tech guide

Molecular Diagnostics Systems

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1. What is the brand name of your company's molecular diagnostic system?	SNAQ-Seq Accukits	MassARRAY System	BioCode MDx-3000
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	RUO	With exception of the MassARRAY Dx and MassARRAY SARS-CoV-2 Panel, all other products are for research use only.	MDx-3000 System (2018)
3. What is the intended use or primary function of the product?	A companion product for targets NGS testing to improve the accuracy, LOD reproducibility. Can make NGS testing quantitative and enable to consolidation of multiple molecular tests to improve efficiency and reduce the time.	Targeted genomic testing of germline and somatic or rare variants in pharmacogenetics, tissue and liquid biopsies, inherited disease, carrier screening, and pathogen detection.	Multiplex molecular diagnosis
4. What type of specimen/sample does the product employ?	Any sample that can be used for NGS is compatible.	Various sources of extractable DNA or RNA including blood, plasma, cellfree, cytology blocks, urine, cell lines, nasal swabs, and buccal swabs.	GPP panel: stool; respiratory panel: nasopharyngeal swab (NPS); SARS-CoV-2: nasopharyngeal swabs (NPS),oropharyngeal swabs (OPS), and nasal swabs or bronchoalveolar lavage (BAL); CoV-2 Flu Plus: nasopharyngeal swabs (NPS)
5. What types of diseases, conditions, or analytes does the system detect?	Can be designed and manufactured to any target needed; e.g., oncology (myeloid/AML, fusions like MET Ex14 skipping, BRCA1/2 etc), AAV sequencing, complexity capture, COVID/flu or pathogen testing, and microbiome.	Copy number variants, deletions, insertions, single and multinucleotide polymorphisms, gene fusions/translocations, and CpG methylation.	Gastrointestinal pathogens; respiratory pathogens, SARS-CoV-2, and fungal analyte specific reagents
6. What platform technologies does the product employ?	Next Generation Sequencing (NGS), on all platforms, with any panel or targets, including LMN, TMO, PacBio, ONT, QIA, Archer and other platforms and panels.	Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF) of samples amplified by polymerase chain reaction (PCR)	Barcoded magnetic beads
7. Under ideal conditions, what is the time to first result; how are the test results made available?	SNAQ-Seq Accukits are a single reagent addition that easily adapted into the current method being used.	Approximately 9 hours for 192 DNA samples for germline genotyping with the 96-system. The software provides the genotypes detected for each sample and assay.	Up to 96 samples can be completed on the MDx-3000 system in <4 hours. Up to three different assay panels can be run on the esystem at the same time.
8. What are the product's maximum capacity and throughput under ideal conditions?	SNAQ-Seq Accukits are a single reagent addition that easily adapted into the current method being used.	384 System: 768 reactions, 96 System: 192 reactions per run. Each reaction can detect up to 50 variants depending on application.	Up to 188 samples can be completed on the system in an 8 hour shift.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	SNAQ-Seq internal standards can serve as a positive control for a negative result, and help establish the LOD for the assay on a per sample basis, and they improve CNV and RNA fusion detection.	On-board liquid handler for analyte transfer and chip preparation. Bidirectional connectivity with laboratory information management system.	Automated PCR, hybridization and detection in the integrated system. The system has auto-check feature, internal control as well LIS connectivity.
10. What types of technical support are available?	Simple protocols (single reagent addition into current lab method) and analysis support.	Global customer support team for onsite and remote application and technical service. Robust development group for creation of custom panels.	Virtual (via text, email, phone, remote viewing)
11. What capabilities, features, or accessories distinguish this product from others on the market?	There are no other mixtures of internal NGS standards available, and use and validation with an internal standard can replace the use of a costly external control, while increasing flow cell utilzation and capacity.	High level of multiplexing enables detection of multiple targets; direct analysis of mass allows for high sensitivity, low cost, and easy analysis; open system allows for a variety of biomarkers that can be targeted-genotyping, methylation profiling, CNV, gene fusions, and low-frequency somatic variants on the same platform.	Utilizing digital barcodes enables high multiplex syndromic panel testing affordable. Data masking enables target specific reporting based on clinician's order.

