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Molecular Probes, Reagents, and Assays

	Affymetrix Santa Clara, Calif (888) 362-2447; www.affymetrix.com	Alere Waltham, Mass (877) 441-7440; www.alere.com	Alere Waltham, Mass (877) 441-7440; www.alere.com
1. What is the brand name of your company's molecular diagnostic probe, reagent, or assay?	CytoScan Dx assay	Alere i Influenza A & B	Alere i Strep A
2. What year was the product first released to market (US, OUS)?	2014	2014	2015
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015).	CE IVD, 2014; FDA 510(k), 2014; CFDA Class I, 2015	FDA 510(k), 2014	FDA 510(k), 2015
4. What is the intended use or primary function of the product?	Intended for the postnatal detection of chromosomal copy number variants (CNVs) in genomic DNA obtained from peripheral whole blood in patients referred for chromosomal testing based on clinical presentation; intended to be used on the GeneChip 3000 Dx system and analyzed by Chromosome Analysis Suite Dx software.	Uses molecular diagnostic technology to detect influenza A and B viruses.	Uses molecular diagnostic technology to detect group A *Streptococcus* bacteria.
5. What type of specimen/sample does the product employ?	Genomic DNA isolated from peripheral blood	Nasal swab	Throat swab
6. What platform technologies does the product employ?	Chromosomal microarray analysis	Molecular diagnostic test utilizing isothermal nucleic acid amplification technology.	Molecular diagnostic test utilizing isothermal nucleic acid amplification technology.
7. What tests can be performed using the named product?	Detection of CNVs associated with developmental delay and intellectual disability, congenital anomalies, and dysmorphic features.	Influenza A and B	Group A *Streptococcus*
8. How much time is required for setup and preanalytical processing; what is the time to first result under optimal conditions?	Turnaround time for a run of up to 24 patients is 3.5 days.	Set up is less than 1 minute; results in less than 15 minutes.	Set up is less than 1 minute; results in less than 8 minutes.
9. How many channels/specimens/samples are tested per run (per plate, etc)?	Each array is designed for a single patient sample. Each run can process six to 24 samples.	One	One
10. Describe any automation options that pertain to the product.	GeneChip 3000 Dx system automates the washing, staining, and scanning steps of the CytoScan Dx assay.	Graphical user interface walks through the simple six-step procedure with animated graphics.	Graphical user interface walks through the simple six-step procedure with animated graphics.
11. How is quality control performed for the product?	Quality control materials are included.	Internal quality control run with each test. External quality control supplied with each kit.	Internal quality control run with each test. External quality control supplied with each kit.
12. Describe the capabilities, features, or accessories that distinguish this product from others on the market.	Only FDA-cleared chromosomal microarray; can analyze the entire genome at one time and detect chromosomal variations of different types, sizes, and genomic locations; provides all reagents required to perform the test, including an easy-to-use and intuitive analysis and reporting software. Not intended to be used for standalone diagnostic purposes, preimplantation, or prenatal testing or screening, population screening, or for the detection of, or screening for, acquired or somatic genetic aberrations.	First CLIA-waived molecular influenza test; employs proprietary isothermal nucleic acid amplification technology, providing highly sensitive and specific results within 15 minutes.	First Group A *Streptococcus* test to use molecular technology; employs proprietary isothermal nucleic acid amplification technology, providing highly sensitive and specific results within 8 minutes.

BioFire Diagnostics LLC Salt Lake City (800) 735-6544; www.biofiredx.com	BioFire Diagnostics LLC Salt Lake City (800) 735-6544; www.biofiredx.com	HTG Molecular Diagnostics Inc Tucson, Ariz (877) 289-2615; www.htgmolecular.com	Randox Biosciences-US Ltd Kearneysville, Wva (866) 472-6369; www.randoxbiosciences.com
FilmArray respiratory panel	FilmArray gastrointestinal panel	HTG Edge system	Familial hypercholesterolemia (FH) arrays I and II
2011	2014	2013	2014
FDA 510(k), 2011	FDA 510(k), 2014	UL/CSA, 2014; CE mark, 2014	CE marked; FDA approval is pending
Detection and identification of infectious diseases for upper respiratory disease syndrome caused by viruses or bacteria.	Detection and identification of gastrointestinal infections.	The system is a 96-well plate-based liquid handler and hybridization unit designed to automate next-generation sequencing library preparation.	In cases of suspected FH, simultaneous detection of 40 FH-causing mutations within the *ApoB*, *LDLR*, and *PCSK9* genes.
