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Abbreviations:

AB = Abstract

CP = Clinical Practice

DD = Dialogue and Discussion

FO = Focus

RR = Research and Reports

WB = Washington Beat

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Addendum A

Table 1. FDA Cleared Viral Molecular Assays as of February 2010.¹⁵

Test	Manufacturer	Test Name	Method
Avian Flu	Centers for Disease Control and Prevention	Influenza A/H5	Real Time RT-PCR
Cytomegalovirus (CMV) Detection	bioMerieux, Inc. Durham, NC	CMV pp67 mRNA	NASBA
	Gentech Diagnostics Pvt. Ltd. New Delhi, India	Hybrid Capture CMV DNA Test	Hybrid Capture with Chemi-luminescent Detection
	Qiagen, Inc. Germantown, MD	HC1 CMV DNA Test	Hybrid Capture
Enterovirus Detection	bioMerieux, Inc. Durham, NC	NucliSENS EasyQ Enterovirus	Real-Time NASBA
	Cepheid Sunnyvale, CA.	Xpert EV	Real Time PCR
HBV Quantification	Roche Molecular Diagnostics Pleasanton, CA	COBAS TaqMan HBV Test for use with the HighPure System	Real Time PCR
HCV Qualitative Detection	Gen-Probe, Inc. San Diego, CA (Distributed by Siemens Healthcare Diagnostics, Deerfield, IL.)	VERSANT HCV RNA	TMA
	Roche Molecular Diagnostics Pleasanton, CA	AMPLICOR HCV Test, v2.0	RT-PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AMPLICOR HCV Test, v2.0	RT-PCR
HCV Quantification	Siemens Healthcare Diagnostics Deerfield, IL	VERSANT HCV RNA 3.0 Assay (bDNA)	bDNA
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AmpliPrep/ COBAS TaqMan HCV test	Real-Time RT - PCR
HIV Drug Resistance Testing	Celera Diagnostics Alameda, CA (Distributed by Abbott Laboratories, Abbott Park, IL.	ViroSeq HIV-1 Genotyping System	Sequencing

	Siemens Healthcare Diagnostics Deerfield, IL	TruGene HIV-1 Genotyping and Open Gene DNA Sequencing System	Sequencing
HIV Quantification	Abbott Molecular Inc., Des Plaines, IL	Abbott Real-Time HIV-1	Real-Time RT-PCR
	bioMerieux, Inc. Durham, NC	NucliSens HIV-1 QT	NASBA
	Roche Molecular Diagnostics Pleasanton, CA	AMPLICOR HIV-1 MONITOR Test, v1.5	RT-PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AMPLICOR HIV-1 MONITOR Test, v1.5	RT-PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AmpliPrep/ COBAS TaqMan HIV-1 Test	Real-Time RT-PCR
	Siemens Healthcare Diagnostics Deerfield, IL.	VERSANT HIV-1 RNA 3.0 Assay (bDNA)	bDNA
HBV/HCV/ HIV for blood, blood component and tissue donations	BioLife Plasma Services, L.P. Deerfield, IL. 60015	Hepatitis C Virus (HCV) Reverse Transcription (RT) Polymerase Chain Reaction Assay	RT-PCR
	BioLife Plasma Services, L.P. Deerfield, IL. 60015	HIV-1 Reverse Transcription PCR Assay	RT-PCR
	Gen-Probe, Inc. San Diego, CA (Distributed by Chiron)	Procleix HIV-1/HCV Assay	TC, TMA, HPA
	Gen-Probe, Inc. San Diego, CA (Distributed by Chiron)	Procleix ULTRIO Assay (HIV-1, HCV, and HBV)	TC, TMA, HPA
	National Genetics Institute Los Angeles, CA	UltraQual HCV RT-PCR Assay	RT-PCR
	National Genetics Institute Los Angeles, CA	UltraQual HIV-1 RT-PCR Assay	RT-PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AmpliScreen HBV Test	PCR

