tech guide

Molecular Diagnostics Systems

	Agena Bioscience San Diego, Calif 858-882-2800 www.agenabio.com	Applied BioCode, Inc. Santa Fe Springs, Calif 833-246-2633 (833-BIO-CODE) www.apbiocode.com	Becton, Dickinson and Company (BD) Franklin Lakes, NJ 201-847-6800 www.bd.com
1. What is the brand name of your company's molecular diagnostic system?	MassARRAY System	BioCode MDx-3000	BD COR System
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	With exception of the MassARRAY Dx and MassARRAY SARS-CoV-2 Panel, all other products are For Research Use Only.	MDx-3000 System, GPP-17 target & RPP-17 target syndromics: FDA 510(k), CE Mark; COVID-19 PCR Test: EUA	CE mark, 2019; FDA PMA 2021
3. What is the intended use or primary function of the product?	Targeted genomic testing of germline and somatic or rare variants in pharmacogenetics, inherited disease, carrier screening, tissue and liquid biopsies, and pathogen detection.	Multiplex molecular diagnosis	Infectious disease molecular diagnostics.
4. What type of specimen/sample does the product employ?	Various sources of extractable DNA or RNA including blood, plasma, cell-free, cytology blocks, urine, cell lines, nasal swabs, and buckle swabs.	Gastrointestinal: stool; respiratory & SARS-CoV-2: nasopharyngeal swab (NPS)	Liquid-based cytology, swab collection device, urine
5. What types of diseases, conditions, or analytes does the system detect?	Copy number variants, deletions, insertions, single and multinucleotide polymorphisms, gene fusions/translocations and CpG methylation.	Gatrointestinal pathogens, respiratory pathogens, SARS-CoV-2, fungal analyte specific reagents	Women's health and sexually-transmitted infections (human papillomavirus [HPV], bacterial vaginosis, vulvovaginal candidiasis, trichomonas vaginalis, chlamydia trachomatis, neisseria gonorrhoeae).
6. What platform technologies does the product employ?	Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF) of samples amplified by polymerase chain reaction (PCR)	Barcoded magnetic beads	Real-time PCR
7. Under ideal conditions, what is the time to first result; how are the test results made available ?	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 patient samples can be completed on the system in 4 hours. Up to 3 different assay panels can be run on the system at the same time.	For HPV, about 4.5 hrs, including liquid-based cytology conversion to molecular aliquot tube; additional results every 1.5 hrs of continuous run time.
8. What are the product's maximum capacity and throughput?	384 System: 768 reactions, 96 System: 192 reactions per run. Each reaction can detect up to 50 variants depending on application.	Up to 188 patient samples can be completed on the system in an 8 hour shift. Up to 3 different assay panels can be run on the system at the same time.	Capacity and throughput depend on configuration and specimen type. Capacity ranges from 350 to 2,100 samples; walkaway time: 6.5 to 8 hours.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Onboard liquid handler for analyte transfer and chip preparation. Bidirectional connectivity with laboratory information management system.	Automate PCR, hybridization, & detection in the integrated system. The system has auto-check, internal control, and connection with LIS systems.	Fully integrated from sample loading and pre-analytic preparation through resulting and sample storage; bidirectional laboratory information system interface
10. What types of technical support are available?	Global customer support team for onsite and remote application and technical service. Robust development group for creation of custom panels.	Virtual (text, email, phone, remote viewing), and in-person support	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.
11. What capabilities, features, or accessories distinguish this product from others on the market?	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. Easy-to-use assay design software enables easy design of multiplexed assays.	Utilize digital barcode platform to provide flexibility, capacity, and syndromic tests. You select the targets that you want; the lowest cost in syndromic testing; random batching mode for faster turnaround time and maximum sample capacity.	Integrated and automated preanalytic functions and high capacity for samples and consumables limit user interactions per shift. The BD Onclarity HPV assay performed on the BD COR System and the BD Viper LT System reports the most individual genotypes of any FDA-approved HPV assay, and utilizes human beta globin as an internal control. Ready-to-use reagents minimize hands-on time for setup.

