone downstream from the location of the starting point of the target substance, and detection of the substance. Inverness Medical Switzerland is a predecessor of Alere.	This patent is directed to a lateral flow test strip that shares many elements with the OraSure device. In particular both devices include capture zones, a sample receiving area, and a sample pad. Because this patent is assigned to OraSure, it is possible that this technology is used in the OraSure device.
Representative Claim(s) (PCT claims, unless otherwise indicated)	1. An assay device for determining the presence and/or amount of an analyte of interest in a liquid sample, said assay device comprising a liquid flow-path comprising: (a) one or more reagents which, when contacted with the liquid sample, provide the analyte of interest in a detectable or more detectable form; (b) a control substance, comprising a control analyte, which, when contacted with said one or more reagents provides the control analyte in a detectable or	1. A lateral flow test strip comprising a sample receiving area for receiving a sample for analysis, and two or more analyte capture zones, wherein each of said two or more analyte capture zones is substantially equidistant to the sample receiving area and arranged in a linear array substantially parallel to the sample receiving area, wherein the sample receiving area comprises a sample pad adjacently disposed along the length of said linear array of the analyte capture

Patent	Patent Family 51	Patent Family 52
	more detectable form; (c) a detection zone for detecting a first labeled binding reagent for the analyte of interest, provided downstream from the one or more reagents; and (d) a control zone for detecting a second labeled binding reagent for the control analyte, provided downstream from the control analyte and from the one or more reagents; wherein detection of the first labeled binding reagent at the detection zone is indicative of the presence and/or amount of the analyte of interest and detection of the second labeled binding reagent at the control zone is indicative of the effectiveness of the one or more reagents in providing the analyte of interest in a detectable or more detectable form.	zones, wherein said sample pad extends beyond the linear array of the analyte capture zones. *(US 7,858,396, below)*
International Patents and Published Applications (Status)		
United States	US 2011/0008909 A1 (Abandoned) No US cases pending in this family.	US 7,858,396 B2 (Issued Dec. 28, 2010; Expires Oct. 25, 2031) No US cases pending in this family.
European Patent Office[2]	*No Publication Identified*	*No Publication Identified*
China	CN 101861207 A (Withdrawn) No CN cases pending in this family.	*No Publication Identified*
India	*No Publication Identified*	*No Publication Identified*
South Africa	*No Publication Identified*	*No Publication Identified*
Brazil	*No Publication Identified*	*No Publication Identified*
African Regional Intellectual Property Organization (ARIPO)[3]	*No Publication Identified*	*No Publication Identified*

Patent	Patent Family 51	Patent Family 52
Organisation Africaine de la Propriété Intellectuelle (OAPI)[4]	*No Publication Identified*	*No Publication Identified*
Eurasian Patent Organization (EAPO)[5]	*No Publication Identified*	*No Publication Identified*
Mexico	*No Publication Identified*	*No Publication Identified*
Russia	*No Publication Identified*	*No Publication Identified*
Indonesia	*No Publication Identified*	*No Publication Identified*
Nigeria	*No Publication Identified*	*No Publication Identified*

[1] If granted and not subject to patent term extension.

[2] The European Patent Office (EPO) includes the following countries: Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, Former Yugoslav Republic of Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, and Turkey.

[3] The African Regional Intellectual Property Organization (ARIPO) includes the following countries: Botswana, Gambia, Ghana, Kenya, Liberia, Lesotho, Malawi, Mozambique, Namibia, Rwanda, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.

[4] The Organisation Africaine de la Propriété Intellectuelle (OAPI) includes the following countries: Benin, Burkina Faso, Cameroon, The Central African Republic, Chad, Comoro Islands, Congo, Equatorial Guinea, Gabon, Guinea, Guinea-Bissau, Ivory Coast, Mali, Mauritania, Niger, Senegal, and Togo.

[5] The Eurasian Patent Organization (EAPO) includes the following countries: Turkmenistan, Republic of Belarus, Republic of Tajikistan, Russian Federation, Republic of Kazakhstan, Azerbaijan Republic, Kyrgyz Republic, Republic of Armenia, and Republic of Moldova.

[6] The present term search was limited to the countries available in the databases searched. As a result, the term searches were not able to identify published applications or patents in South Africa, Brazil, ARIPO, OAPI, EAPO, Mexico, Russia, and Nigeria. However, in some instances, published applications and or patents from one or more of these countries was identified through an INPADOC database, such as Espacenet (EPO) or PATENTSCOPE (WIPO).