

## Molecular Diagnostic Platforms

PCR Platform/ Panelist	FDA Approved Testing Available	Ease of Use	Molecular Expertise Required	Pros	Cons	Batch or Single Test	Contacts
<p><b>Abbott, m2000 RealTime System</b></p> <p><b>Lech Mazur</b></p> <p>Utilizes TagMan real-time PCR</p>	<p>HIV-1 HCV HCV Genotype II HBV CT/NG <i>C. difficile</i> Flu A/B &amp; RSV</p>	<p>Moderate Complexity</p>	<p>Basic <b>Moderate</b> Advanced</p>	<ul style="list-style-type: none"> <li>• Reads barcoded laboratory tubes</li> <li>• Precision automated pipetting</li> <li>• Flexible protocol for various sample types and volumes</li> <li>• Flexible extraction protocols library</li> <li>• Flexible throughput options of 24 to 96 samples</li> <li>• Real-time PCR amplification and detection</li> <li>• <i>maxRatio</i> Data Analysis - multiple validity checks for improved confidence in patient results</li> <li>• Minimal maintenance</li> <li>• Intuitive user interface for easy training</li> <li>• Standardized interface with LIS</li> <li>• Data Archiving - calibrator, control, and patient data logs</li> <li>• Automated quality checks and calibration</li> <li>• Abbott Link - remote Instrument Monitoring</li> <li>• Open channel Capability to develop LDT</li> </ul>	<ul style="list-style-type: none"> <li>• Time from start to initial result &gt;7 hrs</li> <li>• Large footprint requires more space</li> <li>• Large volume of liquid and consumables waste</li> <li>• Instrument could have better reliability</li> <li>• Medium to high price of CE and service agreement</li> </ul>	<p>Batch</p>	<p><b>For Customer Service</b> Call (800) 553-7042 or email <a href="mailto:customerservice@abbottmolecular.com">customerservice@abbottmolecular.com</a></p> <p><b>For Technical Support</b> Call (800) 638-8663 or email <a href="https://www.abbottmolecular.com/us/contact-technical-support.html">https://www.abbottmolecular.com/us/contact-technical-support.html</a></p>

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<p><b>AdvanDX, Quick FISH</b></p> <p><b>Raymond Podzorski</b></p> <p>Utilizes fluorescent- labeled PNA probes to target the species- specific rRNA sequences in a Fluorescence In Situ Hybridization</p>	<p>Staphylococcus QuickFISH BC Enterococcus QuickFISH BC Gram-Negative QuickFISH BC Staphylococcus</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Rapid identification of bacteria directly from positive blood culture bottle</li> <li>• Everything on one slide</li> <li>• Easy to perform</li> <li>• TAT about 20 min</li> <li>• Hands-on time 5 min</li> </ul>	<ul style="list-style-type: none"> <li>• Requires fluorescent microscope</li> <li>• Cost of reagents</li> <li>• Not walk-away automation</li> <li>• No resistance genes targeted</li> </ul>	<p>Single</p>	<p><b>For Customer Service</b> Call (866) 376-0009 Or email <a href="mailto:customerservice@advandx.com">customerservice@advandx.com</a></p> <p><b>For Technical Support</b> Call (866) 376-0009 Or email <a href="mailto:techsupport@advandx.com">techsupport@advandx.com</a></p>
<p><b>BD Diagnostic Systems, Affirm VPIII Microprocessor</b></p> <p><b>Thomas Novicki</b></p> <p>Utilizes non- amplified DNA probes and a visual colorimetric detection system</p>	<p><i>Candida species</i> <i>Gardnerella vaginalis</i> <i>Trichomonas vaginalis</i></p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Accuracy up to 30% higher than slide microscopy</li> <li>• Assay is controlled, sensitive</li> <li>• Does not rely on <i>Trichomonas</i> motility</li> <li>• TAT about 45 min</li> <li>• &lt; 2 min hands-on time</li> <li>• Easy to use and read</li> <li>• Built-in procedural controls for each sample</li> </ul>	<ul style="list-style-type: none"> <li>• Higher cost than wet prep</li> <li>• Absolute 72h limit on transport when using the optional Ambient Temperature Transport System</li> <li>• Unlubricated speculum recommended during collection: not acceptable to many patients</li> </ul>	<p>Single</p>	<p><b>For Customer Service</b> Call (800) 675-0908 Or email <a href="mailto:BD_Womenshealth@bd.com">BD_Womenshealth@bd.com</a></p> <p><b>For Technical Support</b> Call (800) 638-8663 Or email <a href="mailto:technical_services@bd.com">technical_services@bd.com</a></p>