Becton, Dickinson and Company (BD) Franklin Lakes, NJ 201-847-6800 www.bd.com	**Becton, Dickinson and Company (BD)** Franklin Lakes, NJ 201-847-6800 www.bd.com	**Biocartis** Mechelen, Belgium 1-844-443-9552 www.biocartis.com	**ChromaCode, Inc.** Carlsbad, Calif 442-244-4370 www.chromacode.com
BD Viper LT System	BD MAX System	Idylla	ChromaCode HDPCR
FDA 510(k) 2014; CE mark 2014	FDA 510(k), 2012; CE Mark 2011	IVDD CE mark, 2014 FDA 510(k) exempt, 2017	FDA Emergency Use Authorization, 2020; CE-IVDD, 2021
Infectious disease molecular diagnostics of HPV, chlamydia, and gonorrhea	Performs molecular tests with both in vitro diagnostic (IVD) assays that are FDA cleared and open system reagents, so that labs can create and validate laboratory developed tests (LDTs).	A fully-automated, PCR-based molecular testing system for rapid oncology biomarker analysis and infectious disease testing.	High-throughput infectious disease molecular diagnostics
Liquid based cytology samples, vaginal swabs, endocervical swabs, male urethral swabs, urine samples	Cary-Blair preserved stool, endocervical swabs, nasal swabs, unpreserved stool, 10% formalin-fixed stool, urine, vaginal swabs, vaginal-rectal swabs in Lim Broth, rectal swabs.	FFPE tissue, plasma, nasopharyngeal swabs	Nasopharyngeal swabs, oropharymgeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal aspirate, nasal wash, bronchoalveolar lavage (BAL) specimens
Women's health and sexually-transmitted infections (human papillomavirus [HPV], chlamydia trachomatis, neisseria gonorrhoeae)	Women's health and sexually-transmitted infections, enteric infections, healthcare-associated infections, and respiratory infections, inc. COVID-19.	Oncology gene mutations: EGFR, BRAF, KRAS, NRAS, MSI, ALK, ROS1, RET, NTRK1/2/3 rearrangements & MET Exon 14 skipping. Infectious Disease: SARS-CoV-2, Influenza, RSV	SARS-CoV-2
Real-time PCR and SDA	Real-time PCR	RT-PCR	Standard qPCR and extraction instruments
For HPV about 4.5 hours For CT/GC about 3.5 hours	24 samples in approximately 3 hours.	From 85 to 180 minutes, depending on the assay used. Test results are available on the Idylla console immediately upon test completion and also remotely if an Internet connection is established.	Time to result ~4 hours, hands on time ~1.5 hours. Web-based software presents results in plate or individual well formats.
Max capacity 30 samples/batch HPV: 90 results in approximately 9.5 hours CT/GC: 90 results in approximately 8 hours	Processes up to 24 samples per run, and approximately 96 samples per 8-hour shift.	One sample per cartridge per Instrument; up to 30 molecular targets per cartridge. Modular system can connect up to 8 Idylla instruments to one Idylla console.	Scalable: 1-88 samples/96-well plate or 1-373 samples/384-well plate
Fully integrated from extraction through resulting; bidirectional laboratory information system (LIS) interface.	Fully integrated from extraction through resulting; bidirectional laboratory information system (LIS) interface.	The testing process is fully automated, with robust internal processing controls. Hands-on time is approximately 2 min/sample. Connectivity options (LAN, LIS, data portal) are available.	Ability for end-to-end integration into laboratory using common extraction platforms and qPCR instrumentations followed by streamlined data analysis in ChromaCode Cloud.
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 6-month preventative maintenance.	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.	One-year warranty plus extended onsite and online support available for connectivity, repair, maintenance, troubleshooting, etc.	7AM-5PM PST phone, email or chat with maximum 2-hour response. After hours response within 24 hours.
The BD Onclarity HPV assay that runs on the BD Viper LT reports the most individual genotypes of any FDA-approved HPV assay, and utilizes human beta globin as an internal control. Ready-to-use reagents minimize hands-on time for setup. Automated reagent and consumable checks identify potential errors before a run starts.	Offers a range of IVD assays and open-system reagents for creating laboratory-developed tests. Fully automated batch testing.	Fully automated molecular testing with rapid turnaround time; easy to implement and use even in small labs; minimal hands-on time; relevant gene content; fully automated data analysis and easy to interpret report; high-accuracy results with low DNA input. Modular system with small footprint and low cost of ownership.	HDPCR multiplexing technology utilizes existing qPCR instrumentation to achieve 4x analytical capacity. Proprietary ChromaCode Cloud data science takes signals achieved from optimized PCR reagents to increase test capabilities and simplifies result analysis. A familiar workflow with automated extraction eases implementation and adoption.

RT-PCR accuracy, **point-of-care efficiency**

Get leading analytical sensitivity with one easy COVID-19 test for all your patients

Deliver PCR results you and your patients can trust with a simple, time-saving workflow. With the rapid PCR Thermo Fisher Scientific™ Accula™ SARS-CoV-2 Test, you get results for every individual suspected of COVID-19 infection by their healthcare provider—whether they have symptoms or not—in approximately 30 minutes. The test uses a nasal swab sample, is authorized for patient self-collection with clinician oversight, and takes just one minute of hands-on time. Simply follow the prompts on the Accula™ Dock to insert the cassette, load the sample, and close the lid to start the test—no further steps required. Delivering results at the speed you need.

