List of Nucleic Acid Based Tests

U.S. Food & Drug Administration

This is a list of nucleic acid-based tests that have been cleared or approved by the Center for Devices and Radiological Health. These tests analyze variations in the sequence, structure, or expression of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in order to diagnose disease or medical conditions, infection with an identifiable pathogen, and determine genetic carrier status.

This list excludes nucleic acid-based companion diagnostic tests. Those tests are listed at In Vitro Companion Diagnostic Devices [1].

- Human Genetic Tests [2]
- Microbial Tests [3]

List of Human Genetic Tests

Disease	Trade Name	Manufacturer	Submission
Acute Myeloid Leukemia	Vysis EGR1 FISH Probe Kit	Abbott Molecular Inc.	K091960 [4]
B-cell chronic lymphocytic leukemia	Vysis CLL FISH Probe Kit	Vysis	K100015 [5]
	CEP 12 SpectrumOrange Direct Labeled Chromosome Enumeration DNA Probe	Vysis	K962873 [6]
Bladder Cancer	Vysis UroVysion Bladder Cancer Recurrence Kit	Vysis	K033982 [7], K013785 [8], K011031 [9]
Breast Cancer	MammaPrint	Agendia BV	K101454 [10], K081092 [11], K080252 [12], K070675 [13], K062694 [14]
	GeneSearch Breast Lymph Node (BLN) Test Kit	Veridex, LLC.	P060017 [15] S001-S004
	Dako TOP2A FISH PharmDx Kit	Dako Denmark A/S	P050045 [16] S001-S004
Cystic Fibrosis	eSensor® CF Genotyping	Osmetech Molecular	K090901 [17]

	Test	Diagnostics	
	xTAG Cystic Fibrosis 60 Kit v2	Luminex Molecular Diagnostics Inc.	K083845 [18]
	xTAG Cystic Fibrosis 39 Kit v2	Luminex Molecular Diagnostics Inc.	K083846 [19]
	Verigene® CFTR and Verigene® CFTR PolyT Nucleic Acid Tests	Nanosphere, Inc	K083294 [20]
	InPlex CF Molecular Test	Third Wave Technology, Inc.	K063787 [21]
	Cystic Fibrosis Genotyping Assay	Celera Diagnostics	K062028 [22]
	Tag-It Cystic Fibrosis Kit	Tm Bioscience Corporation	K060627 [23], K043011 [24]
	eSensor Cystic Fibrosis Carrier Detection System	Clinical Micro Sensors, Inc.	K060543 [25], K051435 [26]
Drug metabolizing enzymes	INFINITI CYP2C19 Assay	AutoGenomics, Inc.	K101683 [27]
	xTAG® CYP2D6 Kit	Luminex Molecular Diagnostics, Inc.	K093420 [28]
	Invader® UGT1A1 Molecular Assay	Third Wave Technologies Inc.	K051824 [29]
	Roche AmpliChip CYP450 microarray	Roche Molecular Systems, Inc.	K043576 [30], K042259 [31]
	eSensor Warfarin Sensitivity Saliva Test	GenMark Diagnostics	K110786 [32]
	eQ-PCR LC Warfarin Genotyping kit	TrimGen Corporation	K073071 [33]

	eSensor Warfarin Sensitivity Test and XT-8 Instrument	Osmetech Molecular Diagnostics	K073720 [34]
	Gentris Rapid Genotyping Assay - CYP2C9 & VKORCI	ParagonDx, LLC	K071867 [35]
	INFINITI 2C9 & VKORC1 Multiplex Assay for Warfarin	AutoGenomics, Inc.	K073014 [36]
	Verigene Warfarin Metabolism Nucleic Acid Test and Verigene System	Nanosphere, Inc.	K070804 [37]
Coagulation Factors	Invader Factor V	Hologic, Inc.	K100980 [38]
	Invader Factor II	Hologic, Inc.	K100943 [39]
	Illumina VeraCode Genotyping Test for Factor V and Factor II	Illumina, Inc.	K093129 [40]
	eSensor Thrombophilia Risk Test, eSensor FII-FV Genotyping Test, eSensor FII Genotyping Test, eSensor FV Genotyping Test, eSensor MTHFR Genotyping Test	Osmetech Molecular Diagnostics	K093974 [41]
	Xpert HemosIL FII & FV	Cepheid	K082118 [42]
	Verigene F5 Nucleic Acid Test	Nanosphere, Inc.	K070597 [43]