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<p><b>BD Diagnostic Systems, BD MAX</b></p> <p><b>Erik Munson</b></p> <p>Utilizes microfluidics based real-time PCR</p>	<p>Group B Strep (GBS) <i>Clostridium difficile</i> MRSA MRSA/MSSA (nasal)</p>	<p>Moderate Complexity</p>	<p>Basic</p>	<ul style="list-style-type: none"> <li>• Walk-away to an extent</li> <li>• Runs up to 24 samples simultaneously</li> <li>• Results in 2- 3.5 hrs</li> <li>• Some assays run simultaneously</li> <li>• Ability to piggyback runs</li> <li>• Can be utilized as an open platform that can accommodate user developed assays</li> <li>• Minimal maintenance</li> </ul>	<ul style="list-style-type: none"> <li>• Storage considerations</li> <li>• Learning curve</li> <li>• Peculiarities in pipetting</li> <li>• Run failure not revealed until end of processing</li> <li>• Less analytical freedom in IVD form</li> <li>• Redundancy</li> <li>• GBS assay can “hog the instrument”</li> </ul>	<p>Batch</p>	<p><b>For Customer Service</b> Call (800) 675-0908.</p> <p><b>For Technical Service</b> Call (800) 638-8663. Or email <a href="mailto:technical_services@bd.com">technical_services@bd.com</a></p>

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<p><b>BD Diagnostics Systems, BD Viper System with XTR Technology</b></p> <p><b>David Warshauer</b></p> <p>Utilizes Strand Displacement Amplification (SDA) with magnetic extraction (XTR)</p>	<p><i>C. trachomatis</i> <i>N. gonorrhoeae</i> <i>T. vaginalis</i> HSV 1&amp;2</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Reliable</li> <li>• Fully automated</li> <li>• Different agents can be run simultaneously</li> <li>• Up to 4 96-well plates in one 8.5 hour shift</li> <li>• Total hands-on time &lt; 20 minutes per run</li> <li>• High sensitivity and specificity for CT/GC</li> <li>• Multiple specimen types including cyto preservatives</li> <li>• Intended for use with male urethral and urine samples and with female endocervical and urine samples, self-collected vaginal swabs</li> <li>• Easy to learn and use</li> <li>• No workflow separation required</li> <li>• Reasonable cost</li> </ul>	<ul style="list-style-type: none"> <li>• No Backup</li> <li>• Large footprint</li> <li>• Need to bleach carriers—Can use 3% H2O2 on instrument</li> <li>• Slow to develop <b>new</b> assays</li> </ul>	<p>Batch</p>	<p><b>For Customer Service</b> Call (800) 675-0908 Or email <a href="mailto:BD_Womenshealth@bd.com">BD_Womenshealth@bd.com</a></p> <p><b>For Technical Support</b> Call (800) 638-8663 Or email <a href="mailto:technical_services@bd.com">technical_services@bd.com</a></p>