Find out more at **thermofisher.com/mesa**

For Emergency Use Authorization (EUA) Only. For Prescription Use Only. For *In Vitro* Diagnostic Use.

tech guide

Molecular Diagnostics Systems

	DiaSorin Molecular Cypress, Calif 562-240-6500 molecular.diasorin.com	GenMark Diagnostics Carlsbad, Calif 760-308-6245 www.genmarkdx.com	Luminex Corporation Austin, Texas 512-219-8020 www.luminexcorp.com
1. What is the brand name of your company's molecular diagnostic system?	Liaison MDx	The ePlex System	Aries
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE Mark, 2009; Class II, 510(k) exempt	FDA 510(k), 2017. Individual assays have FDA 510(k) and CE Mark.	FDA 510(k), 2015. Individual assays have FDA 510(K)
3. What is the intended use or primary function of the product?	Molecular diagnostics. Detection of viral and bacterial pathogens; viral load monitoring; single nucleotide polymorphism detection.	Molecular in vitro diagnostic testing for up to 40 infectious disease pathogens simultaneously from a single sample.	Sample to answer in vitro diagnostic system.
4. What type of specimen/sample does the product employ?	Assay dependent, including nasopharyngeal swab, nasal wash/aspirate, bronchoalveolar lavage, whole blood, plasma, serum, stool, urine, cerebrospinal fluid, Lim broth, throat swabs, and cutaneous/mucocutaneous swabs, among others.	Nasopharyngeal swab, positive blood culture	Assay dependent; sample types include cutaneous or mucocutaneous lesion specimens, Lim broth enriched specimens, nasopharyngeal swabs, stool specimens, throat swabs, vaginal-rectal swabs.
5. What types of diseases, conditions, or analytes does the system detect?	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, C. difficile,* influenza A H1N1. More than 65 analyte specific reagents.	Respiratory infections, including SARS-CoV-2 and bloodstream infections for gram-positive, gram-negative, fungal pathogens and resistance gene markers	Gastroenteritis, healthcare-associated infections, respiratory infections, women's health.
6. What platform technologies does the product employ?	RT-PCR; quantitative PCR; PCR with melt analysis.	RT-PCR followed by electrochemical detection.	Reverse transcriptase polymerase chain reaction (RT-PCR).
7. Under ideal conditions, what is the time to first result; how are the test results made available ?	Approximately 1 hour. Results are made available on printouts or to a laboratory information system.	Approximately 1.5 hours.	Up to 2 hours
8. What are the product's maximum capacity and throughput?	Direct Amplification Discs can test up to 8 specimens per run. Universal Discs can test up to 96 specimens per run. The instrument has 4 channels for multiplexing.	288 patients samples per day per system with continuous random access, bidirectional LIS via HL7 or ASTM and scalable configuration depending on test volume.	Processes up to 12 samples in less than 2 hours; generates up to 48 results in an 8-hour shift.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	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 automated sample to answer processing of specimens with bidirectional LIS capability configurable to auto-release results based on laboratory rules. Onboard internal controls in every cartridge. Automated tracking of external control program.	Fully automated extraction, amplification, and analysis. Internal barcode scanning matches samples to cassettes. Auto run feature starts the run when the magazine is placed in the instrument. Internal controls verify sample lysis, nucleic acid extraction, and proper performance.
10. What types of technical support are available?	Dedicated technical services team, field application scientists, and field service engineers for installation, training, on-site maintenance, troubleshooting, and minor repairs.	Online and 24/7 phone support. Remote access link to the system for easy and rapid technical support. On-site training, application support and service.	Online and 24/7 phone support; team of molecular application specialists available to serve customers in person.
11. What capabilities, features, or accessories distinguish this product from others on the market?	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.	Sample to answer syndromic testing with <2 minutes hands-on time and ~90 minute result time with automated result release/reporting of comprehensive respiratory and blood culture infection diseases.	Runs up to 12 different in vitro diagnostic and laboratory-developed tests with multiple sample types in a random batch when using a universal assay protocol. Internal barcode scanner, bidirectional laboratory information system connectivity, and position independent results help reduce operator and data input errors.

Luminex Corporation Austin, Texas 512-219-8020 www.luminexcorp.com	**Luminex Corporation** Austin, Texas 512-219-8020 www.luminexcorp.com	**Luminex Corporation** Austin, Texas 512-219-8020 www.luminexcorp.com	**Meridian Bioscience** Cincinnati, Ohio 513-271-3700 www.meridianbioscience.com
FLEXMAP 3D	Verigene	Verigene II	Revogene
FDA 510(k), 2013. Individual assays have FDA 510(k)	FDA 510(k), 2009. Individual assays have FDA 510(k)	FDA 510(K) Exempt, Individual assays will have FDA 510(k)	FDA 510(k), 2017 CE Mark, 2016, Individual assays have FDA 510(k) and are CE marked
Non-automated in vitro diagnostic system.	Sample to answer in vitro diagnostic system.	Sample to answer in vitro diagnostic system.	Molecular diagnostic used as an aid in diagnosis
Assay dependent; sample type purified PCR samples, serum, antibody, and stool preserved in Cary-Blair medium.	Assay dependent; sample types include nasopharyngeal swabs, positive blood culture bottle, and stool preserved in Cary-Blair medium.	Assay dependent; sample types include nasopharyngeal swabs, positive blood culture bottle, and stool preserved in Cary-Blair medium.	Assay dependent; sample types include unformed (liquid or soft) stool specimens, throat swabs, vaginal/rectal swabs, carbapenem-non-susceptible pure colonies of enterobacteriaceae, acinetobacter baumannii, or pseudomonas aeruginosa
Genetic, infectious disease, agricultural samples, transplant matching.	Bloodstream infections, gastroenteritis, respiratory infections.	Bloodstream infections, gastroenteritis, respiratory infections.	Single analyte: C. difficile, group A strep, group B strep Multiplex: carba colony
Bead-based multiplexing assays.	Reverse transcriptase polymerase chain reaction (RT-PCR) for enteric and respiratory tests. Hybridization for blood culture.	Reverse transcriptase polymerase chain reaction (RT-PCR) for enteric and respiratory tests. Hybridization for blood culture.	Real-time polymerase chain reaction (Real-Time PCR)
20 minutes/96 well plate, results exported as a csv file	Up to 2 hours	Up to 2 hours	70 minutes, early call positive feature for some assays
384 well plate every 45 minutes: Ten 384 well plates in an 8-hour shift	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.	Processes up to 6 samples in less than 2 hours; generates up to 24 results in an 8-hour shift.	Less than 2 minutes hands on time. 1 to 8 samples per run. Turnaround time of 70 minutes.
Software package available for automation, LIS software available as well.	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.	Automated extraction, amplification, and hybridization. The system allows internal data storage as well as laboratory information system connectivity. Stackable, permitting two Verigene II systems to be stacked on top of each other. Flex testing allows on-demand laboratories to unmask additional targets are necessary.	Bidirectional communication capability
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.	Online and 24/7 phone support; team of molecular application specialists available to serve customers in person.	Live, technical support available 7 days a week
Multiplexing of up to 500 targets per well.	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.	The system is fully-integrated and performs extraction, amplification, hybridization, and detection, all contained within an all-in-one cartridge. The Flex software gives users the option to unmask additional results as needed. Bidirectional LIS allows for optimized data input and output.	Fully automated, small footpint, simplified sample prep and workflow, multiple sample types coupled with the capability to run different assays within the same run.