	Verigene F2 Nucleic Acid Test Verigene MTHFR Nucleic Acid Test		
	INFINITI System	Autogenomics, Inc.	K060564 [44]
	Factor II (Prothrombin) G20210A Kit	Roche Diagnostics Corporation	K033612 [45]
	Factor V leiden Kit	Roche Diagnostics Corporation	K033607 [46]
	Invader MTHFR 677	Hologic, Inc.	K100987 [47]
	Invader MTHFR 1298	Hologic, Inc.	K100496 [48]
Heart Transplant	AlloMap Molecular Expression Testing	xDx	K073482 [49]
Chromosome abnormalities	AneuVysion	Vysis	K010288 [50], K972200 [51]
	CEP 8 Spectrum orange DNA Probe Kit	Vysis	K953591 [52]
	CEP X Spectrum Orange/ Y SpectrumGreen DNA Probe Kit	Vysis	K954214 [53]
Prostate Cancer	NADiA ProsVue	Iris Molecular Diagnostics	K101185 [54]
	PROGENSA PCA3 Assay	Gen-Probe, Inc.	P100033 [55]
Tissue of Origin	Pathwork Tissue of Origin Test Kit – FFPE	Pathwork Diagnostics Inc.	K120489 [56], K092967 [57]
	Pathwork Tissue of Origin Test	Pathwork Diagnostics Inc.	K080896 [58]

List of Microbial Tests

Microorganism	Trade Name	Manufacturer	Submission
Bacillus Anthracis	JBAIDS Anthrax	Idaho Technology,	K071188 [59],

	Detection System	Inc.	K051713 [60]
Candida tropicalis / Candida albicans / Candida parapsilosis / Candida glabrata / Candida krusei	Affirm VPIII Microbial Identification Test	Microprobe Corp.	K931151 [61], K931374 [62]
	Yeast Traffic Light PNA FISH	AdvanDx, Inc.	K093024 [63], K080719 [64]
	C. albicans / C. glabrata PNA FISH	AdvanDx, Inc.	K092784 [65]
	C. albicans PNA FISH	AdvanDx, Inc.	K092655 [66], K062461 [67]
	C. Albicans screen	Carr-Scarborough Microbiologicals, Inc.	K891476 [68]
Clostridium difficile	Portrait Toxigenic C. difficile Assay	Great Basin Scientific, Inc.	K113358 [69]
	Simplexa C. difficile Universal Direct Assay	Focus Diagnostics, Inc.	K113433 [70]
	Xpert C. difficile/Epi	Cepheid	K110203 [71]
	Illumigene C. difficile DNA Amplification Assay	Meridian Bioscience, Inc.	K110012 [72]
	Illumigene C. difficile Assay	Meridian Bioscience, Inc.	K100818 [73]
	Xpert C. difficile	Cepheid	K091109 [74]
	ProGastro Cd Assay	Prodesse Inc.	K090239 [75]
	BD GeneOhm C. diff Assay	BD Diagnostics/ GeneOhm Sciences, Inc.	K081920 [76]
Coxiella burnetii	Joint Biological Agent Identification and Diagnostic System (JBAIDS) Q Fever Detection Kit	Idaho Technology, Inc.	K103207 [77]
Chlamydia trachomatis / Neisseria gonorrhoeae	Aptima Combo 2 Assay (Panther System)	Gen-Probe, Inc.	K111409 [78]
	Cobas CT/NG Test	Roche Molecular Systems, Inc.	K110923 [79]
	Abbott RealTime CT/NG and Multi-Collect Specimen Collection Kit	Abbott Molecular Inc.	K092704 [80], K080739 [81]
	BD ProbeTec	Becton, Dickinson,	K091724 [82],