	Roche Molecular Diagnostics Pleasanton, CA	COBAS AmpliScreen HCV Test, v2.0	RT-PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AmpliScreen HIV-1 Test, v1.5	RT-PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS TaqScreen MPX	Multiplex Real-Time PCR and RT-PCR
Human Metapneumo-Virus	Prodesse Waukesha, WI	Pro hMPV+ Assay	Multiplex Real-Time RT-PCR
Human Papillomavirus Testing	Hologic, Inc. (Third Wave Technologies) Bedford, MA	Cervista HPV HR (High Risk)	Invader Chemistry
	Hologic, Inc. (Third Wave Technologies) Bedford, MA	Cervista HPV 16/18	Invader Chemistry
	Qiagen, Inc. Germantown, MD	HC2 HR and LR	Hybrid Capture
	Qiagen, Inc. Germantown, MD	HC2 HPV HR	Hybrid Capture
	Qiagen, Inc. Germantown, MD	HC2 DNA with Pap	Hybrid Capture
Influenza Virus Panel	Centers for Disease Control Atlanta, GA	Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel	Real-Time RT-PCR
Respiratory Virus Panel	Luminex Molecular Diagnostics Toronto, Canada	xTAG Respiratory Viral Panel	RT-PCR ASPE, Tag sorting
	Nanosphere, Inc. Northbrook, IL.	Verigene Respiratory Virus Nucleic Acid Test and Verigene Respiratory Virus Test-SP	Multiplex Gold Nanoparticle Probes
	Prodesse Waukesha, WI.	ProFlu+ Assay	Multiplex Real-Time RT-PCR
	Prodesse Waukesha, WI.	ProParaFlu+ Assay	Multiplex Real-Time RT-PCR

West Nile
for blood
donations

Gen-Probe, Inc.
San Diego, CA.

Procleix WNV
Assay

Real-Time
PCR

Roche Molecular
Diagnostics
Pleasanton, CA

COBAS TaqScreen
WNV

TC, TMA
HPA

Abbreviations:

ASPE: Allele Specific Primer Extension

bDNA: Branched Chain DNA Signal Amplification

HPA: Hybridization Protection Assay

NASBA: Nucleic Acid Sequence Based Amplification

PCR: Polymerase Chain Reaction

RT-PCR: Reverse-Transcription PCR

TC: Target Capture

TMA: Transcription Mediated Amplification

Addendum B

Table 3. FDA Cleared Bacterial Molecular Assays as of February 2010.¹

Test	Manufacturer	Test Name	Method
<i>Bacillus anthracis</i>	Idaho Technology, Inc. Salt Lake City, UT	Joint Biological Agent Identification and Diagnostic System Anthrax Detection Kit	Real-time PCR
<i>Clostridium difficile</i>	BD Diagnostics Gene Ohm San Diego, CA	GeneOhm <i>C. diff</i> Assay	Real-time PCR
	Cepheid Sunnyvale, CA	Xpert™ <i>C. difficile</i> Test	Real-time PCR
	Prodesse Waukesha, WI	ProGastro™ Cd Assay	Multiplex Real-time PCR
<i>Chlamydia trachomatis</i> detection (single organism)	BD Diagnostic Systems Sparks, MD	BD ProbeTec™ <i>Chlamydia trachomatis</i> (CT) Q* Amplified DNA Assay	SDA
	Gen-Probe, Inc. San Diego, CA	APTIMA CT Assay	TC, TMA DKA
	Gen-Probe, Inc. San Diego, CA	PACE 2 CT Probe Competition Assay (Ct-confirmation test)	HPA
	Qiagen, Inc. Germantown, MD	HC2 CT ID	Hybrid Capture
	Roche Molecular Diagnostics Pleasanton, CA	AMPLICOR CT/NG Test for <i>Chlamydia trachomatis</i>	PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AMPLICOR CT/NG Test for <i>Chlamydia trachomatis</i>	PCR
	<i>Neisseria gonorrhoeae</i> detection (single organism)	BD Diagnostic Systems Sparks, MD	BD ProbeTec™ <i>Neisseria gonorrhoeae</i> (GC) Q* Amplified DNA Assay
Gen-Probe, Inc. San Diego, CA		APTIMA GC Assay	TC, TMA DKA
Gen-Probe, Inc. San Diego, CA		PACE 2 GC Probe Competition Assay (GC-confirmation test)	HPA
Qiagen, Inc. Germantown, MD		HC2 GC ID	Hybrid Capture