tech guide

Molecular Diagnostics Systems

	OpGen Gaithersburg, Md 301-869-9683 www.opgen.com	OpGen Gaithersburg, Md 301-869-9683 www.opgen.com	PerkinElmer, Inc. Waltham, MA 781-663-6900 https://www.perkinelmer.com/category/vanadis-system
1. What is the brand name of your company's molecular diagnostic system?	Unyvero System and Unyvero LRT Panel	Unyvero LRT BAL Panel	Vanadis cfDNA Platform
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA de novo 510(k), April 2018	FDA 510(k), December 2019	This product is currently for Research Use Only within United States & Canada.
3. What is the intended use or primary function of the product?	Diagnosis of lower respiratory tract infections.	Diagnosis of lower respiratory tract infections	Cell-free DNA testing, to assess the presence of chromosomes 21, 18 & 13.
4. What type of specimen/sample does the product employ?	Endotracheal aspirates.	Bronchoalveolar lavage-like specimens (BAL or mini-BAL)	Whole blood
5. What types of diseases, conditions, or analytes does the system detect?	Lower respiratory tract infections.	Lower respiratory tract infections.	For the analysis of cfDNA, including chromosomes 21, 18, & 13.
6. What platform technologies does the product employ?	Polymerase chain reaction technology with array detection; high multiplexing capability.	Polymerase chain reaction technology with array detection, high multiplexing capability.	Targeted method, rolling circle amplification.
7. Under ideal conditions, what is the time to first result; how are the test results made available ?	4.5 hours; on-screen, printable, laboratory information system capable	4.5 hours; on-screen, printable, laboratory information system capable	Turnaround time is 3-4 days. Reporting software delivers customizable reports with various output options (ex: z-scores). Connects with LIMS.
8. What are the product's maximum capacity and throughput?	Random access, 2 samples per analyzer module, scalable up to 4 analyzers per cockpit, direct from native specimen 180µL.	Random access, 2 samples per analyzer module, scalable up to 4 analyzers per cockpit, direct from native specimen 180µL.	Up to 20,000 samples may be processed per year.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Laboratory information system capable; built-in controls.	Laboratory information system capable; built-in controls.	Automates all critical steps, minimizing hands-on-time and turnaround time, streamlining the process from primary tube to final results.
10. What types of technical support are available?	24/7 via phone and email; field service and field applications for onsite support.	24/7 via phone and email; field service and field applications for onsite support.	Different levels for tech support are available, depending of the needs (L1-L4). Highly educated teams can provide support to both application and service related matters.
11. What capabilities, features, or accessories distinguish this product from others on the market?	FDA-cleared LRT panel detects 29 clinically relevant targets comprised of bacterial pathogens (including atypical bacteria) and the broadest carbapenemase resistance coverage associated with pneumonia; enables rapid diagnosis and earlier selection of optimal antibiotics.	FDA-cleared panel that detects *pneumocystis jirovecii* in addition to a broad spectrum of clinically relevant bacterial pathogens (including atypicals) and antibiotic resistance markers associated with pneumonia; enables rapid diagnosis and earlier selection of optimal antibiotics.	Eliminates the complex while maintaining the high-tech. Enables cost-efficient cfDNA testing using standard microplates and fully automated sample processing, requiring no genetic expertise to operate.

