tech guide
Molecular Diagnostics Systems

	Abbott Molecular Des Plaines, Ill (877) 422-2688 www.molecular.abbott	Abbott Molecular Des Plaines, Ill (877) 422-2688 www.molecular.abbott	Agena Bioscience San Diego (858) 882-2800 www.agenabio.com
1. What is the brand name of your company's molecular diagnostic system?	VP 2000 with VIP upgrade kit	Abbott m2000 RealTime system	MassArray Dx system
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA-registered Class I instrument.	FDA 510(k); CE mark.	FDA-registered Class I instrument.
3. What is the intended use or primary function of the product?	Single system performs deparaffinization, pretreatment, histology/cytology staining, special stains (G-banding and other), and routine slide washing. .	System performs quantitative or qualitative molecular testing for viral load monitoring, genotyping, or pathogen detection. It can also be used for laboratory-developed tests or as a general purpose extractor.	Simultaneously detects multiple nucleic acid analytes. The system performs laboratory-developed tests as well as FDA-regulated in vitro diagnostics.
4. What type of specimen/sample does the product employ?	Hematological, tissue, or urine specimens.	Cerebrospinal fluid, liquid-based cytology, plasma, stool, swabs, urine, whole blood, etc.	DNA and RNA.
5. What types of diseases, conditions, or analytes does the system detect?	Molecular testing, cancer diagnostics, G-banding, fluorescence in situ hybridization (FISH).	Virology, sexually transmitted infections, transplantation diagnostics.	Copy number variants, deletions, insertions, single-nucleotide polymorphisms.
6. What platform technologies does the product employ?	Deparaffinization, pretreatment, histology/cytology staining, special stains (G-banding and other), routine slide washing.	Reverse transcriptase polymerase chain reaction (RT-PCR).	Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS), polymerase chain reaction (PCR), arrays.
7. Under ideal conditions, what is the time to first result; how are the test results made available?	Results vary based on test type.	Assay dependent; varies according to assay protocol and number of samples being tested.	Less than 8 hours.
8. What are the product's maximum capacity and throughput under ideal conditions?	50 slides per run.	System can test up to 192 samples per 8 hours.	System can process one 96-well microtiter plate in a day, and an additional two microtiter plates if processed overnight.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Laboratories can run smaller batch sizes, ensuring efficient reagent usage. When used in combination with universal pretreatment reagents, the processor can batch multiple tissue types to reduce processing time.	Automated molecular system with system checks, liquid level sensing, and features that support good laboratory practices. System can be interfaced bidirectionally and offers optional auto-releasing.	Onboard liquid handler for analyte transfer. Bidirectional connectivity with laboratory information management system.
10. What types of technical support are available?	Application and service teams are available via phone and email.	Service plan options are available.	Agena Care service plans (Plus, Essential, and Value) combine remote and onsite support for application and technical service.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Convenient walkaway automation; performs consistent and standardized FISH assay deparaffinization and pretreatment; validated for use with Vysis FISH pretreatment protocols, including solid tumor and cytological specimens. Open system is compatible with reagents used in today's laboratories.	Automates and enables consolidation of multiple commercial nucleic acid amplification tests, laboratory-developed tests, and third-party assays; accommodates diverse sample types while providing barcoded traceability of primary or laboratory tubes; run control and calibrator efficiency, multiple contamination control safeguards, and maxRatio software.	Using the 96-pad SpectroChip array, up to 4800 genetic variants can be analyzed per run, generating smaller and more manageable genetic datasets to minimize bioinformatic analysis.