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<p><b>Biofire Diagnostics, FilmArray</b></p> <p><b>Thomas Novicki</b></p> <p>Utilizes endpoint melting curve of a nested multiplex PCR</p>	<p>Blood Culture ID Panel (24 pathogens and 3 antibiotic resistance genes)</p> <p>Respiratory Panel (20 respiratory bacteria and viruses)</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>Integrates sample preparation, amplification, detection, and analysis all into one complete process</li> <li>Fast, random access format</li> <li>Sensitive, comprehensive panels</li> <li>Maximizes productivity and reduces costs</li> <li>Software analyzes and reports results in a simple, easy-to-read format</li> <li>Closed system doesn't require separate molecular areas</li> <li>Minimal training required.</li> <li>TAT in 1 hour.</li> <li>2 min of hand-on time</li> <li>Currently favorable reimbursement</li> </ul>	<ul style="list-style-type: none"> <li>Expensive</li> <li>Very low throughput</li> <li>Covers the 'other' respiratory viruses (relevance, and in which settings?)</li> <li>Handle pouches carefully – they can tear</li> <li>Pay close attention to pouch filling, may not fill fully – leading to erroneous results</li> </ul>	<p>Single</p>	<p><b>For Customer Service</b> Call (800) 735-6544 Or email <a href="mailto:info@biofiredx.com">info@biofiredx.com</a></p> <p><b>For Technical Support</b> Call (800) 735-6544 Or email <a href="mailto:support@biofiredx.com">support@biofiredx.com</a></p>

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<p><b>Cepheid GeneXpert 1, 2, 4, 16</b></p> <p><b>Joshua Kropp</b></p> <p>Utilizes real-time PCR</p>	<p>MRSA Enterovirus GBS Flu A panel <i>C.difficile</i> TB</p>	<p>Moderate Complexity</p>	<p><b>Basic</b></p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• 1 min. prep</li> <li>• Some Results &lt; 1 hr.</li> <li>• Fully automates and integrates all the steps required for PCR-based DNA testing: sample preparation, DNA amplification and detection in a self-contained device.</li> <li>• Conducts up to 16 different test concurrently</li> <li>• Customizable to fit any lab with 1, 2, 4, or 16 site modules available</li> <li>• Efficient/LEAN workflow</li> </ul>	<ul style="list-style-type: none"> <li>• Balancing TAT with justified analyzer capacity during peak testing times</li> <li>• Xpert software</li> <li>• Minimized need for highly skilled technologists</li> <li>• Monthly maintenance</li> <li>• Reagent storage/logistics</li> <li>• Assay expense</li> <li>• Limited Test Menu</li> <li>• Customer Service</li> </ul>	<p>Single</p>	<p><b>For Customer Service</b> Call (888) 838-3222</p> <p><b>For Technical Support</b> Call (888) 838-3222, option 2 Or email <a href="mailto:techsupport@cepheid.com">techsupport@cepheid.com</a></p>
<p><b>Cepheid, GeneXpert Infinity</b></p> <p>Utilizes real-time PCR</p>	<p>MRSA Enterovirus GBS Flu A panel <i>C.difficile</i> TB</p>	<p>Moderate Complexity</p>	<p><b>Basic</b></p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Totally automated load and go technology</li> <li>• Available in 48 or 80 modules</li> <li>• Adjustable Touch-Screen</li> <li>• Expanded conveyor and loading area</li> <li>• Complete random access 24/7</li> <li>• High throughput – capable of performing over 2,000 test/day</li> <li>• Interfaces with any LIS</li> </ul>	<ul style="list-style-type: none"> <li>• Best suited for a high test volume lab</li> <li>• Requires more space</li> </ul>	<p>Single or Batch</p>	<p><b>For Customer Service</b> Call (888) 838-3222</p> <p><b>For Technical Support</b> Call (888) 838-3222, option 2 Or email <a href="mailto:techsupport@cepheid.com">techsupport@cepheid.com</a></p>