Becton, Dickinson and Company (BD) Franklin Lakes, NJ 201-847-6800 www.bd.com	**BioGX** Birmingham, AL 205-250-8055	**bioMérieux, Inc.** Salt Lake City, UT 800-682-2666, www.biomerieux-usa.com/	**bioMerieux, Inc.** Salt Lake City, UT 800-682-2666 www.biomerieux-usa.com/
BD COR System	pixl Real-Time PCR Platform	BIOFIRE FILMARRAY Systems	BIOFIRE SPOTFIRE System
CE mark, 2019; FDA PMA 2021	CE-IVD and 510k exempt registered	FDA 510(k), 2013. Individual assays have FDA 510(k) and CE Mark.	FDA 510(k) (2023); CE mark, 2022. UKCA mark, 2022; individual assays have FDA 510(k), CLIA waived (2023).
Infectious disease molecular diagnostics.	Infectious disease molecular diagnostics, real-time PCR analysis, extractrion-free real-time PCR analysis	Automated in vitro diagnostic (IVD) device Systems are intended for use in combination with assay-specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens.	Automated in vitro diagnostic (IVD) device is intended for use in combination with assay-specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens.
Liquid-based cytology, swab collection device, urine	Pre-treated (nucleic acid extraction) and direct processing of human biological samples such as swabs in transport medium, sputum, whole blood, cerebral spinal fluid, nasal wash, urine, stool, or other bodily fluids.	Assay dependent sample types include nasopharyngeal swabs in transport media or saline, bronchoalveolar lavage, sputum, stool sample in Cary Blair medium, cerebrospinal fluid, positive blood culture, synovial fluid.	Nasopharyngeal swabs in viral transport media.
Women's health and sexually-transmitted infections (HPV, bacterial vaginosis, vulvovaginal candidiasis, trichomonas vaginalis, chlamydia trachomatis, neisseria gonorrhoeae). respiratory infections (SARS-CoV-2, influenza A and influenza B.)	Nucleic acid detection from bacteria, viruses, fungi and/or parasites that fall into respiratory, immunocompromised, UTI/STI/wound, drug resistance, enteric and tropical infection disease syndromic groups	Assay dependent reagent panels include upper respiratory infections, lower respiratory tract infections, gastroenteritis, central nervous system infections, bloodstream infections, joint infections.	Reagent panels run on the system detecting respiratory infections.
Real-time PCR	Real-time PCR	RT-PCR with PCR melt curve analysis.	Reverse transcriptase polymerase chain reaction (RT-PCR).
For HPV, about 3 hours, including liquid base cytology conversion to molecular aliquiot tube; additional results about every hour of continuous run time. For other molecular assays, about 2.5 hours; additional result in about 30 min.	Results available in less than 60 minutes	About 1 hour.	About 15 minutes.
Capacity and throughput depend on configuration and specimen type. Capacity ranges from 350 to 2,100 samples; walkaway time: 6.5 to 8 hours.	Processes 1 to 16 samples per run in under 60 minutes, four optical channels (FAM/HEX/ROX/Cy5 equivalent)	Up to 351 patient samples per day based on running the BIOFIRE FILMARRAY Respiratory 2.1 (RP2.1) Panel over a 24-hour day.	Up to 4 samples at a time, generating up to 104 patient samples in an 8-hour shift.
Fully integrated from sample loading and pre-analytic preparation through resulting and sample storage; bidirectional laboratory information system interface	No calibration needed, integrated software/wizard that guides user through PCR run set-up	Automated sample-to-answer sample processing with bidirectional LIS capabilities allowing auto-release of results.	Automated sample-to-answer sample processing with bidirectional point-of-care connectivity capabilities.
We offer 24/7 technical support via phone and chat. We also offer field service, including BD Assurity Linc remote service, on-site instrument service, and annual preventative maintenance.	Product support team that helps to trouble-shoot issues related to the real-time PCR reaction (including run file set-up, results analysis, pretreatment steps if applicable)	Online and 24/7 phone support. Remote system access for rapid, easy, technical support via VILINK. On-site installation, training, application support, and service.	Online and 24/7 phone support. On-site installation, training, application support, and service.
Integrated, automated preanalytic functions and high sample and consumable capacity reduce user interactions. Ready-to-use reagents minimize hands-on setup time. Internal surveillance system monitors reagents and sample handling. Remote Support Services connects BD COR with BD technical support for rapid trouble-shooting and assistance.	Small footprint, lightweight, easy-to-use with touch screen interface, integrated result interpretation and analysis tool, sample-to-answer assays, multiplexing capabilities, amplification reaction visible in real-time on the screen, end result displayed as Ct value for positive samples, open system instrument.	The only sample-to-answer, molecular highly multiplex RT-PCR systems with 6 FDA-cleared and CE marked sydromic tests with ~2 minutes hands-on time and results in about 1 hour.	A scalable point-of-care system with the first CLIA-waived respiratory PCR tests for COVID-19. ~2 minutes hands-on time and results in about 15 minutes. Test for either 5 or 15 respiratory pathogens.