	Chlamydia trachomatis (CT) Qx Amplified DNA Assay	& Co.	K090824 [83], K081824 [84]
	AMPLICOR CT/NG Test for Chlamydia trachomatis	Roche Diagnostics Corp.	K070174 [85], K973707 [86]
	Gen-Probe Aptima for Chlamydia Trochamatis	Gen-Probe, Inc.	K063451 [87], K053446 [88], K043072 [89]
	TIGRIS DTS Automated Analyzer Aptima Assay for Chlamydia trachomatis	Gen-Probe, Inc.	K061413 [90]
	TIGRIS DTS Gen-Probe Aptima Combo 2 Assay	Gen-Probe, Inc.	K060652 [91]
	Cobas Amplicor CT/NG test for Chlamydia trachomatis	Roche Molecular Systems, Inc.	K053287 [92], K973718 [93]
	GEN-PROBE Aptima Combo 2 Assay	Gen-Probe, Inc.	K043224 [94], K032554 [95],
	BDProbeTec ET Chlamydia trachomatis and Neisseria gonorrhoeae Amplified DNA Assays	Becton, Dickinson, & Co.	K012351 [96], K003395 [97], K984631 [98]
	Roche Cobas AMPLICOR Chlamydia trachomatis test	Roche Molecular Systems, Inc.	K964507 [99]
	Gen-Probe AMPLIFIED Chlamydia trachomatis Assay Kit	Gen-Probe, Inc.	K962217 [100]
	LCX Chlamydia trachomatis Assay	Abbott Laboratories	K934622 [101]
	BD Probetec Neisseria Gonorrhoeae (GC) Qx Amplified DNA	Becton, Dickinson, & Co.	K091730 [102], K090971 [103], K090827 [104], K081825 [105]

	Assay		
	AMPLICOR CT/NG Test for Neisseria Gonorrhoeae	Roche Diagnostics Corp.	K070172 [106]
	Gen-Probe Aptima Assay for Neisseria Gonorrhoeae	Gen-Probe, Inc.	K063664 [107], K062440 [108]
	Tigris DTS Gen-Probe Aptima Assay for Neisseria Gonorrhoeae	Gen-Probe, Inc.	K061509 [109]
	COBAS Amplicor CT/NG test for Neisseria gonorrhoeae	Roche Molecular Systems, Inc.	K053289 [110], K974342 [111]
	Hybrid Capture II CT/GC DNA Test	Digene Corp.	K981567 [112]
	Roche AMPLICOR CT/NG test for Neisseria gonorrhoeae	Roche Molecular Systems, Inc.	K974503 [113]
	Digene GC-ID Test Hybrid Capture II	Digene Corp.	K981485 [114]
	Gen-Probe PACE 2C System Chlamydia Trachomatis / Neisseria gonorrhoeae	Gen-Probe, Inc.	K940979 [115]
	PACE2 Neisseria gonorrhoeae probe confirmation assay	Gen-Probe, Inc.	K920301 [116]
	GONOSTAT Gonococcal Detection Kit	Sierra Diagnostics, Inc.	K991268 [117]
	LCX Neisseria gonorrhoeae Assay	Abbott Laboratories	K935833 [118]
Entercoccus faecalis	E. faecalis/OE PNA	AdvanDx, Inc.	K083074 [119]
	GBS PNA FISH	AdvanDx, Inc.	K082612 [120]
	E. faecalis PNA FISH culture identification kit	AdvanDx, Inc.	K063127 [121]
Escherichia coli / Klebsiella pneumoniae / Pseudomonas	GNR Traffic Light PNA FISH	AdvanDx, Inc.	K101558 [122]

aeroginosa	E. coli/P. aeruginosa PNA FISH	AdvanDx, Inc.	K092236 [123], K081309 [124]
	EK/P aeruginosa PNA FISH	AdvanDx, Inc.	K092393 [125], K081433 [126]
	E. coli PNA FISH	AdvanDx, Inc.	K082068 [127]
Francisella tularensis	JBAIDS Tularemia Detection Kit	Idaho Technology, Inc.	K072547 [128]
Leishmania species	SMART Leish	U.S. Army Medical Materiel Development Activity	K081868 [129]
Mycobacterium tuberculosis	BDProbetec ET Mycobacterium tuberculosis complex culture identification kit	Becton, Dickinson, & Co.	K000884 [130]
	Amplified Mycobacterium tuberculosis Direct Test	Gen-Probe, Inc.	P940034 [131]
	Amplicor Mycobacterium tuberculosis test	Roche Molecular Systems, Inc.	P940040 [132]
	SNAP M.tuberculosis complex	Syngene, Inc.	K900292 [133]
	Accuprobe Mycobacterium tuberculosis complex Test	Gen-Probe, Inc.	K896493 [134]
	Rapid Diagnostic System for Mycobacterium tuberculosis	Gen-Probe, Inc.	K871795 [135]
	Rapid Identification Test for Mycobacterium tuberculosis complex	Gen-Probe, Inc.	K862614 [136]
Mycobacterium species	Accuprobe Mycobacterium avium complex culture	Gen-Probe, Inc.	K921435 [137], K896494 [138], K897078 [139]
	Accuprobe Mycobacterium kansasii Identification Test	Gen-Probe, Inc.	K904463 [140]

