	Abbott Molecular	Avellino Lab USA Inc	bioTheranostics
	Des Plaines, Ill (800) 554-7042 www.abbottmolecular.com	Menlo Park, Calif (650) 396-3741 www.avellinolab.com/us	San Diego (877) 886-6739 www.biotheranostics.com
1) What is the name of your company's molecular diagnostics testing product?	Abbott RealTime m2000 System	Avellino-GENE Detection System (AGDS) Test	CancerTYPE ID
2) For what purpose/condition/disease is the product designed?	Rapid and highly automated PCR-based molecular diagnostic testing for infectious diseases	The Avellino-GENE Detection System (AGDS) Test was developed to detect Avellino Corneal Dystrophy (ACD) - a disease that causes grey-white granular deposits on the cornea, which over time can lead to blindness. It is the world's first genetic test to detect and identify the gene mutation with 100% accuracy.	CancerTYPE ID uses the differential expression of 92 genes to aid in the determination of tumor site of origin in patients with metastatic cancer of uncertain, indeterminate, or differential diagnosis.
3) What is the specimen type (eg, serum, cultured cell lines, tissue, etc)?	Plasma, serum, whole blood, urine, spinal fluid, tissue, and mucosal swabs	Buccal swab with swipes taken from the inside of both cheeks. Ten swipes each cheek collects sufficient epithelial cells for analytical and diagnostic purposes.	Formalin-fixed, paraffin embedded (FFPE) tissue from fine needle aspirations, cytologic specimens, core needle biopsies, excisional biopsies, and/or surgical samples
4) Please note the platforms used (eg, bead arrays, microarrays, PCR, RT-PCR, etc).	The Abbott RealTime system employs real-time polymerase chain reaction (PCR) technology for DNA and RNA amplification and detection.	Real-Time PCR	qRT-PCR
5) What is the turnaround time for test results, and how much tech time is required per assay setup?	Results are available in between 4.5 hours and 6.5 hours, and the automated system eliminates many manual steps associated with sample transfer and preparation for PCR analysis, which minimizes technician time required to perform PCR assays.	The sample(s) are sent by the clinic within 7 days of collection and sent by overnight courier to Avellino Lab USA (a certified CLIA diagnostic facility). Test results are typically sent to the requesting physician at the end of the same day of sample receipt, with guaranteed 48 hours turnaround.	Turnaround time is 5 business days.
6) How many channels/specimen samples are tested per run (per plate, etc)?	96 specimens can be performed in a single RealTime m2000 run	Up to 90 samples per run	N/A
7) Is this an automated or manual system, and what are the space/ environmental requirements?	The Abbott RealTime m 2000 is fully automated and compact. The m2000sp measures 66.2 inches x 69.5 inches x 31.3 inches.	The company is currently using a manual method. The testing requires an amplicon-free environment. This fall, the analytical process will become semiautomated (liquid handling and data processing), which will quadruple sample throughput.	N/A
8) Is the product FDA-cleared/pending/ approved?	Yes, the RealTime m2000 system is FDA-approved to perform assays for HIV viral load, HCV viral load, HBV viral load, HCV Genotyping, and CT/NG.	Avellino Lab USA's molecular testing lab was validated with inspection received by the California Department of Public Health – Laboratory Field Services representatives and approved (and subsequently certified) as a CLIA licensure in 2012.	No
9) Can the system be incorporated in the LIS?	Yes	Yes. In progress and scheduled for completion this fall.	Yes
10) Is this unit acquired by purchase, lease, or reagent rental, and what is the cost per assay?	Information regarding system acquisition plans and pricing is available from local Abbott sales representatives.	Most clinics choose to incorporate the cost of the Avellino-GENE Detection System (AGDS) Test into the total cost of the LASIK surgery. The AGDS Test is affordable and a small fraction of the total cost of refractive surgery (LASIK, LASEK, PRK, etc).	CancerTYPE ID is offered as a laboratory-developed test (LDT) through bioTheranostics' CLIA-certified, CAP-accredited diagnostic laboratory in San Diego.