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<p><b>Focus Diagnostics, 3M Integrated Cycler</b></p> <p><b>Sue Kehl</b></p> <p>Utilizes real-time PCR</p>	<p><i>C. difficile</i> – U HSV 1 &amp; 2 - D Flu A/B &amp; RSV – U&amp;D Flu H1N1 2009 – U</p>	<p>Direct Tests (D) - Moderate Complexity</p> <p>Universal Tests (U) – High Complexity</p>	<p>Direct Tests - Basic</p> <p>Universal Tests - Advanced</p>	<ul style="list-style-type: none"> <li>• Scalable – two options: Universal disk – 96 sample capability and Direct disk – 8 sample capability</li> <li>• Need for extraction is assay dependent with the Universal disk</li> <li>• No extraction required for the Direct disk - all in one reaction mix in single use vials</li> <li>• Flexible – perform multiple assays simultaneously as well as multiplex (4 channel capability)</li> <li>• Qualitative and quantitative software</li> <li>• Small and fast</li> <li>• Real-time data display</li> <li>• Higher volume testing</li> <li>• 96 patient samples per run in &lt; 80 minutes</li> <li>• Results in about an hour</li> <li>• LIS compatible</li> <li>• Bidirectional connectivity – can upload sample ID and easily edit</li> <li>• Bar-code scanning</li> </ul>	<ul style="list-style-type: none"> <li>• Open platform has more risk of contamination</li> <li>• Quality control software rudimentary - No editing capability</li> <li>• Universal disk wells tiny and close together</li> </ul>		<p><b>For Customer Service</b> Call (800) 838-4548, option 1</p> <p><b>For Technical Support</b> Call (800) 838-4548, option 3</p>

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<p><b>GenMark Diagnostics, eSensor XT-8</b></p> <p><b>Erik Reisdorf</b></p> <p>Utilizes multiplex PCR</p>	<p>Respiratory Viral Panel Cystic Fibrosis Thrombophilia Warfarin</p>	<p>High Complexity</p>	<p>Basic <b>Advanced</b></p>	<ul style="list-style-type: none"> <li>• Scalable modular system with 1 to 3 analyzers</li> <li>• Simple, touch-screen user interface</li> <li>• No equipment maintenance or instrument calibration</li> <li>• Random access system capable of processing multiple test types simultaneously</li> <li>• Superior performance characteristics</li> <li>• Includes all the major viral respiratory pathogens (IVD)</li> <li>• Influenza subtyping capability</li> <li>• Co-infection detections</li> <li>• Can be completed in less than one day</li> <li>• Batch 1 to 24 specimens per test run</li> <li>• LIMS interface</li> <li>• Long expiration date</li> </ul>	<ul style="list-style-type: none"> <li>• High cost \$\$\$</li> <li>• Extraction step required</li> <li>• New instrument in development...</li> <li>• Rhinovirus-centric probe design</li> <li>• Does not include respiratory bacterial pathogens</li> <li>• Open platform has more risk of contamination</li> </ul>	<p>Single or Batch</p>	<p><b>For Customer Service</b> Call (800) 373-6767, option 1 Or email <a href="mailto:CustomerService@genmarkdx.com">CustomerService@genmarkdx.com</a></p> <p><b>For Technical Support</b> Call (800) 373-6767, option 2 Or email <a href="mailto:TechnicalSupport@genmarkdx.com">TechnicalSupport@genmarkdx.com</a></p>



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<p><b>Great Basin Corporation, Portrait PA500 Benchtop Analyzer</b></p> <p><b>Eric Beck</b></p> <p>Utilizes multi-target multiplex PCR</p>	<p><i>C. difficile</i></p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>Fairly simple to operate</li> <li>Multiplexes up to 64 distinct targets in a single assay</li> <li>Closed system eliminates laboratory contamination and separate work spaces</li> <li>Results in 90 minutes or less depending on the target of interest</li> <li>On-demand testing; no batching of tests that delays results</li> <li>Result interpretation is simple (pos/neg)</li> <li>No instrument cost</li> </ul>	<ul style="list-style-type: none"> <li>Low Throughput</li> <li>Separate Computer for each module</li> <li>Several sample manipulation steps prior to testing – the caps can be tricky to close and the blister packs occasionally pop</li> <li>20 minute set-up time</li> </ul>	<p>Single</p>	<p><b>For Customer Service</b> Call (888) 360-4022</p> <p><b>For Technical Support</b> Call (888) 333-9763</p>