Applied BioCode Santa Fe Springs, Calif (833) 246-2633 www.apbiocode.com	**Becton, Dickinson and Company (BD)** Sparks, Md (410) 316-4000 www.bd.com	**Becton, Dickinson and Company (BD)** Sparks, Md (410) 316-4000 www.bd.com	**Bio-Rad Laboratories** Hercules, Calif (925) 474-8632 www.bio-rad.com
9/7/19	BD Max system	BD Cor system	QXDx AutoDG ddPCR system
FDA 510(k), 2018; CE mark, 2018.	FDA 510(k), 2016; CE mark, 2016.	CE mark, 2019.	CE mark, 2017; FDA Class II exemption, 2019.
Aids in the diagnosis of gastrointestinal infections.	Molecular diagnostics.	Infectious disease molecular diagnostics.	System includes software for performing BCR-ABL testing, and research use only software for performing laboratory-developed tests.
Unpreserved stool samples or stool preserved in Cary-Blair transport medium.	Cary-Blair preserved stool, endocervical swabs, nasal swabs, unpreserved stool, 10% formalin-fixed stool, urine, vaginal swabs, vaginal-rectal swabs in Lim Broth.	Liquid-based cytology, swab collection device, urine.	DNA or RNA from all sample types.
Gastrointestinal pathogen panel simultaneously detects and identifies nucleic acids from 11 bacteria, 3 viruses, and 3 parasites.	Women's health and sexually-transmitted infections, enteric infections, and healthcare-associated infections.	Women's health and sexually-transmitted infections (bacterial vaginosis, chlamydia, gonorrhea, human papillomavirus, *Trichomonas vaginalis*, vulvovaginal candidiasis).	The system can detect multiple molecular markers (eg, copy number variants, rearrangements, single-nucleotide variants)
Utilizes reverse transcriptase polymerase chain reaction (RT-PCR) for target amplification, and an array of barcoded magnetic beads for target capture and detection.	Reverse transcriptase polymerase chain reaction (RT-PCR).	Reverse transcriptase polymerase chain reaction (RT-PCR).	Droplet digital polymerase chain reaction (ddPCR).
Time to all results is about 3.5 hours after extraction for 94 samples, and less for smaller batches. Results are available onscreen, by printable PDF, or by export to the laboratory information system (LIS).	1–4 samples in approximately 1.5 hours; 24 samples in approximately 3 hours.	For human papillomavirus, approximately 4.5 hours, including liquid-based cytology conversion to molecular aliquot tube; additional results every 1.5 hours of continuous run time.	Assay dependent; 2.5 hours for 1 column (8 wells); 5 hours for a full plate (96 wells).
The system can process a run of up to 94 samples in about 3.5 hours. Multiplex capability with different barcodes is limited only by design capability.	Processes up to 24 samples per run, and approximately 96 samples per 8-hour shift.	Capacity and throughput depend on configuration; depending on specimen type, specimen capacity ranges from 350 to 2,100. System offers approximately 6.5 to 8 hours of walkaway time.	Produces 384 reactions per 8-hour shift.
PCR, target capture, and detection steps are automated with network and LIS connectivity. The system automatically checks for consumables and monitors robotic movements.	Fully integrated from extraction through resulting; bidirectional laboratory information system interface.	Fully integrated from sample loading through resulting and sample storage; bidirectional laboratory information system interface	Droplet generation is performed by automated droplet generator, which creates droplets for a 96-well plate in less than 1 hour.
Remote instrument diagnostics, field service support, hotline phone support.	In-field and phone-based applications support; field service; accessible via phone and email.	In-field and phone-based applications support; field service; accessible via phone and email.	24-hour onsite service and phone technical support.
Runs multiplex panels in a scalable throughput format; selective masking capability allows easy adjustment for variations in test orders; user-defined mode supports laboratory-developed tests in CLIA high-complexity labs.	Offers a range of IVD assays and open-system reagents for creating laboratory-developed tests. Fully automated batch testing.	Integrated and automated preanalytic functions; high capacity for samples and consumables.	First FDA-cleared ddPCR system; no standard curves are required due to absolute quantification; greater tolerance to endogenous interfering substances.

