GeneXpert II

GeneXpert IV
*GeneXpert **Xpress** IV*

GeneXpert XVI

The GeneXpert® System

Molecular diagnostics made fast, accurate, and easy.

With the GeneXpert® system and the Xpert® test menu, Cepheid delivers actionable results when clinicians need them most.

Only GeneXpert **Xpress** IV systems are intended for use in CLIA Waived settings.

Cepheid®
A better way.

GeneXpert® System
Clinical IVD Test Menu

			Number of Tests	Catalog Number
Respiratory	Xpert® **Xpress** CoV-2/Flu/RSV ***plus****^	Rapid test for detection of the viruses causing COVID-19, Flu A, Flu B, and RSV, with the addition of a third gene for SARS-CoV-2, positive results in as soon as 25 minutes for SARS-CoV-2[#]	10	XP3COV2/FLU/RSV-10
	Xpert® **Xpress** CoV-2 ***plus****^	Rapid detection of the current pandemic coronavirus SARS-CoV-2, the virus that causes COVID-19, with the addition of a third gene for SARS-CoV-2, positives in as soon as 20 minutes[†]	10	XP3SARS-COV2-10
	Xpert® **Xpress** Strep A*	Rapid detection of Group A Streptococcus DNA in as soon as 18 minutes[†]	10 120	XPRSTREPA-10 XPRSTREPA-120
	Xpert® **Xpress** Flu/RSV*	Rapid detection and differentiation of Flu A, Flu B, and RSV in as soon as 20 minutes[‡]	10	XPRSFLU/RSV-10
	Xpert® **Xpress** Flu*	Rapid detection of Flu A and Flu B in as soon as 20 minutes[‡]	10	XPRSFLU-10
Healthcare-Associated Infections & Other Infectious Diseases	Xpert® MRSA NxG	Active MRSA surveillance testing in around 45 minutes[†]	10 120	GXMRSA-NXG-10 GXMRSA-NXG-120
	Xpert® SA Nasal Complete	Pre-surgical testing for *S. aureus* and MRSA in about an hour	10	GXSACOMP-10
	Xpert® MRSA/SA Blood Culture	Detection of MRSA and *S. aureus* in positive blood cultures in about an hour	10	GXMRSASA-BC-10
	Xpert® MRSA/SA SSTI	Detection of MRSA & *S. aureus* skin and soft tissue infections in about an hour	10	GXMRSASA-SSTI-10
	Xpert® Carba-R	Detection of the carbapenem-resistance genes encoding KPC, NDM, VIM, OXA-48 and IMP in around 50 minutes from isolates, rectal swabs, or perirectal swabs	10	GXCARBAR-10
	Xpert® Norovirus	Rapid identification and differentiation of Norovirus GI and GII in less than one hour[†]	10	GXNOV-10
	Xpert® EV	Fast molecular diagnostic testing for enterovirus in 2.5 hours	10	GXEV-100N-10
	Xpert® *C. difficile/Epi*	Detection and differentiation of *Clostridioides difficile* & the epidemic 027 strain in around 40 minutes	10	GXCDIFF/EPI-10
	Xpert® *vanA*	On-demand testing to assist with VRE surveillance in around 45 minutes[†]	10	GXVANA-10
TB & Emerging Infectious Diseases	Xpert® MTB/RIF	Detection of MTB and rifampin resistance mutations in less than two hours	10	GXMTB/RIF-US-10
	Xpert® Ebola^	Detection of Ebola Zaire virus in around 90 minutes	10	GXEBOLA-10
Women's & Sexual Health	Xpert® CT/NG	Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in around 90 minutes	10 120	GXCT/NG-10 GXCT/NG-120
	Xpert® TV	Detection of *Trichomonas vaginalis* in male and female specimens in around 40 minutes[†]	10	GXTV-10
	Xpert® GBS	Intrapartum screening for Group B *streptococcus* during labor/delivery less than 1 hour	10	GXGBS-100N-10
	Xpert® GBS LB	Antepartum screening from LIM broth for Group B *streptococcus* in as soon as about 40 minutes[†]	10 120	GXGBSLB-10 GXGBSLB-120
Oncology & Genetics	Xpert® BCR-ABL Ultra	On-demand measurement of BCR-ABL p210 transcript levels for individuals with CML in under 2 hours	10	GXBCRABL-US-10
	Xpert® FII & FV	Identification of genetic risk factors for thrombosis in around 30 minutes	10	GXFIIFV-10

All tests listed are non-waived unless otherwise stated.

* *In Vitro* Diagnostic devices for use in High and Moderate Complexity or CLIA waived patient care settings. See Package Inserts for details.

^ These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories. Xpert **Xpress** CoV-2 ***plus*** has been authorized only for the detection of nucleic acids from SARS-CoV-2, and not for any other viruses or pathogens. Xpert **Xpress** CoV-2/Flu/RSV ***plus*** has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens. The emergency use of these products is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

\# For positives when running SARS-CoV-2 only, using Xpert **Xpress** CoV-2/Flu/RSV ***plus***; otherwise, the test will have a runtime of approximately 36 minutes.

† With early assay termination (EAT) for positive results; otherwise, the full test runtime is approximately 30 minutes.

‡ With EAT for positive results. Reporting negatives and combined reporting in 30 minutes.

US-IVD. *In Vitro* Diagnostic Medical Device.

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