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LIAISON MDX	SeptiCyte RAPID	VERIGENE	FLEXMAP 3D
Class II, 510(k) exempt; CE Marked per IVDR. Individual assays have FDA 510(k).	FDA 510(k), 2021 and CE-IVD mark, 2020	Class II, 510(k) exempt; CE Marked per IVDD & IVDR. Individual assays have FDA 510(k).	Class II, 510(k) exempt; CE Marked per IVDD & IVDR. Individual assays have FDA 510(k).
Molecular diagnostic sample-to-answer in vitro diagnostic system.	In vitro diagnosis of sepsis to differentiate infection-positive from infection-negative systemic inflammation in patients suspected of sepsis	Molecular diagnostic sample-to-answer in vitro diagnostic system.	Molecular diagnostic sample-to-answer in vitro diagnostic system.
Assay dependent, including cerebrospinal fluid, nasopharyngeal swab, nasal wash/aspirate, bronchoalveolar lavage, whole blood, plasma, serum, stool, urine, saliva, Lim broth, throat swabs, and cutaneous/mucocutaneous swabs.	Whole blood samples from PAXgene Tube or EDTA Tube	Assay dependent; sample types include nasopharyngeal swabs, positive blood culture bottle, and stool preserved in Cary-Blair medium.	Assay dependent; sample type purified PCR samples, serum, antibody, and stool preserved in Cary-Blair medium.
Congenital Cytomegalovirus, Influenza A/B and RSV; COVID-19; herpes simplex viruses 1 and 2; varicella zoster virus, group A streptococcus; group B streptococcus; Bordetella pertussis and B. parapertussis, and C. difficile. More than 65 analyte specific reagents.	It quantifies the relative expression levels of host response genes	Bloodstream infections, gastroenteritis, respiratory infections.	Genetic, infectious disease, agricultural samples, transplant matching.
RT-PCR; quantitative PCR; PCR with melt analysis.	Real-time PCR	RT-PCR for enteric and respiratory tests. Hybridization for blood culture.	xMAP Technology for bead-based multiplexing assays.
Approximately 1 hour. Results are made available on printouts or to a laboratory information system.	The results are available within 1 hour	Up to 2 hours.	20 minutes/96-well plate, results exported as a .csv file.
Direct amplification discs: up to 8 specimens per run. Universal discs: up to 96 specimens per run. Has 4 channels for multiplexing.	The test is performed on Biocartis's Idylla Platform. Can independently run up to 8 samples simultaneously	With a configuration of 3 VERIGENE Processor SPs and one VERIGENE Reader, the VERIGENE System can run up to 12 samples in an 8-hour shift.	384-well plate every 45 minutes: Ten 384-well plates in an 8-hour shift.
Bidirectional laboratory information system connectivity; fluid check to prevent false negative results caused by insufficient sample volume; spectral calibration auto-generation feature; generation of quality control reports; third-party automated disc set-up.	Fully integrated end-to-end automated process with less than 2 min hands on time. Each test cartridge contains sample processing control to ensure validity of each test run. Bidirectinal LIS interface, availability of user enabled LAN and Cloud connectivity	Automated extraction, amplification, and hybridization. The reader allows internal data storage as well as laboratory information system connectivity. Scalable, permitting up to 32 VERIGENE Processor SPs to be attached to a single Verigene Reader. Allows on-demand testing.	Software package available for automation, LIS software available as well.
Dedicated technical services team, field application scientists, and field service training, on-site engineers.	Technical support via phone, email. Availability of user enabled remote troubleshooting.	Online and 24/7 phone support; team of molecular application specialists available to serve customers in person.	Online and 24/7 phone support; team of molecular application specialists available to serve customers in person.
Measures only 12 inches by 8 inches by 12 inches; amplification curves available and results easy to interpret; convenient software navigation; able to run IVD and LDT assays.	FDA-cleared host response test that accurately differentiates sepsis from infection-negative systemic inflammation in patients within one hour.	System consists of one or more processor SPs and a reader. The processor SP combines nucleic acid extraction, purification, amplification, and hybridization. The reader manages sample data, reads results, allows for result printing, and offers LIS connectivity.	Multiplexing of up to 500 targets per well.