Bionano Genomics San Diego (858) 888-7600 https://bionanogenomics.com	**ChromaCode** Carlsbad, Calif (442) 244-4370 www.chromacode.com	**DiaSorin Molecular** Cypress, Calif (562) 240-6500 https://molecular.diasorin.com	**ELITechGroup** Torino, Italy +39 011 97 61 91 www.elitechgroup.com
Saphyr	ChromaCode high-definition polymerase chain reaction (HDPCR) multiplexing technology	Liaison MDx	ELITe InGenius
Research use only.	Research use only.	CE mark, 2009; FDA 510(k), 2010.	CE mark, 2015; FDA 510(k), 2018.
Uses an extremely long-read technology to perform whole-genome imaging for the detection of structural variation (SV).	Research use only.	Molecular diagnostics.	Diagnostic testing.
Bone marrow aspirates; cultured cells; extremely long, ultra high-molecular-weight DNA from fresh or frozen blood, fresh or frozen tissue.	Cultured isolates, rectal/perirectal swabs in liquid transport, serum, synovial fluid, whole blood.	Assay and user mode dependent. Sample types include cerebrospinal fluid, cutaneous/mucocutaneous swabs in transport media, nasopharyngeal swabs, plasma, serum, stool, throat swabs, urine, whole blood.	Amniotic fluid, biopsy, blood culture, bronchoalveolar lavage, cavitary liquid, cerebrospinal fluid, genital swab, nasal swab, nasopharyngeal aspirate, nasopharyngeal swab, plasma, rectal swab, saliva, serum, sputum, stool, throat swab, urine, white blood cell, whole blood.
Analyzes chromosomal aberrations >500bp that contribute to inherited genetic disorders as well as germline and somatic cancers.	Multidrug resistance markers, tick-borne disease panel, and toxigenic *C. difficile* panel.	*Bordetella pertussis* and *parapertussis*, *C. difficile*, cytomegalovirus, dengue, Epstein-Barr virus, herpes simplex virus 1&2, Group A Strep, Group B Strep, influenza, respiratory syncytial virus, varicella-zoster virus.	Monitors immunocompromised patients for healthcare-associated infections, including gastrointestinal infections, genetic factors, meningitis/encephalitis, sexually transmitted infections, respiratory infections.
The Saphyr chip linearizes long labelled molecules of DNA; the Saphyr Instrument images the molecules to detect structural abnormalities. Company offers solutions to isolate and label ultra-high molecular weight DNA, and bioinformatics tools to identify structural variants.	HDPCR is compatible with popular real-time polymerase chain reaction instruments.	Polymerase chain reaction (PCR), real-time PCR (qPCR), reverse transcriptase PCR (RT-PCR).	Polymerase chain reaction (PCR), real-time PCR (qPCR), reverse transcriptase PCR (RT-PCR).
Constitutional samples (100x coverage) take 4 days from sample to result. Heterogeneous cancer or mosaic samples (400x coverage) take 5 days from sample to result.	After extraction, real-time PCR (qPCR) cycling times average 2.5–3.0 hours.	Results generated in about 1 hour. Results are made available via the system software and can be bidirectionally integrated with the laboratory information system (LIS).	Extraction only, results in 30 minutes. Amplification only, results in 120 minutes. Qualitative results in 2 hours. Quantitative results in 2 hours 30 minutes.
Constitutional sample-to-results workflow for heterozygous SV calling on human blood: 100x coverage per sample, average of 30 samples per week, 1 technician per instrument.	HDPCR multiplexing enables 8–20 targets per panel in a single well, meaning approximately 90 highly multiplexed tests per 96-well plate.	Direct discs can test up to 8 specimens per run; universal discs can test up to 96 specimens per run.	Universal extraction and independent PCR for 12 samples; with multiplexing capability and melting analysis due to 6-color dyes.
Automatic optimization of run conditions maximizes throughput, protects sample integrity, eliminates need for instrument wash cycles between runs; automatically detects and analyzes all major SV types.	Each test has onboard calibrators and a positive internal control; software automatically checks to ensure proper controls are met before revealing results.	Bidirectional LIS connectivity; third-party automated disc set-up; fluid check to prevent false negatives due to not adding sample; ability to check amplification curves after a run; open channel availability.	
Support team, technical resources, software downloads, Bionano U (education).	24/7 technical support.	Dedicated technical services team and field application scientists available for onsite maintenance, troubleshooting, and minor repairs.	Dedicated technical support hotline; online support through website; field application specialists for direct customer support; technicians for direct interventions.
Rapid, high-throughput, long-range genome mapping with unmatched SV discovery and sensitivity capabilities. Creates a de novo map for every imaged genome to accurately detect any abnormalities.	Leverages existing qPCR instrumentation and widely used, low-cost chemistries.	Measures only 12 inches x 8 inches x 12 inches; provides easy-to-interpret results in about an hour; can be used with two different discs, allowing versatility for differing test volumes; can connect up to four instruments on a single laptop.	Fully automates the molecular diagnostics workflow; features 12 independent channels; growing menu of more than 40 CE-marked assays; open mode capabilities; eluate storage.

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Simplexa™ VZV Direct Kit

Fast and accurate molecular testing for varicella-zoster virus using CSF sample.

- **The smallest sample volume:**
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  CLIA moderate complexity with minimal hands on time providing results in about an hour.
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- **Comprehensive Offering:**
  Simplexa™ Direct molecular kits are also available for HSV 1 & 2, Flu A/B & RSV, Bordetella, Group A Strep, Group B Strep, and *C. difficile*.

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The quality of treatment starts with diagnosis.