11) How is QC handled? Is it internal, external, or both? Is this part of the reagent supplied, or is an external source required?	The RealTime m2000 system utilized an internal control for sample preparation and PCR validity control, and also utilizes onboard external controls. Realtime m2000 system software also performs quality control checks and reporting.	Avellino Lab uses both in-house and external QC materials. QC materials are not supplied by the reagent kit. One of the QC materials requires cloning by an external company.	N/A

bioTheranostics San Diego (877) 886-6739 www.biotheranostics.com	EKF Molecular Diagnostics Lts Cardiff, Wales UK www.ekfdiagnostics.com	GenMark Diagnostics Carlsbad, Calif (760) 448-4300 www.genmarkdx.com	GenMark Diagnostics Carlsbad, Calif (760) 448-4300 www.genmarkdx.com
PRÉCIS Precision Medicine	PointMan DNA Enrichment Kits	eSensor Cystic Fibrosis Genotyping Test	eSensor Respiratory Viral Panel (RVP)
PRÉCIS Precision Medicine includes biomarker profiles for non-small cell lung cancer, colorectal cancer, breast cancer, gastric cancer, melanoma, and GIST.	PointMan DNA Enrichment Kits are designed to enrich rare mutated gene sequences in the KRAS, BRAF, and EGFR T790M sequences that are associated with melanoma, lung, and colorectal cancers.	The eSensor Cystic Fibrosis Genotyping Test simultaneously detects and identifies a panel of mutations and variants in the CFTR gene.	The eSensor RVP is designed to detect 14 respiratory virus types and subtypes to drive informed clinical decisions regarding respiratory infection.
Formalin-fixed paraffin embedded (FFPE) tissue from fine needle aspirations, cytologic specimens, core needle biopsies, excisional biopsies, and/or surgical samples	PointMan DNA Enrichment Kits will enrich mutant DNA from many sample types including formalin-fixed paraffin embedded (FFPE) and fresh frozen tissue, whole blood and plasma, and cultured human cell lines.	CF Genotyping Test specimen type is whole blood collected using EDTA as the anticoagulant.	The eSensor RVP specimen type is a nasopharyngeal swab (NPS) obtained from individuals exhibiting signs and symptoms of respiratory infection.
qRT-PCR, IHC, FISH	PointMan DNA Enrichment kits can be used on all RT/Q-PCR platforms.	The test is a qualitative nucleic acid multiplex test designed for use on the eSensor XT-8 system.	The eSensor Respiratory Viral Panel (RVP) is a qualitative nucleic acid multiplex in vitro diagnostic test intended for use on the eSensor XT-8 system.
Turnaround time is 7 to 10 business days	Run times for PointMan kits typically take less than 2 hours depending on Q-PCR platform. Setup time is limited only by the user's ability and experience with pipetting into 96-well plates.	The eSensor turnaround time is a total of 4 hours from initiation of the test to result reporting. Total hands-on time is less than 40 minutes, including nucleic acid extraction.	The eSensor turnaround time is a total of 6 hours from initiation of the test to result reporting. Total hands-on time is less than 60 minutes, including nucleic acid extraction.
N/A	Each PointMan DNA Enrichment Kit includes sufficient reagent for 24 reactions.	The eSensor CF Genotyping Test can process one to 24 specimens in 4 hours and up to 96 specimens in 6 hours.	The eSensor RVP workflow can process one to 24 specimens in 6 hours and up to 96 specimens in under 8 hours.
N/A	PointMan DNA Enrichment Kits are consumable products for use on existing Q-PCR platforms.	The eSensor XT-8 system is a random-access electrochemical detection system, which generates a single-page objective result report. Prior to detection, specimens require automated or manual nucleic acid extraction and RT-PCR amplification.	The eSensor XT-8 system is a random-access electrochemical detection system that generates a single-page objective result report. Prior to detection, specimens require automated or manual nucleic acid extraction and RT-PCR amplification.
No	**THE KITS ARE AVAILABLE FOR RESEARCH-USE ONLY.** FDA clearance expected in 2014. Clinical labs can assess the kits and submit them for external quality assessment (eg, NEQAS).	GenMark's eSensor Cystic Fibrosis Genotyping Test is FDA-cleared for use on the eSensor XT-8 system.	GenMark's eSensor Respiratory Viral Panel is FDA cleared for use on the eSensor XT-8 system.
Yes	N/A	The eSensor XT-8 system is capable of being networked and transferring text file data to the LIS.	The eSensor XT-8 system is capable of being networked and transferring text file data to the LIS.
PRÉCIS biomarker testing is offered as a laboratory-developed test (LDT) through bioTheranostics' CLIA-certified, CAP-accredited diagnostic laboratory in San Diego.	PointMan DNA Enrichment kits cost between $1,314 and $1,500 per kit, giving a per reaction cost of approximately $55 to $62 per reaction.	GenMark offers programs for purchase and reagent rental with cost per test based on contracted test volume.	GenMark offers programs for purchase and reagent rental with cost per test based on contracted test volume.
N/A	PointMan DNA Enrichment Kits are currently manufactured to ISO 9001. Additionally, internal controls are provided with each kit so that PCR conditions and sample quality can be confirmed.	Each CF Genotyping Test cartridge contains onboard positive and negative controls to monitor for proper performance of the test. It is recommended that a PCR blank, or negative control, be included with each run of the CF Genotyping Test. External controls are commercially available through vendors such as the Coriell Institute and MMQCI.	eSensor RVP is supplied with bacteriophage MS2 internal control to monitor test processing from viral nucleic acid isolation through detection. An external negative and positive control should be included with each batch. External respiratory viral panel controls are offered by Zeptometrix.