	SNAP Mycobacterium avium complex	Syngene, Inc.	K900202 [141]
	Accuprobe Mycobacterium intracellulare Culture Identification Test	Gen-Probe, Inc.	K897077 [142]
	Accuprobe Mycobacterium gordonae culture identification Test	Gen-Probe, Inc.	K896492 [143]
	Rapid Diagnostic System for Mycobacterium gordonae	Gen-Probe, Inc.	K890089 [144]
	Rapid Diagnostic System for Mycobacteria	Gen-Probe, Inc.	K864597 [145]
	Rapid Identification Test for Mycobacterium avium	Gen-Probe, Inc.	K862613 [146]
	Gen-Probe Mycobacterium Rapid Confirmation System	Gen-Probe, Inc.	K860782 [147]
Staphylococcus aureus	BD Max MRSA Assay	BD Diagnostics (GeneOhm Sciences Canada, Inc.)	K120138 [148]
	Staphylococcus QuickFISH BC	AdvanDx, Inc.	K113371 [149]
	MRSA/SA ELITe MGB	EliTechGroup Epoch Biosciences.	K112937 [150]
	Verigene Staphylococcus Blood Culture (BC-S) Nucleic Acid Test	Nanosphere, Inc.	K112424 [151]
	NucliSENS EasyQ MRSA Assay	bioMerieux, Inc.	K102740 [152]
	Xpert MRSA/SA Blood Culture Assay	Cepheid	K101879 [153], K082140 [154]
	Xpert MRSA/SA Nasal Complete Assay	Cepheid	K100822 [155]

	LightCycler MRSA Advanced Test	Roche Molecular Systems, Inc	K091409 [156]
	BD GeneOhm MRSA ACP Assay	BD Diagnostics (GeneOhm Sciences Canada, Inc.)	K093346 [157]
	S. aureus and/or other Staphylococcus species PNA FISH Culture	AdvanDx, Inc.	K092166 [158]
	Xpert MRSA/SA SSTI Assay	Cepheid	K080837 [159]
	BD GeneOhM StaphSR Assay	BD Diagnostics (GeneOhm Sciences Canada, Inc.)	K071026 [160]
	S. aureus PNA FISH	AdvanDx, Inc.	K091827 [161], K060099 [162]
	Xpert MRSA	Cepheid	K070462 [163]
	IDI-MRSA Assay	Infectio Diagnostic, Inc.	K042357 [164], K033415 [165]
Streptococci	Xpert GBS LB Assay	Cepheid	K121539 [166]
	illumigene Group A Streptococcus (GBS) DNA Amplification Assay	Meridian Bioscience, Inc.	K122019 [167]
	illumigene Group B Streptococcus (GBS) DNA Amplification Assay	Meridian Bioscience, Inc.	K121044 [168]
	BD Max GBS Assay	Becton, Dickinson, & Co.	K111860 [169]
	Cepheid Smart GBS Assay	Cepheid	K062948 [170]
	Xpert GBS	Cepheid	K060540 [171]
	IDI-Strep B Assay	Infectio Diagnostic, Inc.	K022504 [172]
	Gen-Probe Accuprobe Group B Streptococcus culture identification kit	Chugai Pharmaceuticals Co, Ltd.	K974572 [173]
	Accuprobe Streptococcus pneumoniae culture confirmation	Gen-Probe, Inc.	K902908 [174]

Trichomonas vaginalis	Aptima Trichomonas vaginalis assay	Gen-Probe, Inc.	K102911 [175]
	Affirm/VP Identification Test G. Vaginalis and T. vaginalis	Microprobe Corp.	K923133 [176]
Yersinia pestis	JBAIDS Plague Detection Kit	Idaho Technology, Inc.	K072631 [177]

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