tech guide

Molecular Diagnostics Systems

	Applied BioCode, Inc. Santa Fe Springs, California, 833-246-2633 (833-BIO-CODE) www.apbiocode.com	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
1. What is the brand name of your company's molecular diagnostic system?	BioCode MDx-3000	BD COR System	BD MAX System
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	MDx-3000 System (2018)	CE mark, 2019; FDA PMA 2021	FDA 510(k), 2012; CE Mark 2011
3. What is the intended use or primary function of the product?	Multiplex Molecular Diagnosis	Infectious disease molecular diagnostics.	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).
4. What type of specimen/ sample does the product employ?	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)	Liquid-based cytology, swab collection device, urine	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.
5. What types of diseases, conditions, or analytes does the system detect?	Gastrointestinal pathogens; respiratory pathogens, SARS-CoV-2, and fungal analyte specific reagents	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.)	Women's health and sexually-transmitted infections, enteric infections, healthcare-associated infections, and respiratory infections, inc. COVID-19. Monkeypox RUO assay.
6. What platform technologies does the product employ?	Barcoded magnetic beads	Real-time PCR	Real-time PCR
7. Under ideal conditions, what is the time to first result; how are the test results made available?	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.	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.	24 samples in approximately 3 hours.
8. What are the product's maximum capacity and throughput under ideal conditions?	Up to 188 samples can be completed on the system in an 8 hour shift.	Capacity and throughput depend on configuration and specimen type. Capacity ranges from 350 to 2,100 samples; walk-away time: 6.5 to 8 hours.	Processes up to 24 samples per run, and approximately 96 samples per 8-hour shift.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Automated PCR, hybridization and detection in the integrated system. The system has auto-check feature, internal control as well LIS connectivity.	Fully integrated from sample loading and pre-analytic preparation through resulting and sample storage; bidirectional laboratory information system interface	Fully integrated from extraction through resulting; bidirectional laboratory information system (LIS) interface.
10. What types of technical support are available?	Virtual (via text, email, phone, remote viewing)	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.	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?	Utilizing digital barcodes enables high multiplex syndromic panel testing affordable. Data masking enables target specific reporting based on clinician's order.	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.	Offers a range of IVD assays and open-system reagents for creating laboratory-developed tests. Fully automated batch testing.

Biocartis Mechelen, Belgium 1-844-443-9552 www.biocartis.com	**bioMérieux, Inc.** 100 Rodolphe Street Durham, NC 27712 800-682-2666, http://www.biomerieux-usa.com/	**Luminex Corporation** Austin, Texas 512-219-8020 www.luminexcorp.com	**Luminex Corporation** Austin, Texas 512-219-8020 www.luminexcorp.com
Idylla	BIOFIRE FILMARRAY Systems	ARIES	FLEXMAP 3D
IVDD CE mark, 2014 FDA 510(k) exempt, 2017	FDA 510(k), 2013. Individual assays have FDA 510(k) and CE Mark.	FDA 510(k), 2015. Individual assays have FDA 510(k).	FDA 510(k), 2013. Individual assays have FDA 510(k).
A fully-automated, PCR based molecular testing system for rapid oncology biomarker analysis and infectious disease testing.	Automated in vitro diagnostic (IVD) devices Systems are intended for use in combination with assay-specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens.	Sample to answer in vitro diagnostic system.	Non-automated in vitro diagnostic system.
FFPE tissue, plasma, nasopharyngeal swabs	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.	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 type purified PCR samples, serum, antibody, and stool preserved in Cary-Blair medium.
Oncology gene mutations: EGFR, BRAF, KRAS, NRAS, MSI, ALK, ROS1, RET, NTRK1/2/3 rearrangements & MET Exon 14 skipping. Infectious Disease: SARS-CoV-2.	Assay dependent reagent panels include upper respiratory infections, lower respiratory tract infections, gastroenteritis, central nervous system infections, bloodstream infections, joint infections.	Gastroenteritis, healthcare-associated infections, respiratory infections, women's health.	Genetic, infectious disease, agricultural samples, transplant matching.
RT-PCR	RT-PCR with PCR melt curve analysis.	Reverse transcriptase polymerase chain reaction (RT-PCR).	Bead-based multiplexing assays.
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.	About 1 hour.	Up to 2 hours	20 minutes/96 well plate, results exported as a csv file
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.	Up to 351 patient samples per day based on running the BIOFIRE FILMARRAY Respiratory 2.1 (RP2.1) Panel over a 24-hour day.	Processes up to 12 samples in less than 2 hours; generates up to 48 results in an 8 hour shift.	384 well plate every 45 minutes: Ten 384 well plates in an 8-hour shift
All consumables required to perform sample preparation, amplification, and detection are provided in a single, liquid-tight, disposable cartridge. The testing is fully automated, with robust internal processing controls. Hands-on time is approx. 2 min/sample. Connectivity options are available.	Automated sample-to-answer sample processing with bidirectional LIS capabilities allowing auto-release of results.	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."	Software package available for automation, LIS software available as well.
One-year warranty plus extended onsite and online support available for connectivity, repair, maintenance, troubleshooting, etc.	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; 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.
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.	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.	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 resultshelp labs reduce operator and data input errors.	Multiplexing of up to 500 targets per well.