Quidel Corporation	Randox Laboratories	Randox Laboratories	Rheonix
San Diego 800-874-1517 www.quidel.com	Antrim, United Kingdom 866-4-RANDOX www.randox.com	Antrim, United Kingdom 866-4-RANDOX www.randox.com	Ithaca, NY 607-257-1242 www.rheonix.com
Solana	Vivalytic	Randox Discovery	Rheonix Encompass MDx workstation
FDA 510(k); CE Mark, 2015	CE Mark, 2019	Pending regulatory authorization	FDA emergency use authorization (EUA) for Rheonix Covid-19 MDx assay, 2020.
A benchtop instrument that combines proprietary helicase-dependent amplification (HDA) with fluorescence detection to deliver molecular results.	Vivalytic is a cartridge-based, near-patient platform that consolidates the complex molecular workflow into a fully automated analyzer.	Molecular and immunoassay diagnostic testing that consolidates multiple workloads into one compact benchtop platform.	The Rheonix solution performs multiplexed qualitative detection of nucleic acids from clinically relevant organisms.
Assay dependent; sample types include nasal/nasopharyngeal swabs, throat swabs, unformed stool, vaginal swabs, urine, cutaneous or mucocutaneous lesions.	Nasopharyngeal swab, oropharyngeal, urine.	Nasopharyngeal swab, oropharyngeal, urine, bronchoalveolar lavage, sputum.	Respiratory and saliva specimens for COVID-19 assay under EUA. Multiplexed assays in development for a range of clinical sample types.
Influenza A and B, respiratory syncytial virus, human metapneumovirus, *Streptococcus* spp., *Bordetella pertussis* and *B. parapertussis, Clostridium difficile, Trichomonas vaginalis,* herpes simplex virus 1 and 2, varicella zoster virus.	Multiplex tests include SARS-CoV-2, respiratory, genitourinary, and hospital-acquired infections.	Simultaneous detection of hundreds of targets from a single patient sample. Multiplex tests are available covering genetic markers, infectious diseases, oncology, and immunoassay testing as well as SARS-CoV-2.	COVID-19 under EUA; additional multiplexed viral and bacterial assays under development or FDA review.
Helicase-dependent amplification with fluorescence detection.	Technologies depend upon the test application. End-point polymerase chain reaction tests utilize patented biochip technology. Lo-plex Vivalytic tests are based on real-time qualitative PCR and melting curve analysis.	Three interconnected modules operate independently. Module I does nucleic acid extraction; Module II does multiplex end-point polymerase chain reaction; and Module III is for both immunoassay and molecular workflows.	For pathogen detection, the system performs fully automated end-point detection, including cell lysis, nucleic acid purification, and PCR/RT-PCR amplification.
Results can be reported and stored in multiple ways, including USB data export and printing. Test, quality control, and calibration results are stored onboard; compatible with middleware and laboratory information systems.	Assay dependent. Results will be displayed on the touchscreen.	3 hours to first batch with results for subsequent batches every hour after. Time to result is assay dependent.	24 samples in 3.5 to 5 hours, depending on assay.
System is easily accessible and can be seamlessly integrated; workflow is easy and flexible, capable of testing a single specimen or batching up to 12 tests.	1 patient sample per cartridge at one time, up to a maximum of 10 patient samples in 8 hours; one main power cable can power up to eight analyzers.	3 hours for 16 patient samples per batch; capable of 48 patient samples in 5 hours and 64 patient samples in 8 hours.	Up to 24 batched samples per fully automated run.
Intuitive touchscreen interface with guided operation and customizable settings; four USB ports, barcode technology, external printer, and laboratory information system connectivity. Results are reported onscreen and stored in the instrument and can be saved to a USB drive, printed, or sent to the LIS.	Automated molecular system capable of performing nucleic acid extraction amplification and detection. Cartridges utilize microfluidics for accurate diagnostic testing and include all reagents on-board. Each cartridge is room temperature storage, single use, and cannot be reopened after the patient sample has been added.	Automated molecular system capable of performing nucleic acid extraction, amplification, and detection. Patented biochip technology, based on a chemiluminescent signal, allows simultaneous detection of multiple targets from a single sample.	Fully automated workstation performs multiplexed detection of up to 22 targets in a range of raw sample types. Fully enclosed solution minimizes sample handling and reduces the possibility of bacterial or viral contamination.
24 hours, 7 days a week via phone or email.	Technical support via telephone, email, and video calling applications.	Technical support via telephone, email, video calling and onsite visits for installations and preventative maintenance.	In-field and remote technical service and support. Ongoing commitment to supporting customers' instrument, reagent and consumable requirements.
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.	Lightweight near-patient system that consolidates molecular workflow into a fully automated process; the user performs only four steps: scan sample code, scan cartridge code, insert sample into cartridge and close lid; insert cartridge into analyzer. Two diagnostics are available to detect covid-19: a singleplex assay, and a 10-plex array.	Fully automated multiplex analyzer consolidates the normal workload of multiple laboratory rooms into one benchtop platform; capable of detecting SARS-CoV-2 and Sarbecovirus. Utilizes ready-to-use cartridge-based prefabricated reagents and on-board visualization software.	Easy-to-use system enables fully automated sample-to-answer results on a single instrument. Requires minimal training and minimizes hands-on time, enabling same-day testing for regional and local labs. Highly scalable and cost-effective system enables labs to expand throughput as needed.