HTG Molecular Diagnostics Tucson, Ariz (877) 289-2615 www.htgmolecular.com	**Luminex** Austin, Texas (512) 219-8020 www.luminexcorp.com	**Luminex** Austin, Texas (512) 219-8020 www.luminexcorp.com	**MDxHealth** Irvine, Calif (866) 259-5644 www.mdxhealth.com
HTG EdgeSeq system	Aries system	Verigene system	ConfirmMDx and SelectMDx for prostate cancer
CE mark. Individual assays are CE marked or are commercially available as research use only assays.	FDA 510(k), 2015. Individual assays have FDA 510(k).	FDA 510(k), 2009. Individual assays have FDA 510(k).	Laboratory-developed tests (CAP/CLIA).
Facilitates the analysis of gene expression profiles from a wide variety of sample types to evaluate target biomarkers for companion diagnostics.	Sample-to-result in vitro diagnostic system.	Sample-to-result in vitro diagnostic system.	Molecular diagnostics that aid in the decision of whether to perform an initial or repeat prostate biopsy.
Cells and cell lysates; extracted RNA (as little as 10 ng); formalin-fixed, paraffin-embedded tissue (as little as a single 5 µm section); PAXgene stabilized plasma or serum (15 µL).	Assay dependent; sample types include cutaneous or mucocutaneous lesion specimens, Lim broth enriched specimens, nasopharyngeal swabs, stool specimens, throat swabs, vaginal-rectal swabs.	Assay dependent; sample types include nasopharyngeal swabs; positive blood culture bottle; stool preserved in Cary-Blair medium.	ConfirmMDx requires high-grade prostatic intraepithelial neoplasia, atypical small acinar proliferation, or atypia prostate biopsy tissue. SelectMDx requires urine sample.
CE-marked assays detect gene rearrangements in non-small cell lung cancer patients, and subtype diffuse large B-cell lymphoma tumors.	Gastroenteritis, healthcare-associated infections, respiratory infections, women's health.	Bloodstream infections, gastroenteritis, respiratory infections.	Clinically significant prostate cancer genes.
Next-generation sequencing (NGS); compatible with most commercially available systems.	Reverse transcriptase polymerase chain reaction (RT-PCR).	Reverse transcriptase polymerase chain reaction (RT-PCR) for enteric and respiratory tests. Hybridization for blood culture.	ConfirmMDx uses methylation-specific reverse transcriptase polymerase chain reaction (RT-PCR). SelectMDx uses RT-PCR.
Time to first result for complete gene profiles on up to 2,560 gene targets is 36 hours.	Turnaround time is 2 hours.	Turnaround time is 2 hours.	ConfirmMDx report is ready for distribution in 7–10 business days. SelectMDx patient report is ready for distribution in 5 business days.
Maximum capacity is 96 samples; produces gene expression profiles for up to 2,560 gene targets on 96 samples in approximately 36 hours; processes as few as 8 samples and as many as 96 samples per run.	Processes up to 12 samples in less than 2 hours; generates up to 48 results in an 8-hour shift.	With a configuration of three Verigene Processor SPs and one Verigene Reader, the Verigene system can run up to 12 samples in an 8-hour shift.	N/A
Utilizes quality control standards in every sample; barcode labeling for sample identification; supports quality control and statistics management packages; supports network connectivity in research, laboratory, and clinical settings.	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.	Verigene Processor SP features automated extraction, amplification, and hybridization; Verigene Reader allows internal data storage as well as laboratory information system (LIS) connectivity; scalable, permitting up to 32 Verigene Processor SPs to be attached to a single Verigene Reader; allows on-demand testing.	N/A
Onsite training programs and service/support programs; global technical support and service accessible via phone and email.	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.	N/A
Low specimen input requirements, without the need for DNA or RNA extraction; highly multiplexed assay (> 2,500 targets) results with walk-away automation; simplified data reporting and biostatistical analysis for targeted next-generation sequencing.	Simultaneously 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 labs reduce operator and data input errors.	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 results printing, and offers LIS connectivity.	Proprietary tests with high performance characteristics.

New FDA Regulations, Hospital Glucose Meters

FDA Product Code PZI, 2019:
"Blood Glucose Meter for Near-Patient Testing"①

FDA Product Code NBW, 2016:
"Blood Glucose Test System, Over the Counter."② "These device types are not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because they have not been evaluated for use in these professional healthcare settings."③

Use of a meter cleared by the FDA as NBW is considered "OFF LABEL" when used anywhere in a hospital. Is your hospital glucose meter cleared as FDA Product Code PZI for hospital use or NBW cleared and off label for hospital use?