Meridian Bioscience Cincinnati, Ohio 513-271-3700 www.meridianbioscience.com	**PerkinElmer, Inc.** Waltham, MA 781-663-6900 www.perkinelmer.com/category/vanadis-cfdna-platform	**Qiagen Inc.** 19300 Germantown Rd, Germantown, MD 20874, United States, Tracy Gambrell 240-751-0276; www.qiagen.com/neumodx)	**QuidelOrtho** San Diego, CA 800-174-1517 www.quidel.com
Revogene	Vanadis cfDNA Platform	NeuMoDx 96, NeuMoDx 288	Solana
FDA 510(k), 2017 CE Mark, 2016, Individual assays have FDA 510(k) and are CE marked	This product is currently for research use only within the United States. Not for use in diagnostic procedures.	The NeuMoDx SARS-CoV-2 Assay FDA EUA 2020.; The NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay FDA EUA- 2021.	FDA 510(k); CE Mark, 2015
Molecular diagnostic used as an aid in diagnosis	Cell-free DNA testing, to assess the presence of chromosomes 21, 18 & 13.	Infectious disease molecular diagnostics - IVD and self-developed assays	A benchtop instrument that combines proprietary HAD with fluorescence detection to deliver molecular results.
Sample types include unformed stool specimens, throat swabs, nasopharyngeal, oropharyngeal, anterior nasal, mid-turbinate nasal, vaginal/rectal swabs	Whole blood	Plasma, serum, universal/viral transport media, CSF, whole-blood, growth media, cytology media, saliva, nasopharyngeal, oropharyngeal, nasal swabs and bronchoalveolar lavage (BAL)	Assay dependent; sample types include nasal/nasopharyngeal swabs, throat swabs, unformed stool, vaginal swabs, urine, cutaneous, or mucocutaneous lesions.
Single analyte - SARS-CoV-2, C. difficile, Group A Strep, Group B Strep Multiplex - Carba colony	For the analysis of cfDNA, including chromosomes 21, 18 & 13	Respiratory - blood-borne pathogens, transplant, sexual reproductive health, vector-borne pathogens	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.
Real-time reverse-transcriptase polymerase chain reaction (Real-Time RT-PCR)	Targeted method, rolling circle amplification.	RT-PCR (5-plex)	Helicase-dependent amplification with fluorescence detection.
Early call feature for certain assays. Deliver positive results in as soon as 42 minutes	Processing time is 3-4 days. Reporting software delivers customizable reports with various output options (ex: z-scores). Connects with LIMS.	60 minutes DNA/80 minutes RNA	Assay dependant; results can be avialable 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.
Up to 8 samples per run	Up to 20,000 samples may be processed per year.	The NeuModDx 96 - Up to 144 samples in an 8-hour shift. The NeuMoDx 288 - Up to 288 samples in an 8-hour shift.	The workflow is easy and flexible, capable of testing a single sample or batch testing up to 12 tests.
Bidirectional LIS communication capability	Automates all critical steps, minimizing hands-on-time and processing time, streamlining the process from primary tube to final categorizations.	Seamless bidirectional LIS integration with ASTM and HL7 protocols. Remote access allows monitoring for improved service and support.	Intuitive touch screen interface with guided operation and customizable settings; four USB ports, barcode technology, external printer, and LIS connectivity.
Live, technical support available 7 days a week	Different levels for tech support are available, depending of the needs (L1-L4). .	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.
Fully automated, small footprint, simplified sample prep and workflow, multiple sample types coupled with the capability to run different assays within the same run and a user-friendly interface with a bidirectional communication capability. Capable of single analyte and multiplex testing.	Without NGS or PCR, any laboratory can analyze cfDNA samples in-house with Vanadis. The platform enables cost-efficient cfNDA analysis, requiring only one lab technician for operation (no genetic expertise necessary). Determinations available in as soon as 72 hours.	Easy to learn, easy to use, easy to maintain. Intuitive software and simple loading workflow. Reagents that are ready-to-use, room temperature and with month-long on-deck stability. Adaptable to evolving needs - batch, random access, and STAT loading options. Consolidation to a single platform. Seamless combination of self-developed and IVD tests."	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.