Targeted and syndromic molecular solutions for clinical utility based on your patient testing

Find the right test, for the right patient, at the right time with our FDA-cleared assays and expanding test menu.

LIAISON® MDX

Healthcare-Associated Infections
- Simplexa® *Candida auris* Direct Kit (In Development)[1]
- Simplexa® *C. difficile* Direct Kit
- Simplexa® MRSA Direct Kit (In Development)[1]

Respiratory
- Simplexa® Bordetella Direct Kit
- Simplexa® COVID-19 Direct Kit **Now, FDA cleared!**
- Simplexa® COVID-19 & Flu A/B Direct Kit **Now, FDA cleared!**
- Simplexa® Flu A/B & RSV Direct Gen II Kit
- Simplexa® Group A Strep Direct Kit
- Simplexa® SARS-CoV-2 Variants Direct Kit (RUO)[2]

Herpes Viruses
- Simplexa® HSV 1 & 2 Direct Kit (Swab)
- Simplexa® VZV Swab Direct Kit

Meningitis/Encephalitis
- Simplexa® HSV 1 & 2 Direct Kit (CSF)
- Simplexa® VZV Direct Kit (CSF)

Women's/Neonatal Health
- Simplexa® Congenital CMV Direct Kit
- Simplexa® GBS Direct Kit

VERIGENE®

VERIGENE® Enteric Pathogens Test

VERIGENE® Gram-Negative Blood Culture Test

VERIGENE® Gram-Positive Blood Culture Test

VERIGENE® Respiratory Pathogens *Flex* Test

Prepare yourself for this winter season with the most rapid FDA-cleared molecular targeted test for respiratory: Simplexa® COVID-19 & Flu A/B Direct assay.

DiaSorin Molecular

Luminex
A DiaSorin Company

To learn more, contact us at cs.molecular@diasorin.com or info@luminexcorp.com.

For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions.

1. This assay is under development and not currently FDA cleared for IVD use.
2. RUO - This product is for Research Use Only. Not for use in diagnostic procedures.