Nasopharyngeal swabs in viral transport medium	Stool in Cary-Blair transport medium	Cell lines; formalin-fixed, paraffin-embedded (FFPE) tissue; frozen tissue; plasma; purified RNA; serum.	Genomic DNA extracted from a blood sample
FilmArray is an automated sample-to-answer system for nucleic acid extraction, nested polymerase chain reaction amplification, and detection.	FilmArray is an automated sample-to-answer system for nucleic acid extraction, nested polymerase chain reaction amplification, and detection.	The system uses the company's qNPA chemistry system from post sample preparation up to the addition of molecular barcodes and sequencing tags.	Biochip array technology, a unique multiplexing method that combines PCR, probe hybridization, and chemiluminescence detection.
20 upper respiratory disease targets consisting of 17 viruses and three bacteria.	22 of the most common gastrointestinal pathogens, including bacteria, parasites, and viruses.	miRNA and mRNA gene expression	The arrays enable simultaneous detection of 40 FH-causing mutations (20 mutations per array) within the *ApoB*, *LDLR*, and *PCSK9* genes.
2 minutes set-up time; test turnaround time is about 1 hour.	2 minutes set-up time; test turnaround time is about 1 hour.	Sample preparation takes 2 hours (30 minutes hands-on), with a total turnaround time of 36 hours.	PCR setup is 5 to 15 minutes, depending on batch size. DNA extraction time is typically 1 hour, depending on the laboratory method employed. Time to first result from extracted blood DNA sample is approximately 3 hours.
One patient sample tested per run for 20 assay targets.	One patient sample tested per run for 22 assay targets.	Eight to 96 samples may be run per plate.	One negative control is required per run; minimum batch of three biochips, maximum batch of 54 in a single imaging run; 54 biochips per kit.
FilmArray is an automated sample-to-answer system.	FilmArray is an automated sample-to-answer system.	Receives lysed samples and automates target capture and protection to produce an untagged sequencing library.	FH multiplex PCR reactions performed off board on thermal cycler; amplicon hybridization and conjugation steps are automated using Electronics International analyzer package thermoshakers.
Test panels contain internal controls.	Test panels contain internal controls.	Assays use positive and negative controls, and in some instances, External RNA Controls Consortium (ERCC) probes.	Quality control performed internally and externally. Internally on each biochip: reference and correction spots ensure the analyzer charged-coupled device camera is precisely aligned; additionally, extraction controls are included for sample adequacy. Externally: each run should include a non-template or negative control; positive controls are not supplied with the kit.
Sample-to-answer system that requires minimal hands-on time; reports results for a comprehensive list of pathogens, depending on the syndrome, in about 1 hour, which helps physicians better manage their patients.	Sample-to-answer system that requires minimal hands-on time; reports results for a comprehensive list of pathogens, depending on the syndrome, in about 1 hour, which helps physicians better manage their patients.	Targeted NGS sample and library prep is simplified using a lysis-only chemistry, with no nucleic acid extraction necessary, and a simple, automated workflow. Sample input amounts are very low (eg, a single 5 µm FFPE slide section), and the easy-to-use data output streamlines analysis.	The FH 40-mutation panel identifies roughly 80% of the most commonly occuring FH-causing mutations and can be used as a rapid qualifier for deeper sequencing approaches. The panel is split across two biochips, allowing cost-effective subsequent cascade mutation screening in the family members of index cases.

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	Randox Biosciences-US Ltd Kearneysville, Wva (866) 472-6369; www.randoxbiosciences.com	Roche Diagnostics Inc Indianapolis (800) 428-5076; www.usdiagnostics.roche.com	Siemens Healthcare Diagnostics Tarrytown, NY (877) 229-3711; usa.healthcare.siemens.com/laboratory-diagnostics
1. What is the brand name of your company's molecular diagnostic probe, reagent, or assay?	STI multiplex array	Cobas Strep A test for use on the Cobas Liat analyzer	Siemens tissue preparation solution
2. What year was the product first released to market (US, OUS)?	2014	2014 (US, OUS)	2011
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015).	CE marked; FDA approval is pending	FDA 510(k), 2014	FDA Class I exempt, 2011; CE-IVD mark (reagents and system), 2011
4. What is the intended use or primary function of the product?	Multiplex polymerase chain reaction (PCR)-based biochip array for simultaneous detection of 10 sexually transmited infections from one single patient sample.	The qualitative in vitro diagnostic test detects *Streptococcus pyogenes* (group A β-hemolytic *Streptococcus*, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis.	Provides a fully automated process, including onboard deparaffinization and lysis, for the isolation of high-quality nucleic acids (both DNA and RNA with one IVD reagent kit).