tech guide

Molecular Diagnostics Systems

	Seegene Technologies Walnut Creek, Calif 925-448-8172 www.seegenetech.com	Seegene Technologies Walnut Creek, Calif 925-448-8172 www.seegenetech.com	Seegene Technologies Walnut Creek, Calif 925-448-8172 www.seegenetech.com
1. What is the brand name of your company's molecular diagnostic system?	STARlet IVD	STARlet-AIOS	Novaplex SARS-CoV-2 Variants Assays with STARlet IVD
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA-registered Class I instrument/FDA emergency use authorization	Under development - 2022 launch	Research use only
3. What is the intended use or primary function of the product?	Automated liquid handling workstation which processes primary and secondary sample tubes for nucleic acid extraction and PCR setup	Complete automation system with in-built extraction and PCR thermocycler	High multiplex molecular PCR Assays for detection of SARS-CoV-2 variant mutations
4. What type of specimen/sample does the product employ?	Simultaneous extraction of multiple sample types: universal extraction kit for extraction of bacterial, viral, genomic, parasitic, fungal DNA and/or RNA from multiple specimen types	Simultaneous extraction of multiple sample types: universal extraction kit for extraction of bacterial, viral, genomic, parasitic, fungal DNA and/or RNA from multiple specimen types	Sputum, nasopharyngeal swab, nasopharyngeal aspirate, bronchoalveolar lavage, oropharyngeal swab, saliva
5. What types of diseases, conditions, or analytes does the system detect?	Molecular testing, COVID-19/ other respiratory viruses, HPV, sexually transmitted infections, GI	Molecular testing, COVID-19 / Other respiratory viruses, GI, STI	Molecular testing; SARS-CoV-2 variants mutations
6. What platform technologies does the product employ?	Automated liquid handler/nucleic acid extraction system	Fully automated system with liquid handling and real-time PCR	Real-time PCR
7. Under ideal conditions, what is the time to first result; how are the test results made available ?	90 minutes for extraction; 4 hours for extraction to final results with the STARlet IVD system and Bio-Rad CFX96 thermocycler	1st run: < 5.5 hours; subsequent runs: 2.5 hours	4 hours for extraction to final results with the STARlet IVD system and Bio-Rad CFX96 thermocycler
8. What are the product's maximum capacity and throughput?	Up to 94 samples per run. Can process up to 1,034 samples over a 24-hour period.	94 samples per run	Up to 94 samples per run. Can process up to 1,034 samples over a 24 hour shift.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Fully automated extraction; minimal hands-on time; automated data interpretation and laboratory information system interlocking with Seegene Viewer software.	Fully automated from extraction to PCR detection and data interpretation; automated data interpretation and laboratory information system interlocking with Seegene Viewer software; minimal hands on time	Automated or self-setup; automated data interpretation and laboratory information system interlocking with Seegene Viewer software.
10. What types of technical support are available?	Onsite and remote technical support from regional service center; expert instrument installation; In-person and online training	Onsite and remote technical support from regional service center; expert instrument installation; In-person and online training	Onsite and remote technical support from regional service center; expert instrument installation; In-person and online training
11. What capabilities, features, or accessories distinguish this product from others on the market?	Fully automated extraction system with small footprint; can be used with multiple sample types	Fully automated system with small footprint; can be used with multiple sample types	High level of multiplexing allows detection of multiple targets within a single sample tube