Broad range of targeted and syndromic solutions for your molecular respiratory testing.

Be prepared for the upcoming flu season with multiple testing options.

Influenza season is overwhelming for any clinical lab experiencing fluctuations in samples submitted for testing. Respiratory season and testing workflows have changed due to COVID-19. Select the right test for the right patient at the right time. We offer flexible and easy molecular testing solutions to meet your lab's needs.

ARIES®

Automation for On-Demand Diagnosis.

ARIES® Flu A/B & RSV Assay

ARIES® SARS-CoV-2 Assay[1]

NxTAG®

Scalable Throughput for Comprehensive Respiratory Pathogen Detection.

NxTAG® Respiratory Pathogen Panel + SARS-CoV-2[1]

22 pathogens in one well

LIAISON MDX®

Sample-to-Answer Molecular Kits.

Simplexa™ COVID-19 Direct Kit[1]

Simplexa™ Flu A/B & RSV Direct Gen II Kit

Simplexa™ SARS-CoV-2 Variants Direct Kit (RUO)[2]

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

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For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions. Please contact Luminex at support@luminexcorp.com to obtain the appropriate product information for your country of residence.

1. In Vitro Diagnostic Use Under Emergency Use Authorization. This test has not been FDA cleared or approved. This test has been authorized by the FDA under an EUA for use by authorized laboratories.

2. For Research Use Only. Not for use in diagnostic procedures.

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	Randox Laboratories Antrim, United Kingdom 866-4-RANDOX www.randox.com	Randox Laboratories Antrim, United Kingdom 866-4-RANDOX www.randox.com	Roche Diagnostics Indianapolis, IN dialog.roche.com
1. What is the brand name of your company's molecular diagnostic system?	Vivalytic	Randox Discovery	cobas BKV for use on cobas 6800/8800 Systems
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE Mark, 2019	Pending regulatory authorization	FDA 510(k), 2020
3. What is the intended use or primary function of the product?	Vivalytic is a cartridge-based, near-patient platform that consolidates the complex molecular workflow into a fully automated analyzer.	Molecular and immunoassay diagnostic testing; consolidates multiple workloads into one compact benchtop platform.	Is intended for use as an aid in the management of BKV in transplant patients
4. What type of specimen/ sample does the product employ?	Nasopharyngeal swab, oropharyngeal, urine.	Nasopharyngeal swab, oropharyngeal, urine, bronchoalveolar lavage, sputum.	Plasma, urine
5. What types of diseases, conditions, or analytes does the system detect?	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.	BKV viral load
6. What platform technologies does the product employ?	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.	PCR, including multiplexing capability
7. Under ideal conditions, what is the time to first result; how are the test results made available?	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.	Time to first results of less than 3.5 hrs for the first 96 results. Results available on-screen, printable, and via LIS. Auto-release of valid results available.
8. What are the product's maximum capacity and throughput (eg, channels/ specimens/samples tested per run) under ideal conditions?	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 96 samples and controls per fully automated run. 6800 System has maximum throughput of 1,440 tests/24 hrs. 8800 System offers throughput of 4,128 tests/24 hrs.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	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. .	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 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.
10. What types of technical support are available?	Technical support via telephone, email, and video calling applications.	Technical support via telephone, email, video calling and onsite visits for installations and preventative maintenance.	24/7 via phone and email; field service and field applications for onsite support.
11. What capabilities, features, or accessories distinguish this product from others on the market?	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, 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.