	Roche Molecular Diagnostics Pleasanton, CA	AMPLICOR CT/NG Test for <i>Neisseria gonorrhoeae</i>	PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AMPLICOR CT/NG Test for <i>Neisseria gonorrhoeae</i>	PCR
<i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> detection	Abbott Molecular, Inc. Des Plaines, IL	Abbott Real-time CT/NG	Real-time PCR
	BD Diagnostics – GeneOhm San Diego, CA	BD ProbeTec™ ET <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> amplified DNA Assay	SDA
	Gen-Probe, Inc. San Diego, CA	APTIMA Combo 2 Assay	TC, TMA DKA
	Gen-Probe, Inc. San Diego, CA	PACE 2C CT/GC	HPA
	Qiagen, Inc. Germantown, MD	HC2 CT/ GC Combo Test	Hybrid Capture
	Roche Molecular Diagnostics Pleasanton, CA	AMPLICOR CT/NG Test	PCR
	Roche Molecular Diagnostics Pleasanton, CA	COBAS AMPLICOR CT/NG Test	PCR
<i>Enterococcus faecalis</i>	AdvanDX Woburn, MA	<i>Enterococcus faecalis</i> PNA FISH	PNA FISH
<i>E. coli</i> and <i>Pseudomonas aeruginosa</i>	AdvanDX Woburn, MA	<i>E. coli/P. aeruginosa</i> PNA-FISH	PNA FISH
<i>E. coli</i> , <i>Klebsiella pneumoniae</i> and <i>Pseudomonas aeruginosa</i>	AdvanDX Woburn, MA	<i>EK/P. aeruginosa</i> PNA-FISH	PNA FISH
<i>Francisella tularensis</i>	Idaho Technology, Inc. Salt Lake City, UT	Joint Biological Agent Identification and Diagnostic System Tularemia Detection Kit	Real-time PCR
Group A	Gen-Probe, Inc.	Group A Strep Direct	HPA

<i>Streptococci</i> Detection	San Diego, CA		
Group B <i>Streptococci</i> Detection	AdvanDX Woburn, MA	GBS PNA FISH	PNA FISH
	BD Diagnostics-GeneOhm San Diego, CA	IDI-Strep B™ Assay	Real-time PCR
	Cepheid Sunnyvale, CA	Smart GBS	Real-time PCR
	Cepheid Sunnyvale, CA	Xpert™ GBS	Real-time PCR
	Gen-Probe, Inc. San Diego, CA	Group B AccuProbe	HPA
MRSA for <i>Staph</i> <i>aureus</i> - Screening Assay	BD Diagnostics-GeneOhm San Diego, CA	IDI-MRSA™ Assay	Real-time PCR
	Cepheid Sunnyvale, CA	Xpert™ MRSA	Real-time PCR
MRSA for <i>Staph</i> <i>aureus</i> - Diagnostic Assay for Blood Cultures	BD Diagnostics-GeneOhm San Diego, CA	GeneOhm StaphSR	Real-time PCR
	Cepheid Sunnyvale, CA	Xpert™ MRSA/SA	Real-time PCR Blood Culture Assay
	AdvanDx Woburn, MA	<i>S. aureus</i> PNA FISH	PNA FISH
MRSA for <i>Staph</i> <i>aureus</i> - Diagnostic Assay for Skin and Soft Tissue Infection	Cepheid Sunnyvale, CA	Xpert™ MRSA/SA Skin and Soft Tissue Infection Test	Real-time PCR
<i>MTB</i> Detection	Gen-Probe, Inc. San Diego, CA	AMPLIFIED™ <i>Mycobacterium</i> <i>tuberculosis</i> Direct Test	TMA
<i>Mycobacteria</i> <i> spp.</i> , different fungi and bacteria culture confirmation	Gen-Probe, Inc. San Diego, CA	AccuProbe Culture Identification Tests	HPA
<i>Staph aureus</i>	AdvanDx Woburn, MA	<i>S. aureus</i> PNA FISH	PNA FISH

Vancomycin
Resistance

Cepheid
Sunnyvale, CA

Xpert vanA test

Real-time PCR

Abbreviations

DKA: dual kinetic assay

FISH: fluorescent *in situ* hybridization

HPA: hybridization protection assay

PCR: polymerase chain reaction

PNA: peptide nucleic acid

SDA: strand displacement amplification

TC: target capture

TMA: transcription mediated amplification