5. What type of specimen/sample does the product employ?	Genomic DNA extracted from urine or urogenital swab samples	Throat swabs collected in a liquid amies collection and transport system	Formalin-fixed, paraffin-embedded (FFPE) or fresh-frozen (FF) tissue samples
6. What platform technologies does the product employ?	Biochip array technology, a unique multiplexing method that combines PCR, probe hybridization, and chemiluminescence detection.	Nucleic acid purification and real-time polymerase chain reaction (PCR) technology, targeting a segment of the *Streptococcus pyogenes* genome.	Uses magnetic nanoparticle-based isolation and proprietary iron oxide coated with a nanolayer of silica.
7. What tests can be performed using the named product?	*Chlamydia trachomatis, Haemophilus ducreyi*, Herpes simplex virus 1 and 2, *Mycoplasma genitalium, Mycoplasma hominis, Neisseria gonorrhoea, Trichomonas vaginalis, Treponema pallidum,* and *Ureaplasma urealyticum.*	Cobas Liat Strep A assay	Any molecular tests, including end-point and real-time polymerase chain reaction (PCR) and reverse transcription PCR; Sanger and next-generation sequencing, microarrays.
8. How much time is required for setup and preanalytical processing; what is the time to first result under optimal conditions?	PCR setup is 5 to 15 minutes, depending on batch size. DNA extraction time is typically 1 hour, depending on the laboratory method employed. Time to first result using extracted swab or urine DNA is 6 hours.	A result can be obtained in less than 20 minutes.	Dependent on the number of samples loaded and the protocol chosen (DNA, RNA, or split method); ranges from 3 to 4 hours for 48 samples. Hands-on time is 15 minutes, including loading reagents and samples.
9. How many channels/specimens/samples are tested per run (per plate, etc)?	One negative control is required per run; minimum batch of three biochips, maximum batch of 54 in a single imaging run; 108 biochips per kit.	The analyzer can run one sample at a time.	From one to 48 samples per run; sample kit can be split into four runs within 2 weeks.
10. Describe any automation options that pertain to the product.	Sexually transmitted infection (STI) multiplex PCR reactions performed off board on thermal cycler; amplicon hybridization and conjugation steps are automated using Electronics International analyzer package thermoshakers.	The Cobas Liat automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time PCR. The assay targets a well-conserved region of the Strep A genome. An internal process control processes target bacteria through all steps of the assay process and monitors the presence of inhibitors in the sample preparation and PCR.	Employs a fully automated tissue-extraction process; 0.903 m x 1.124 m x 1.2 m benchtop; requires environmental conditions of 18°C to 32°C; 24% to 80% relative humidity, noncondensing; 0 to 2,000 m altitude.
11. How is quality control performed for the product?	Quality control performed internally and externally. Internally on each biochip: reference and correction spots ensure the analyzer charged-coupled device camera is precisely aligned; additionally, extraction controls are included for sample adequacy. Externally: each run should include a non-template or negative control; positive controls are not supplied with the kit.	A positive and negative control kit is available to run quality control for the Strep A assay. Additionally, in less than 3 minutes, the Cobas Liat performs a full system check at power on, including configuration and check of all subsystems.	This is a sample-handling platform and does not require Siemens onboard quality control; customers have their own control samples.
12. Describe the capabilities, features, or accessories that distinguish this product from others on the market.	The STI panel is the most comprehensive multiplex PCR microarray-based test, including primary, secondary, and asymptomatic coinfections for a complete sexual health profile.	Ability to run real-time PCR tests and receive results in 20 minutes or less.	The only fully automated solution for the extraction of nucleic acids from FFPE and FF tissue samples. It includes a tissue preparation system and the Versant tissue preparation reagents kit.