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<p><b>Hologic/Gen-Probe, PANTHER System</b></p> <p><b>Tracy Felland</b></p> <p>Utilizes NAAT probes</p>	<p>Aptima Combo 2 for (CT/GC)</p> <p>APTIMA ATV for (Trichomonas)</p> <p>APTIMA HPV</p> <p>APTIMA HPV GT for (HPV 16, 18/45 Genotyping)</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Fully automated from sample to result – true walkaway freedom</li> <li>• Direct primary tube random access sampling</li> <li>• Multiple assays processed concurrently from a single specimen</li> <li>• Quality control reporting</li> <li>• Contamination mitigation</li> <li>• Intuitive software with a guided task-driven interface</li> <li>• Results in about 3.5 hours</li> <li>• Hands-on time &lt; 30 minutes</li> <li>• Processes 275 samples in 8 hours</li> <li>• Direct tube sampling with no uncapping</li> <li>• Designed to <u>help small to medium sized laboratories</u> maximize operator efficiency and productivity</li> </ul>	<ul style="list-style-type: none"> <li>• Reagent preparation</li> <li>• Reagent expiration date only 72 hours on the instrument.</li> <li>• Need to unload and refrigerate reagents everyday if test volumes are low.</li> <li>• Use of 50% bleach</li> <li>• Run failure not revealed until end of processing.</li> </ul>	<p>Single or Batch</p>	<p><b>For Customer Service</b> Call (800) 523-5001, Press 1</p> <p><b>For Technical Support</b> Call ( 888) 484-4747</p>

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<p><b>Hologic/Gen-Probe Tigris</b></p> <p><b>Erik Munson</b></p> <p>Utilizes target capture-based transcription-mediated amplification</p>	<p>Aptima Combo 2 for (CT/GC) Aptima <i>C. trachomatis</i> Aptima <i>N. gonorrhoea</i> Aptima <i>Trichomonas</i> HPV genotyping</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>Automates all phases of molecular diagnostics testing from sample preparation, amplification, and detection to reporting results</li> <li>Direct tube sampling with no uncapping</li> <li>Multiple specimen types and assays run simultaneously</li> <li>No manual pipetting</li> <li>High throughput</li> <li>Walk away to an extent</li> <li>Many preventative measures throughout system to lessen chances of contamination</li> <li>Processes 450 samples in 8 hours</li> <li>Designed for high volume larger laboratories</li> <li>Performance characteristics of TMA</li> <li>Minimal daily, weekly maintenance</li> </ul>	<ul style="list-style-type: none"> <li>Use of 50% bleach</li> <li>Extensive Monthly Maintenance</li> <li>Many moving parts</li> <li>Run failure not revealed until end of processing</li> <li>Lots of consumables (storage)</li> <li>Redundancy</li> </ul>	<p>Batch</p>	<p><b>For Customer Service</b> Call (800) 523-5001, Press 1</p> <p><b>For Technical Support</b> Call (888) 484-4747</p>

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<p><b>Luminex xTAG</b></p> <p><b>Erik Reisdorf</b></p> <p>Utilizes multiplex PCR</p>	<p>Respiratory Virus Panel (RVP) Gastrointestinal Pathogens Panel (GPP) Autoimmune: ANA, RF, others</p> <ul style="list-style-type: none"> <li>Infect Disease Serology: EBV</li> </ul>	<p>Moderate Complexity</p>	<p>Basic <b>Advanced</b></p>	<ul style="list-style-type: none"> <li>Tests for multiple viruses in a single test</li> <li>Non-proprietary open platform.</li> <li>Customizable panels available</li> <li>High throughput - up to 96 samples per test run</li> <li>Low multiplex panel costs</li> <li>Good customer support</li> </ul>	<ul style="list-style-type: none"> <li>Well trained staff required</li> <li>Not all agents included on the panels are FDA cleared</li> <li>Labor intensive</li> <li>6.5 hrs per run</li> <li>High cost per test for small test volumes</li> <li>High instrument maintenance</li> <li>Instrument calibrators and controls with each run</li> <li>Extraction required</li> <li>Not as robust as other assays</li> <li>Short expiration dates</li> </ul>	<p>Batch</p>	<p><b>Luminex, Madison</b> 1224 Deming Way Madison, WI 53717-1944 United States Phone: 877-885-6617 Fax: 608-662-9185</p> <p><b>For Customer or Technical Support</b> Call (877) 785-2323 Or email <a href="mailto:support@luminexcorp.com">support@luminexcorp.com</a></p>