Seegene Technologies	**Seegene Technologies**	**Thermo Fisher Scientific**	**Thermo Fisher Scientific**
Walnut Creek, Calif 925-448-8172 www.seegenetech.com	Walnut Creek, Calif 925-448-8172 www.seegenetech.com	Waltham Mass 1-800-955-6288 www.thermofisher.com/amplitude	Waltham, Mass 1-800-955-6288 www.thermofisher.com/amplitude
Novaplex SARS-CoV-2/FluA/FluB/RSV Assay	Novaplex SARS-CoV-2 2019 -nCoV Assay with STARlet IVD	Thermo Fisher Scientific Amplitude Solution	Applied Biosystems TaqPath COVID-19 Combo Kit
Research use only	FDA Emergency Use Authorization	US FDA Emergency Use Authorization, 2021; Health Canada Interim Order, 2021	EUA, CE-IVD 2020
High multiplex molecular PCR assay for simultaneous detection and differentiation of SARS-CoV-2, Flu A, Flu B, and RSV	In-vitro diagnostic (IVD) real-time reverse transcriptase polymerase chain reaction (RT-PCR) test intended for the qualitative detection of SARS-CoV-2 viral nucleic acids.	Diagnosis	For in vitro diagnostic use.
Sputum, nasopharyngeal swab, nasopharyngeal aspirate, bronchoalveolar lavage, throat swab, saliva	Sputum, nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, mid-turbinate	Saliva (pending EUA), nasopharyngeal and anterior nasal swab specimens	Bronchoalveolar lavage (BAL) mid-turbinate swabs, nasal swabs, nasopharyngeal swabs, nasopharyngeal aspirate (nasal aspirate), oropharyngeal swabs
Molecular testing; SARS-CoV-2/flu A/flu B/RSV	Molecular testing; SARS-CoV-2	COVID-19, flu A/B (pending CE IVD approval), RSV (pending CE IVD approval)	COVID-19
Real-time PCR	Real-time PCR	RT-PCR	PCR
4 hours for extraction to final results with the STARlet IVD system and Bio-Rad CFX96 thermocycler	4 hours for extraction to final results with the STARlet IVD system and Bio-Rad CFX96 thermocycler	3.2 hours to first result, subsequent batches every 60-75 minutes. Results are uploaded to the customer LIMS/EMR system.	End-to-end workflow for the in vitro diagnosis of 94 specimens in under 3 hours, or 382 specimens in under 6.5 hours
Up to 94 samples per run. Can process up to 1034 samples over a 24 hour shift.	Up to 94 samples per run. Can process up to 1034 samples over a 24 hour shift.	Up to 8,000 samples per 24 hrs via highly automated processing.	End-to-end workflow for the in vitro diagnosis of 94 specimens in under 3 hours, or 382 specimens in under 6.5 hours.
Automated or self-setup; automated data interpretation and laboratory information system interlocking with Seegene Viewer software.	Automated or self-setup; automated data interpretation and laboratory information system interlocking with Seegene Viewer software.	Bi-directional LIS interface. SampleManager integrated software solution for end-to-end sample tracking and workflow management. Fully automated sample transfer, plate preparation, extraction, purification and qPCR workflow.	N/A
Onsite and remote technical support from regional service center; expert instrument installation; In-person and online training	Onsite and remote technical support from regional service center; Expert instrument installation; In-person and online training	Customer Concierge throughout system installation; Dedicated Customer Success Manager; Access to 24/7 Priority Support phone and email support, 365 days a year*; < 24-hour on-site response time within major metropolitan areas; Cutting-edge digital remote support for troubleshooting. *English language only	Interpretive Software
Simultaneous detection and differentiation of target nucleic acids of S gene, RdRP gene, and N gene of SARS-CoV-2, influenza A virus (Flu A), influenza B virus (Flu B) and human respiratory syncytial virus (RSV) in a single tube	Detection and identification of target genes (E gene, RdRP gene, N gene) specific for COVID-19 in a single tube	Scalable, automated, high throughput molecular diagnostic system that delivers peace of mind of assured consumable supply, coupled with dedicated 24/7 service and support. Offering sample-to-result COVID-19 testing, the Amplitude Solution requires minimal hands-on time, equipment, & staffing.	Built-in redundancy (3 targets) compensates for emerging SARS-CoV-2 mutations and variants, helping to provide confidence in your results.Authorized on some of the most-used real-time PCR instruments in the worldl Authorized for use with seven specimen types, requiring only 200 to 400 µL of sample

tech guide

Molecular Diagnostics Systems

	Thermo Fisher Scientific Waltham, Mass 1-800-955-6288 www.thermofisher.com/amplitude	Thermo Fisher Scientific Waltham, Mass 1-800-955-6288 www.thermofisher.com/amplitude	Thermo Fisher Scientific Waltham, Mass 1-800-955-6288 www.thermofisher.com/amplitude
1. What is the brand name of your company's molecular diagnostic system?	Applied Biosystems TaqMan SARS-CoV-2 Mutation Panel	Applied Biosystems Applied Biosystems TaqPath COVID-19, Flu A, Flu B Combo Kit	Applied Biosystems TaqPath COVID-19 Fast PCR Combo Kit 2.0
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	RUO/research use only	FDA Emergency Use Authorization (EUA) Only	EUA, CE-IVD 2021
3. What is the intended use or primary function of the product?	For research use only. Not for use in diagnostic procedures.	For prescription use only. For in vitro diagnostic use.	For Emergency Use Authorization (EUA) Only. For Prescription Use Only. For In Vitro Diagnostic Use.
4. What type of specimen/ sample does the product employ?	RNA extracted from SARS-CoV-2 samples with a CT value of less or equal to 30	Nasopharyngeal swab and anterior nasal swab specimens	Raw saliva using sterile collection tube, utilizing RNase P human internal control
5. What types of diseases, conditions, or analytes does the system detect?	SARS-CoV-2 Mutations	COVID-19, flu A, and flu B	COVID-19
6. What platform technologies does the product employ?	PCR	RT-PCR	RT-PCR
7. Under ideal conditions, what is the time to first result; how are the test results made available ?	1 hour and 10 min from extracted RNA to results	Time-to-results of approximately three hours. The Applied Biosystems Pathogen Interpretive Software automatically converts genetic analysis data into a readable report.	2 hours, sample to result, using a combination of a single KingFisher purification system and an Applied Biosystems real-time PCR system.
8. What are the product's maximum capacity and throughput?	This scalable solution lets you run a few or hundreds of samples to identify one or many mutations	One thousand reactions per kit. Up to 94 samples can be run simultaneously.	End-to-end workflow for the in vitro diagnosis of 94 specimens in under 2 hours, or 384 specimens in under 5.5 hours. ~4500 results per day.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	N/A	Real-time RT-PCR genetic analysis and automated translation of data into patient diagnosis.	Use of RT-PCR genetic analysis and automated translation of data into patient diagnosis. Validation of results is performed automatically by the interpretive software based on performance of the positive and negative controls.
10. What types of technical support are available?	Training support, analysis software	24/7 service & support; consumables, instruments, software	Interpretive Software; 24/7 service & support; consumables, instruments, software
11. What capabilities, features, or accessories distinguish this product from others on the market?	Customizable—build your own custom panel from a menu of verified real-time PCR assays that allows you to identify currently relevant SARS-CoV-2 mutations and adapt quickly as additional mutations and variants emerge Convenient—use your current real-time PCR instrumentation to conduct follow-up testing of SARS-CoV-2 samples Scalable—run a few or hundreds of samples to identify for one or many mutations Unique, streamlined workflow	Simultaneously differentiates between COVID-19, flu A, and flu B. Helps identify cases of co-infection. Increases testing throughput and lab efficiency. Automated results by pathogen interpretaive software helps reduce risk of user interpretation error.	An advanced assay design using multiple targets on orf1a, orf1b, and N genes compensates for current and emerging SARS-CoV-2 mutations, helping provide continued confidence in results now and into the future Fast direct-to-PCR workflow provides increased speed from raw saliva samples to results, enabling widespread, high-frequency testing.