Great Basin Corp Salt Lake City (801) 990-1055 www.gbscience.com	Life Technologies Corp Carlsbad, Calif (800) 955-6288 www.lifetechnologies.com	Life Technologies Corp Carlsbad, Calif (800) 955-6288 www.lifetechnologies.com	Meridian Bioscience Inc Cincinnati (513) 271-3700 www.meridianbioscience.com
Portrait Benchtop Analyzer and the Portrait Toxigenic C. diff Assay	Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument	QuantStudio Dx Real-Time PCR Instrument	illumigene Group A Streptococcus
For the detection of toxigenic *Clostridium difficile*	The Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument is a real-time nucleic acid amplification and detection system that measures nucleic acid signals from reverse transcribed RNA and converts them to comparative quantitative readouts using fluorescent detection of dual-labeled hydrolysis probes.	The QuantStudio Dx Real-Time PCR Instrument is intended to perform fluorescence-based PCR to provide detection of FDA-cleared and approved nucleic acid sequences in human-derived specimens.	Detects *Streptococcus pyogenes* in throat swab specimens.
Human stool samples collected from patients suspected of having *Clostridium difficile* infection	Any human-derived specimens from which DNA or RNA can be extracted	Any human-derived specimens from which DNA or RNA can be extracted	Throat swab sample (Liquid Amies, without charcoal; Liquid Stuart)
Automated thermophilic blocked primer helicase-dependent (bpHDA) amplification technology coupled with chip-based detection	RT-PCR/qPCR	RT-PCR/qPCR	Loop-Mediated Isothermal Amplification (LAMP) technology
Turnaround time is 65 to 90 minutes; tech time is about 3 minutes.	Typical qPCR runs can range from 30 minutes to 2 hours.	Typical qPCR runs can range from 30 minutes to 2 hours.	Less than 1 hour, with 2- to 3-minute tech time
One	Up to 96 tests per run	Up to 96 tests per run	10
Automated. The Portrait analyzer dimensions are 6.3 inches x 17.2 inches x 21.4 inches.	7500 Fast Dx Real-time PCR Instrument is a manual system. Dimensions are 13.4 inches x 17.8 inches x 49 inches.	Dimensions: 35.7 inches x 29.4 inches x 44.3 inches	Not applicable
Yes, as of May 1, 2013	FDA-cleared	FDA-cleared	FDA-cleared
Not at this time	Yes	Yes	No
Reagent rental, assays are ~$25, depending on volume	Purchased, lease, or reagent rental. Cost per test depends on the test being provided.	Purchased, lease, or reagent rental. Cost per test depends on the test being provided.	Based on volume commitments
Both: Test cartridge has integrated control features that are automatically performed with every assay. External positive and negative controls should be used to monitor for correct procedural technique and reagent integrity. Positive external controls are not provided. The negative control is run without adding any sample to the assay.	Preventive maintenance is available from Life Technologies. QC protocol is defined by the test or by the user, and functionality is provided by the Instrument software.	Preventive maintenance is available from Life Technologies. QC protocol is defined by the test or by the user, and functionality is provided by the Instrument software.	Both internal and external controls. External controls may be purchased separately.

Meridian Bioscience Inc Cincinnati (513) 271-3700 www.meridianbioscience.com	Randox Kearneysville, WVa (866) 472-6369 www.randox.com	Roche Diagnostics Indianapolis (317) 521-2000 www.mylabonline.com	Siemens Healthcare Diagnostics Tarrytown, NY (877) 229-3711 usa.healthcare.siemens.com
illumigene Mycoplasma	STI Multiplex Array	cobas HPV Test	Siemens Tissue Preparation Solution
Detects *Streptococcus pyogenes* in throat swab specimens.	Simultaneous detection of 10 sexually transmitted infections from one single patient sample	The test provides individual genotyping results for HPV 16 and 18, while simultaneously reporting 12 other high-risk HPV types as a pooled result.	The Siemens Tissue Preparation Solution includes a Tissue Preparation System and the VERSANT Tissue Preparation Reagents kit. Together, this solution provides a more efficient and reproducible process for the isolation of high-quality nucleic acids from formalin-fixed paraffin-embedded (FFPE) tissue samples.