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Revogene	QIAstat-Dx system	Solana	Vivalytic
FDA 510(k), 2017 CE Mark, 2016, Individual assays have FDA 510(k) and are CE marked	QIAstat-Dx Analyzer: FDA 510(k), 2019. Individual assays have EUA or CE mark.	FDA 510(k); CE Mark, 2015	CE Mark (2019)
Molecular diagnostic used as an aid in diagnosis	Automated, PCR-based in vitro diagnostic system for infectious disease testing. Fast detection and differentiation of nucleic acid from multiple pathogens at once.	A benchtop instrument that combines proprietary helicase dependent amplification (HDA) with fluorescence detection to deliver molecular results.	Enables sample to answer, cartridge-based molecular diagnostic testing; capable of both high-plex and low-plex testing. Nucleic acid extraction, PCR amplification.
Assay dependent; sample types include unformed (liquid or soft) stool specimens, throat swabs, nasopharyngeal, oropharyngeal, anterior nasal, mid-turbinate nasal, vaginal/rectal swabs, Carbapenem-non-susceptible pure colonies of Enterobacteriaceae, Acinetobacter baumannii, or Pseudomonas aeruginosa	Assay-dependent sample types include nasopharyngeal swabs in universal transport medium or stool samples in Cary Blair-medium.	Assay dependent; sample types include nasal/nasopharyngeal swabs, throat swabs, unformed stool, vaginal swabs, urine, cutaneous, or mucocutaneous lesions.	Nasopharyngeal or oropharyngeal swabs, swab (cultures, wounds, axilla, groin, and perineum), sputum, & urine
Single analyte - SARS-CoV-2, C. difficile, Group A Strep, Group B Strep; multiplex - Carba colony	Respiratory tract infections, gastroenteritis.	SARS CoV-2, influenza A & B, RSV, human metapneumovirus, Streptococcus spp., Bordetella pertussis and B. parapertussis, C. difficile, Trichomonas vaginalis, herpes simplex virus 1 and 2, varicella zoster virus.	Comprehensive test menu encompasses a wide spectrum of infections, spanning respiratory, genitourinary, gastrointestinal, and hospital-acquired conditions, including screening for SARS-CoV-2 (COVID-19), sexually transmitted infections, as well as MRSA/SA.
Real-time reverse-transcriptase polymerase chain reaction (real-time RT-PCR)	Multiplex RT-PCR; viewable Ct value and amplification curves for all detected pathogens	Helicase-dependent amplification with fluorescence detection.	RT-PCR
Early call feature for certain assays. Deliver positive results in as soon as 42 minutes	Around 1 hour	Assay dependant; results can be available in as soon as 25 minutes or up to 50 minutes. Results available on touch screen, can be stored internally, on a USB, or LIS system.	Time to result is assay dependent, results will be displayed on the Vivalytic touchscreen as either quantitative or qualitative.
Up to 8 samples per run	Up to 4 patient samples in ~1 hour or up to 80 samples per day when the QIAstat-Dx Analyzer 1.0 is equipped with 1 operational module and 4 analytical modules.	The workflow is easy and flexible, capable of testing a single sample or batch testing up to 12 tests.	One patient sample/cartridge at one time. In 8 hours can test up to a maximum of 10 patient samples/cartridges; assay dependent.
Bidirectional LIS communication capability	Cloud-based connectivity through the QIAsphere app allows users to connect their instruments and get remote instrument status notifications, proactive remote technical service, bidirectional LIS integration and customized epidemiology dashboards.	Intuitive touch screen interface with guided operation and customizable settings; four USB ports, barcode technology, external printer, and LIS connectivity.	Sample-to-answer, cartridge-based molecular diagnostic testing. High-plex & low-plex capability, fully automated with no peripherals needed. Space-saving, hygienic solution.
Live, technical support available 7 days a week	QIAsphere provides proactive and predictive remote service. Phone, email and chat technical service support. Field application specialist team provides on-site training.	24 hours, 7 days a week via phone or email.	Technical support is accessible via telephone, email, and video calling applications.
Fully automated, small footpint, simplified sample prep and workflow, multiple sample types coupled with the ability to run different assays within the same run and a user-friendly interface with a bidirectional communication capability. Can perform single analyte and multiplex testing.	The only sample to insight multiplex RT-PCR diagnostic system that provides comprehensive answers in around 1 hour, as well as Ct values and amplification curves for all detected pathogens. Easy to learn, easy to use, and easy to maintain with less than 1 minute of hands-on time and just 1 sample handling step.	Small footprint and simplified workflow facilitate decentralization of the instruments to bring them closer to the patient. Incorporates proprietary wireless data management and surveillance ecosystem.	Vivalytic is a lightwieght near patient system, which consolidates the complex molecular workflow into a fully automated process. It is a closed system to reduce the risk of contamination. The Vivalytic user is required to complete four easy steps to run a test.

Identifying respiratory pathogens: the first step to managing infection

The diagnosis challenge

Acute respiratory infections are one of the world's leading causes of death and disabilty.[1] These include both upper respiratory tract infections – like the common cold – and lower respiratory tract infections – such as pneumonia or bronchitis.