Thermo Fisher Scientific	Thermo Fisher Scientific	UgenTec	Vela Operations
Waltham, Mass 1-800-955-6288 www.thermofisher.com/amplitude	Waltham MA 1-800-955-6288 www.thermofisher.com/amplitude	Cambridge, Mass www.ugentec.com	Salt Lake City, Utah 888-320-7636 www.gbscience.com
Applied Biosystems TaqPath COVID-19 RNase P Combo Kit 2.0	Thermo Fisher Scientific Accula SARS-CoV-2 Test	FastFinder	Great Basin Scientific
EUA, CE-IVD 2021	SARS-CoV-2: FDA EUA, 2020	ISO13485	CE mark, 2012; FDA 510(k), 2012
For Emergency Use Authorization (EUA) Only. For Prescription Use Only. For In Vitro Diagnostic Use.	Qualitative, visual detection of nucleic acid from SARS-CoV-2, collected from individuals suspected of COVID-19 by their healthcare provider	PCR data analysis, QC, workflow automation and lab intelligence	Molecular diagnostic testing for infectious disease
Mid-turbinate swabs, nasal swabs, nasopharyngeal swabs, utilizng RNase P human internal control	Nasal swab, nasal mid-turbinate swab	PCR cycler raw output	Raw and preserved stool, blood, nasopharyngeal swabs, vaginal/ rectal swabs.
COVID-19; EUA symptomatic & asymptomatic claims	SARS-CoV-2	Infectious disease, oncology, pathogen testing	*C. difficile,* group B streptococcus, *Bordetella pertussis, Salmonella* spp., *shigella* spp., *campylobacter jejuni, E. coli,* and others.
RT-PCR	RT-PCR and lateral flow technology	qPCR, endpoint PCR, genotyping	Polymerase chain reaction.
3 hours sample to result, using a combination of a single KingFisher purification system and an Applied Biosystems real-time PCR system.	30 minutes. Test results are visually detected on a lateral flow strip.	Processes 96, 384, and other formats in seconds.	90 minutes, with an electronic readout.
End-to-end workflow for the in vitro diagnosis of 964 specimens in under 3 hours, or 384 specimens in under 6.5 hours. ~2700 results per day.	1 test per instrument, 2 tests per hour	No hard limit. Diagnostic labs process anywhere from a few plates to 200,000 samples per day on FastFinder.	On-demand (one specimen per run)
Use of RT-PCR genetic analysis and automated translation of data into patient diagnosis. Validation of results is performed automatically by the interpretive software based on performance of the positive and negative controls.	No calibration required for Accula Dock	connect all major thermocyclers & key major liquid handlers, integrate Laboratory information management systems (LIMS), automate SOPs and assay IFUs	Autodetection of specimens; remote troubleshooting.
Interperative Software; 24/7 service & support; consumables, instruments, software	Telephone and email technical support	Phone, e-mail, on-site & online training, customer success team, help desk, FAS network.	Phone, email, remote access to analyzer.
An advanced assay design using multiple targets on orf1a, orf1b, and N genes compensates for current and emerging SARS-CoV-2 mutations, helping provide continued confidence in results now and into the future. RNase P human internal control helps ensure accuracy and integrity for symptomatic and asymptomatic (EUA) sensitive detection	Combines the accuracy of PCR with unparalleled speed and simplicity, delivering visual results in approximately 30 minutes. The system delivers highly accurate PCR testing at the point of care with a simple workflow and sensitivity comparable to laboratory-based PCR.	Cut down sample analysis time to seconds. Only review curves that matter. Integrated, real-time QC and lab intelligence. Audit-ready result repository. Automate the assay IFU. Clinical-grade medical device software platform. From sample to result without the manual steps. For the whole lab—across assay menu, instruments and sample types.	Analyzer is able to process both low-plex assays and multiplex panels.