① U.S. Food and Drug Administration. Product classification [Product Code PZI]. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=678

② U.S. Food and Drug Administration. Product classification [Product Code NBW]. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=631

③ U.S. Food and Drug Administration. Self-monitoring blood glucose test systems for over-the-counter use. Draft guidance for industry and Food and Drug Administration staff. Silver Spring, MD: 2018.https://www.fda.gov/media/119828/download

	NeuMoDx Molecular Ann Arbor, Mich (888) 301-6639 www.neumodx.com	**NeuMoDx Molecular** Ann Arbor, Mich (888) 301-6639 www.neumodx.com	**Qiagen** Hilden, Germany (800) 362-7737 www.qiagen.com
1. What is the brand name of your company's molecular diagnostic system?	NeuMoDx 96 molecular system	NeuMoDx 288 molecular system	QIAstat-Dx
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	BSI CE mark, 2019; Emergo CE mark, 2019.	Emergo CE mark, 2017; BSI CE mark, 2018; FDA 510(k), 2018.	FDA 510(k), 2019.
3. What is the intended use or primary function of the product?	Intended for in vitro diagnostic (IVD) use in performing validated nucleic acid testing in clinical laboratories. Supports creation of laboratory-developed tests.	Intended for in vitro diagnostic (IVD) use in performing validated nucleic acid testing in clinical laboratories. Supports creation of laboratory-developed tests.	Intended for in vitro diagnostic (IVD) syndromic testing.
4. What type of specimen/sample does the product employ?	Enriched broth, plasma, serum, swab, urine, whole blood.	Enriched broth, plasma, serum, swab, urine, whole blood.	Nasopharyngeal swab eluted in universal transport medium.
5. What types of diseases, conditions, or analytes does the system detect?	Infectious diseases, sexually transmitted infections, women's health.	Infectious diseases, sexually transmitted infections, women's health.	Respiratory infections.
6. What platform technologies does the product employ?	Reverse transcriptase polymerase chain reaction (RT-PCR).	Reverse transcriptase polymerase chain reaction (RT-PCR).	Real-time polymerase chain reaction (qPCR).
7. Under ideal conditions, what is the time to first result; how are the test results made available?	DNA test time to first result is approximately 60 minutes. RNA test time to first result is approximately 85 minutes.	DNA test time to first result is approximately 60 minutes. RNA test time to first result is approximately 85 minutes.	Results for 20 respiratory targets are available in about 1 hour.
8. What are the product's maximum capacity and throughput under ideal conditions?	Handles 96-sample capacity at initial load; continuous, random-access processing thereafter.	Handles 288-sample capacity at initial load; continuous, random-access processing thereafter.	Can be scaled up to 4 analytical modules with one operational module; maximum throughput is 7 samples per analyzer per 8-hour shift, for a total of 28 samples per 8-hour shift.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Fully integrated molecular diagnostic testing from sample to result; automated inventory management; automated reflex testing capabilities; automated daily system maintenance; laboratory information system connectivity.	Fully integrated molecular diagnostic testing from sample to result; automated inventory management; automated reflex testing capabilities; automated daily system maintenance; laboratory information system connectivity.	Automated sample preparation and detection with preloaded dry and wet reagents; onboard swab elution; mechanical cell disruption and liquefaction; internal controls; automatic analysis with threshold cycle (Ct) values, amplification curves, and laboratory information management system connectivity.
10. What types of technical support are available?	Technical support center accessible 24/7 via phone and email; 24/7 onsite/remote field service; onsite/remote applications support; hardware/software/assay escalation support.	Technical support center accessible 24/7 via phone and email; 24/7 onsite/remote field service; onsite/remote applications support; hardware/software/assay escalation support.	Technical services for remote support; field service and field application specialists for onsite support.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Fully automated, continuous random-access analyzer utilizing proprietary NeuDry technology and real-time PCR chemistry in multi-sample microfluidic cartridges to deliver enhanced performance, efficiency, and rapid turnaround.	Fully automated, continuous random-access analyzer utilizing proprietary NeuDry technology and real-time PCR chemistry in multi-sample microfluidic cartridges to deliver enhanced performance, efficiency, and rapid turnaround.	Utilizing a streamlined workflow requiring less than a minute of hands-on time, detects 20 respiratory targets in about 1 hour. Provides Ct values and amplification curves, allowing for greater insight into results.