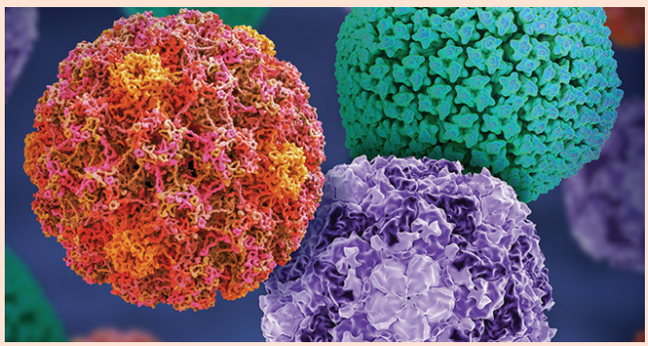
A wide variety of pathogens cause respiratory infections. These range from viruses like severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) to bacteria such as *Streptococcus*. And many can present similar symptoms.

This poses a challenge for diagnosis. Antibiotic treatment is often initiated in primary care settings, even when a viral infection is a strong possibility – leading to unnecessary or inappropriate prescribing of antibiotics.[2,3]

Better testing, better treatment

Early, accurate diagnosis is key to identifying the cause of a respiratory infection and ensuring the right therapy. To optimize time-to-treatment, diagnosis cannot always rely on culture alone.

Other methods have been developed to improve sensitivity, specificity, and detection time. These tests may be run on fully automated, high-throughput systems, point-of-care solutions, or syndromic testing solutions. Delivering timely, reliable results empowers healthcare professionals to make more informed treatment decisions – while elevating the overall value of testing locations.



A global leader

Addressing the complexity of respiratory tract infections calls for a comprehensive approach. As the world's leading supplier of in vitro diagnostic solutions, Roche invests heavily in research and development to deliver technologies that address real-world needs.

We offer a wide-ranging portfolio to help detect and manage respiratory disease – from the world's first commercially available PCR test for SARS-CoV-2 to molecular point-of-care multiplex assays that can differentiate common viral agents.

Learn more about how Roche can help you provide patients with a reliable diagnosis, when and where it's needed most.

go.roche.com/goldpcr

[1] Forum of International Respiratory Societies. The global impact of respiratory disease. 2017. https://static.physoc.org/app/uploads/2019/04/22192917/The_Global_Impact_of_Respiratory_Disease.pdf

[2] Centers for Disease Control and Prevention. Be Antibiotics Aware: Smart Use, Best Care. 2021. https://www.cdc.gov/patientsafety/features/be-antibiotics-aware.html

[3] Hersh AL, et al. Antibiotic prescribing in ambulatory pediatrics in the United States. *Pediatrics*. 2011;128(6):1053–1061.