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<p><b>Meridian Bioscience, Illumipro-10</b></p> <p><b>Don Undersma</b></p> <p>Utilizes Loop Mediated Isothermal Amplification (LAMP) technology <a href="http://vimeo.com/13391184">http://vimeo.com/13391184</a></p>	<p><i>C. difficile</i> Strep Group A Strep Group B Mycoplasma</p>	Moderate Complexity	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Rapid TAT: &lt;2 min. prep and results &lt; 1 hr.</li> <li>• Low maintenance</li> <li>• Small footprint</li> <li>• 7 simple steps</li> <li>• No capitol equipment burden</li> <li>• Room temperature storage of kits</li> <li>• Optimal flexibility for stat or batch runs</li> <li>• Walk away capability once sample prep is completed</li> <li>• Provides continuous access while running up to 10 samples at a time</li> </ul>	<ul style="list-style-type: none"> <li>• Crucial 10 minute incubation step during specimen processing that cannot be exceeded</li> </ul>	Batch or Single	<p><b>For Customer Service</b> Call (800) 543-1980 Or email <a href="http://www.meridianbioscience.com/Contact/">http://www.meridianbioscience.com/Contact/</a></p> <p><b>For Technical Service</b> Call (800) 343-3858</p>
<p><b>Nanosphere, Verigene Processor SP with Verigene Reader</b></p> <p><b>Raymond Podzorski</b></p> <p>Utilizes slide based microarray with nanoparticle detection</p>	<p>Flu/RSV <i>C. difficile</i> Gram positive blood culture panel Gram negative blood culture panel</p>	Moderate Complexity	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• System is modular so that workflow and throughput can be customized by each laboratory</li> <li>• Minimal hands-on time - about 5 minute</li> <li>• Almost totally automated</li> <li>• On-demand, random access testing</li> <li>• Rapid turnaround time</li> </ul>	<ul style="list-style-type: none"> <li>• Cost of reagents</li> <li>• Requires 2-2.5 hours on the instrument</li> <li>• Intervention required for detection</li> </ul>	Single	<p><b>Nanosphere, Inc. (Main Office)</b> 4088 Commercial Ave Northbrook, IL 60062 Call (888) 837-4436</p> <p><b>For Technical Service</b> Call (888) 837-4436, option 2</p>

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<p><b>Quidel, AmpliVue</b></p> <p><b>Timothy Uphoff</b></p> <p>Utilizes Helicase Dependent Amplification (HDA) with a colorimetric lateral flow device for detection</p>	<p><i>C. difficile</i> Group B Strep HSV 1 &amp; 2</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Doesn't require a large capital investment</li> <li>• Requires no equipment beyond a thermal block with a heated lid</li> <li>• Easy to use</li> <li>• High throughput</li> <li>• Very sensitive</li> </ul>	<ul style="list-style-type: none"> <li>• Critical timing between incubation steps</li> <li>• Must read between 10-30 min</li> <li>• No printed result</li> </ul>	<p>Single</p>	<p><b>For Customer Service</b> Call (800) 874-1517 Or email <a href="mailto:custserv@quidel.com">custserv@quidel.com</a></p> <p><b>For Technical Support</b> Call (800) 874-1517, option 2, then option 1 Or email <a href="mailto:technicalsupport@quidel.com">technicalsupport@quidel.com</a></p>