Thermo Fisher Scientific Waltham, Mass 1-800-955-6288 www.thermofisher.com/amplitud	**Thermo Fisher Scientific** Waltham, Massachusetts 800-556-2323 thermofisher.com	**Thermo Fisher Scientific** Waltham, Massachusets Minotta, Mauricio Mauricio.Minotta@thermo-fisher.com	**Thermo Fisher Scientific** Waltham, Massachusets Minotta, Mauricio Mauricio.Minotta@thermo fisher.com
Applied Biosystems Applied Biosystems TaqPath COVID-19, Flu A, Flu B Combo Kit	Thermo Fisher Scientific Accula System	Applied Biosystems QuantStudio 7 pro DX real Time PCR System	Applied Biosystem QuantStudio 5 DX Real Time PCR System
US FDA, Emergency Use Authorization (EUA) 2020; European Directive, CE-IVD 2020	Accula SARS-CoV-2 Test: FDA, EUA, 2020 Accula Flu A/Flu B Test: FDA, 510(k), 2018	The QuantStudio 7 Pro Dx Real-Time PCR System is available in all regions that recognize CE-IVD certification and is also listed with the FDA as a class II medical device.	The QuantStudio 5 Dx Real-Time PCR System is available in all regions that recognize CE-IVD certification and is also listed with the FDA as a class II medical device.
For in vitro diagnostic use. .	Point of care testing Refer to the test instructions for use (IFU)	The automated Applied Biosystems QuantStudio 7 Pro Dx Real-Time PCR System is an in vitro diagnostic device intended to perform fluorescence-based PCR to detect nucleic acid sequences in human-derived specimens.	The Applied Biosystems QuantStudio 5 Dx Real-Time PCR System is an in vitro diagnostic device intended to perform fluorescence-based PCR to provide detection of nucleic acid sequences in human-derived specimens.
Nasopharyngeal swab and anterior nasal swab specimens	Accula SARS-CoV-2 Test: anterior nasal swab Accula Flu A/Flu B Test: nasal swab"	see above	see above
COVID-19, flu A, and flu B	SARS-CoV-2, Flu A/Flu B	Nucleic acid sequences in human-derived specimens.	Nucleic acid sequences in human-derived specimens.
RT-PCR	RT-PCR	Real-time PCR	Real-time PCR
Time-to-results of approximately 3 hours. The Applied Biosystems Pathogen Interpretive Software automatically converts genetic analysis data into a readable report.	Time to result is approximately 30 minutes. Test results are visually detected on a lateral flow strip.	Results available in less than 30 minutes	Results available less than 30 min
One thousand reactions per kit. Up to 94 samples can be run simultaneously.	1 test per instrument, results in approximately 30 minutes	Throughput flexibility with interchangeable blocks (96-well 0.2 mL and 384-well) and automation capability	mid throughput: 96-well, 0.2 mL Applied Biosystems VeriFlex Blocks
Real-time RT-PCR genetic analysis and automated translation of data into patient diagnosis.	Hands-on time is approximately 1-2 minutes per sample.	Digital remote support allows instant service engineer access to the instrument system, solving 70% of cases in minutes, not days."	Simple, powerful software—users can easily set up a run, lay out assays, control the instrument, and conduct plate analysis
24/7 service & support; consumables, instruments, software	Technical support can be provided via email or phone using the options below: Email: techsupport@thermofisher.com, Phone: (800) 955 6288, option 2	Superior service and support. Remote support and remote help	Superior support—comprehensive range of service and support options available globally
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.	The Thermo Fisher Scientific Accula SARS-CoV-2 Test has analytical sensitivity with a limit of detection (LoD) among the lowest measured in the FDA SARS-CoV-2 Reference Panel (475 NDU per mL). The system delivers rapid, accurate PCR testing at the point of care, with qualitative results in ~30 minutes.	Open system for both development and routine diagnostics. Reduce manual work and user errors. Maximize uptime and facilitate collaboration. Scalable configuration options for instrument and computers. Plug and play design with flexible options for sending and receiving data automatically. Customizable visualization of interpretive results.	Powerful, user-friendly multi-mode (RUO and IVD) software. Standardization and security SAE administrator console. High performance 1.5-fold sensitivity; 10 orders of magnitude of linear dynamic range. 96-well, 0.2 mL Applied Biosystems VeriFlex Blocks. Intuitive touchscreen interface updated for multiple languages. Software mode for test development or diagnosis.