Rheonix, Inc. Ithaca, NY 607-257-1242 www.rheonix.com	**Roche Diagnostics** Indianapolis, IN https://diagnostics.roche.com/us/en/products/systems/eplex-system-sys-356.html	**Roche Diagnostics** Indianapolis, IN https://diagnostics.roche.com/us/en/products/product-category.html	**Seegene USA, Inc.** Irvine, CA 800-725-2167 https://seegeneus.com/ info.seegeneusa@seegene.com
Rheonix Encompass MDx workstation for FDA cleared and authorized assays. Rheonix Encompass Optimum workstation for RUO assays.	GenMark ePlex	cobas 5800/6800/8800 Systems	Seegene STARlet, Seegene NIMBUS, Seegene Launcher, Seegene Viewer
FDA 510(k), 2021, cTUVus 2022	FDA 510(k), 2017	cobas 6800/8800 Systems (2015) cobas 5800 System (2022) Individual assays have FDA 510(k) or PMA.	All Products are for research use only. Not for use in diagnostic procedures.
Fully automated, multiplexed molecular diagnostics. Open system for RUO and customer developed assays.	Automated in vitro diagnostic device designed to perform multiplex nucleic acid tests for the simultaneous detection and identification of nucleic acid targets by processing single-use cartridges developed and manufactured by GenMark Diagnostics, Inc."	Molecular diagnostics - IVD and LDT assays	High multiplex real-time PCR and syndromic testing
Wide range of sample types including swabs, urine, stool, blood, bacterial isolates, buccal swabs.	Respiratory (nasopharyngeal swab in viral or universal transport media), blood culture (positive blood culture bottle)	Includes but is not limited to: liquid-based cytology, plasma, serum, VTM, cobas PCR media, saline	Human samples including urine, vaginal swabs, stool, and respiratory swabs.
Respiratory pathogens (FDA EUA); STI pathogens (FDA 510(k)); multiple sydromic panels in development. Open system for RUO/customer-developed assays for pathogen detection, SNP detection, and other capabilities.	Blood culture identification including comprehensive coverage of gram positive, gram negative, and fungal pathogens and resistance genes. Respiratory targets that include over 20 of the most common pathogens that cause disease together on a single rapid test.	Infectious disease: respiratory, women's health, sexually transmitted infections, transplant, virology, LDT tests	Detection of nucleic acid targets from infectious disease pathogens: drug resistance markers (antimicrobial resistance), fungal pathogens, gastrointestinal pathogens, H. pylori, HPV detection, meningitis pathogens, respiratory pathogens, sexually transmitted pathogens, urinary tract pathogens, organisms involved in vaginosis and vaginitis, vector-borne pathogens, molecular controls
Microarray detection, multiplex PCR, bead-based purification	The ePlex system as PCR based platform utilizing proprietary electrowetting and eSensor technologies to facilitate digital microfluidics, and the principles of DNA hybridization for electrochemical detection	PCR, including multiplexing capability	Multiplex real-time PCR
3.5-4.5 hours; Results available on-screen, printable, and via LIS.	Results in about 90 minutes with the flexibility to run 3-24 test bays simultaneously.	2.5 hours for up to 24 results on the cobas 5800 System. < 3.5 hours for up to 96 results for cobas 6800/8800 Systems. Results available on-screen, printable, can be fully integrated with LIS. Auto-release of results available.	Short TAT - 4 hours from extraction to final results
24 samples per run, up to 34 analytical targets per sample.	With the flexibility to utilize between 3 & 24 bays, throughput varies from 36 to 288 patient samples per 24 hour day depending on instrument configuration.	cobas 5800 System: up to 528 tests/24 hours. cobas 6800 System: up to 1,440 tests/24 hours. cobas 8800 System: up to 4,128 tests/24 hours.	Up to 188 samples in 8 hrs.
Fully automated molecular systems capable of performing sample transfer, nucleic acid extraction, amplification, and detection.	Bi-directional LIS, onboard external control tracking, remote support capability, onboard system monitoring for proactive troubleshooting, random access and continuous throughput.	Fully automated molecular systems capable of performing sample transfer, nucleic acid extraction, amplification, and detection. Walkaway time of up to 8 hours, and auto-release of valid control and sample results.	Real-time PCR combines amplification and detection into 1 step. Run controls and exogenous controls provide confidence in results. The short TAT and high multiplex assays enable identification and detection of multiple pathogens in a single PCR reaction (up to 10 targets)
On-site installation, training, application support, and service. Remote diagnostic capabilities; phone and onsite support	24/7 via phone and email; remote support; field service and field applications for onsite support.	24/7 via phone and email; field service and field applications for onsite support.	800-725-2167; https://seegeneus.com; info.seegeneusa@seegene.com
Fully automated sample to answer system; highly scalable; low training requirements	Large touchscreen with an intuitive user interface. Onboard software suites such as templated comments, external control tracking, customizable surveillance monitoring, pending order sample tracking, and report capabilities.	Easy-to-use, fully automated instrument that can process multiple tests, sample types, and targets simultaneously. Ability to consolidate infectious disease, transplant, respiratory, STI, women's health, and open channel testing on a single platform. Standardized and streamlined workflow."	We have made important contributions to the field of multiplex PCR testing with the DPO, TOCE, and MuDT technologies. Employed across various products, these innovations make it possible to detect from among multiple pathogens in a single PCR channel, increasing the total number of candidate pathogens in a single PCR reaction, compared to standard practice.