PCR Platform/ Panelist	FDA Approved Testing Available	Ease of Use	Molecular Expertise Required	Pros	Cons	Batch or Single Test	Contacts
<p><b>Roche Diagnostics, cobas 4800 System</b></p> <p><b>Eric Beck</b></p> <p>Utilizes multiplex real-time PCR</p>	<p><i>Chlamydia trachomatis</i> <i>Neisseria gonorrhoeae</i> HPV</p> <p>eGFR non-Small Cell Lung Cancer Mutation panel</p> <p>KRAS Colorectal Cancer Mutation panel</p> <p>BRAF Mutation test</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<p><b>cobas x 480 Instrument</b></p> <ul style="list-style-type: none"> <li>Fully automated sample preparation from primary vials</li> <li>Ready-to-use, load-and-go reagents</li> <li>Instrument set-up and maintenance is very easy</li> <li>Less than 20-minute set-up for full run of 94 samples</li> <li>Processes up to 384 specimens/day</li> </ul> <p><b>cobas z 480 Stand Alone Analyzer</b></p> <ul style="list-style-type: none"> <li>Real-time PCR with digital data capture provides accurate qualitative results with no gray zone – no equivocal retesting</li> <li>Advanced results algorithm eliminates the need for manual curve analysis</li> <li>Intuitive user interface</li> <li>Minimal training time</li> <li>Designed for lower throughput laboratories</li> <li>Approved for male urethral and urine samples &amp; female endocervical swabs</li> <li>Up to 132 patient samples in 8 hours</li> <li>Amperase selectively destroys deoxyuridine-containing amplicon for contamination control</li> <li>Internal Control – use to verify negative results</li> </ul>	<p><b>cobas x 480 Instrument</b></p> <ul style="list-style-type: none"> <li>Utilizes test kits in entirety regardless of sample number</li> <li>Once reagents are scanned they can never be used again (even if there is an error prior to testing)</li> <li>Work list can be time consuming to prepare</li> </ul> <p><b>cobas z 480 Stand Alone Analyzer</b></p> <ul style="list-style-type: none"> <li>Stand alone instruments cannot run FDA approved assays</li> <li>There are a lot of disposables required</li> </ul>	<p>Batch</p>	<p><b>Roche Diagnostics</b> 9115 Hague Road Indianapolis, IN 46250-0457 USA Phone: 800-428-5074 <a href="http://www.roche-diagnostics.us">http://www.roche-diagnostics.us</a></p>

PCR Platform/ Panelist	FDA Approved Testing Available	Ease of Use	Molecular Expertise Required	Pros	Cons	Batch or Single Test	Contacts
<p><b>Roche Diagnostics, Cobas Taqman Analyzer 48 or 96</b></p> <p><b>Eric Beck</b></p> <p>Utilizes multiplex real-time PCR</p>	<p>HIV-1 HBV HCV</p>	<p>Moderate Complexity</p>	<p>Basic</p> <p>Advanced</p>	<ul style="list-style-type: none"> <li>• Works with the COBAS® AmpliPrep Instrument and Docking Station to fully automate sample preparation, amplification, and detection</li> <li>• Bi-directional interface capability</li> <li>• Very little maintenance required (taqman)</li> <li>• Can load test cartridges on instrument multiple times (unlike COBAS 4800)</li> <li>• Multiple assays all utilizing very similar assay setup</li> <li>• Can be used as an automated nucleic acid extractor</li> </ul>	<ul style="list-style-type: none"> <li>• Ampliprep is sensitive to dust</li> <li>• Significant amount of daily maintenance (Ampliprep/ Sample racks)</li> <li>• No standalone PCR capability</li> <li>• Significant amount of daily maintenance</li> <li>• PCR tube transfer device doesn't always lock; can lead to dropped tubes</li> <li>• Instrument has a significant footprint and requires a very clean environment</li> </ul>	<p>Batch</p>	<p><b>Roche Diagnostics</b> 9115 Hague Road Indianapolis, IN 46250-0457 USA Phone: 800-428-5074 <a href="http://www.roche-diagnostics.us">http://www.roche-diagnostics.us</a></p>