Throat and nasopharyngeal swab specimens (0.85% Saline, M4, M4-RT, M5, UTM-RT)	Genomic DNA is extracted from urine or urogenital swab samples.	Cervical specimens collected in PreservCyt solution using an endocervical brush/spatula. The test is also FDA-approved for the use of primary vial samples after cytology processing on either the ThinPrep 3000 (T3000) system or the ThinPrep 2000 (T2000) system.	Formalin-fixed paraffin-embedded and fresh frozen tissue samples
Loop-Mediated Isothermal Amplification (LAMP) technology	The array utilizes Biochip Array Technology, a unique multiplexing method. It is based on a combination of multiplex PCR, probe hybridization, and chemiluminescence detection to allow screening of viral, bacterial, and protozoan STIs.	The test is performed on the cobas 4800 System. The system is also cleared/approved for the cobas CT/NG (*Chlamydia trachomatis*/*Neisseria gonorrhoeae*), the cobas BRAF V600 Mutation Test, and the cobas EGFR Mutation Test.	The Siemens Tissue Preparation Solution uses magnetic particle-based isolation and proprietary iron oxide bead technology.
Less than 1 hour for turnaround time after extraction	The STI Multiplex Array has a rapid turnaround time from sample to result in less than 5 hours.	The setup time is about 30 minutes for a test run, and test turnaround time (sample-in, results out) is less than 5 hours.	The turnaround time is dependent on the number of samples loaded and the protocol chosen (DNA, RNA, or Split Method). This is from 3 to 4 hours. The hands-on-time is 15 minutes, including loading reagents and samples.
10	One biochip is required per patient sample and one negative control is required per run. This will vary between assays.	The cobas 4800 System can run up to 94 patient specimens and two control samples per run.	The system runs up to 48 samples per run.
N/A	The Evidence Investigator is a semiautomated, benchtop biochip analyzer that offers complete patient profiling.	The cobas 4800 System offers automation of nucleic acid purification, PCR (polymerase chain reaction) setup, and real-time PCR amplification and detection. It can also be used with manual specimen preparation kits.	The Siemens Tissue Preparation Solution employs a fully automated tissue extraction process. The dimensions are 0.903 m x 1.124 m x 1.2 m. The required environment conditions are 18º to 30ºC; 24% to 80% relative humidity, noncondensing; 0 to 2,000 m altitude.
FDA-cleared	**FDA approval is pending**	Yes	The system is listed with the FDA as Class 1 exempt, and the reagents are IVD.
Based on volume commitments	The Evidence Investigator is LIMS-integrated for convenient reporting.	Yes, it is designed for bidirectional LIS communication to simplify test ordering while supporting integrity of results (no manual data entry required).	No LIS capabilities are available.
Both internal and external controls. External controls may be purchased separately.	Any of the above purchasing options can be considered.	The cobas 4800 System can be leased or purchased; the cost per assay depends on a variety of contract-related factors, including test volume.	Contact local Siemens representative
Both internal and external controls. External controls may be purchased separately.	QC for biochip is handled both internally and externally. Randox has reference and correction spots at the same location on each chip to ensure that the CCD camera within the Evidence Investigator is aligned properly. For each run, Randox has a negative control. Randox also has an internal extraction control.	The cobas HPV Test includes a ß-globin (cellular) internal control for sample adequacy, to provide confidence in negative results, and two kit quality controls that are available from Roche.	This is a sample-handling platform and does not require onboard quality control.

Thermo Fisher Scientific

Portage, Mich
(800) 346-4364
www.thermoscientific.com

ImmunoCAP Allergen Components
ImmunoCAP Allergen Components are intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE-mediated allergic disorders. ImmunoCAP Allergen component testing reveals sensitization to unique proteins of the whole allergen test to help the clinician diagnose and optimize management.
Human serum or plasma (EDTA or Na-Heparin)
Closed system. ImmunoCAP Allergen Components can only be run on Phadia 100, Phadia 250, Phadia 1000, Phadia 2500, and Phadia 5000.
Setup time approximately 15 to 20 minutes. First result in 103 minutes, and depending on platform, a result is produced every minute (Phadia 250) or a result every 15 seconds (Phadia 1000, 2500) after the first result is generated.
Depends on instrument size; can range from 48 tests to 4,800 tests. Random access to load samples.
Automated platform varies based on size–specifications can be provided per instrument upon request.
ImmunoCAP allergen components are FDA-cleared for milk, egg, peanut, peach, Timothy grass, and birch. Many more allergen components are in submission for FDA clearance or are getting ready to be packaged for review. See website for complete list available to your region.
Yes
Purchase or instrument use agreement. For pricing, contact your Fisher Healthcare or Thermo Scientific representative.
QC is external and run as a patient sample; available separately from Thermo Fisher Scientific. The automated instruments also have a number of built-in, internal checks to help ensure quality assay results.