Quidel San Diego (800) 874-1517 www.quidel.com	**Roche Diagnostics** Indianapolis (800) 428-5074 www.usdiagnostics.roche.com	**Roche Diagnostics** Indianapolis (800) 428-5074 www.usdiagnostics.roche.com	**Streck** La Vista, Neb (800) 843-0912 www.streck.com
Solana	Cobas 6800/8800 systems	Cobas Liat PCR system	Streck Zulu RT
FDA 510(k), 2015; CE mark, 2015.	FDA 510(k), 2015. Individual assays have FDA PMA or 510(k).	FDA 510(k), 2014. Individual assays have FDA 510(k).	Research use only. FDA clearance and CE mark anticipated January 2020.
A benchtop instrument that combines proprietary helicase-dependent amplification (HDA) with fluorescence detection to deliver molecular test results.	Assay dependent; In vitro diagnostics for screening, diagnosis, and monitoring.	Aids in differential diagnosis.	Diagnostics for oncology, infectious disease, and research.
Assay dependent; sample types include cutaneous or mucocutaneous lesions, nasal/nasopharyngeal swabs, throat swabs, unformed stool, urine, vaginal swabs.	Assay dependent; sample types include cervical specimens collected in PreservCyt Solution, endocervical swab specimens, meatal swab specimens, plasma/serum, urine (male and female), vaginal swab specimens.	Assay dependent; sample types include nasopharyngeal swab specimens in viral transport medium, throat swab specimens in universal transport medium.	DNA or RNA from any source.
Bordetella pertussis and *parapertussis*, *Clostridium difficile*, *Streptococcus* spp., herpes simplex virus 1&2, human metapneumovirus, influenza A&B, respiratory syncytial virus, *Trichomonas vaginalis*, varicella-zoster virus.	*Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) cytomegalovirus, hepatitis B virus, hepatitis C virus, HIV 1, *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG).	Influenza A/B, Group A Strep, respiratory syncytial virus (RSV).	Open system capable of testing a variety of conditions.
Helicase-dependent amplification (HDA) with fluorescence detection.	Real-time polymerase chain reaction (qPCR).	Real-time polymerase chain reaction (qPCR).	Real-time polymerase chain reaction (qPCR).
Results can be reported and stored in multiple ways, including USB data export and optional printing. Test, quality control, and calibration results are stored onboard; system is compatible with middleware and laboratory information systems.	Assay dependent; first 96 test results and controls available in less than 3.5 hours. Results made available through hard copy or via an HL7 interface to the laboratory information system (LIS).	Influenza A/B and RSV, 20 minutes to first result; Strep A, 15 minutes to first result.	Results from extracted DNA in less than 60 minutes. Results are reported as amplification curves detecting the presence of a specific nucleic acid marker for a specific condition.
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 at a time.	Cobas 6800 produces up to 384 results in 8 hours and 1,344 results in 24 hours; Cobas 8800 produces up to 960 results in 8 hours and 3,072 results in 24 hours. Mixed runs of up to 3 assays can be performed on one 96-well plate. Offers 12-reagent casette storage, with all consumables onboard.	Single channel; one test at a time.	Offers 6 optical channels; handles 4 modules of 8 wells each, for a total capacity of 32 samples at a time.
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. .	Fully automated nucleic acid extraction from primary or secondary tubes; multichannel detection; advanced contamination control; LIS connectivity with up to 3 orders per sample; open channel for automation of laboratory-developed tests; track connectable.	Built-in automatic quality checks and controls; fully automated PCR process.	N/A
Technical support is available 24/7 via phone or email.	Phone, email, and field support are available 24/7/365.	Phone and email support are available 24/7/365. Field support is available as needed.	Technical support available via phone or website.
Small footprint and simplified workflow facilitate decentralization of the instruments to bring them closer to the patient. Incorporates Virena proprietary wireless data management and surveillance ecosystem.	Refrigerated reagent storage; 350 samples onboard; contamination control with physical design separating system from lab environment and chemical control via amperase; no reagent preparation, calibration, or daily maintenance required; CLIA moderately complex designation.	CLIA-waived platform delivers results in 20 minutes or less; confirmation of negative results not required. Small, closed, easy-to-use system minimizes risk of contamination, requires only 1 minute of hands-on time, and no maintenance.	Fastest real-time thermal cycler on the market, capable of reporting the results of a 40-cycle qPCR reaction in under 20 minutes.