



US-IVD Xpert® Test Menu

*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.

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

US-IVD Xpert® Test Menu

Number
of Tests Catalog Number

Respiratory	Xpert Xpress CoV-2/Flu/RSV <i>plus</i> *	Rapid test for detection and differentiation of SARS-CoV-2, FluA, FluB and RSV, with the addition of a third gene for SARS-CoV-2, and positive results in as soon as 25 minutes for SARS-CoV-2 [#]	10	XPRS4PLEX-10
	Xpert Xpress CoV-2/Flu/RSV <i>plus</i> **^	Rapid test for detection and differentiation of SARS-CoV-2, FluA, FluB and RSV, with the addition of a third gene for SARS-CoV-2, and positive results in as soon as 25 minutes for SARS-CoV-2 [#]	10	XP3COV2/FLU/RSV-10
	Xpert Xpress CoV-2 <i>plus</i> *	Rapid detection of 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	XPRS-COV2-10
	Xpert Xpress CoV-2 <i>plus</i> **^	Rapid detection of 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 <i>Streptococcus</i> DNA in as soon as 18 minutes [‡]	10	XPRSTREPA-10
	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
HAI & Critical Infections	Xpert MRSA NxG	Active MRSA surveillance testing in around 45 minutes [§]	10	GXM RSA-NXG-10
	Xpert SA Nasal Complete	Pre-surgical testing for <i>S. aureus</i> and MRSA in about an hour	10	GXSACOMP-10
	Xpert MRSA/SA Blood Culture	Detection of MRSA and <i>S. aureus</i> in positive blood cultures in about an hour	10	GXMRSASA-BC-10
	Xpert MRSA/SA SSTI	Detection of MRSA & <i>S. aureus</i> in 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, and 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 <i>C. difficile</i> /Epi	Detection and differentiation of <i>Clostridioides difficile</i> & the epidemic 027 strain in around 40 minutes	10	GXCDIFF/EPI-10
TB, Virology, & Emerging Infectious Diseases	Xpert <i>vanA</i>	Detection of the <i>vanA</i> gene sequence associated with vancomycin-resistant enterococci (VRE)	10	GXVANA-10
	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
	Xpert Mpox^	Detect monkeypox virus clade II and non-variola Orthopoxvirus DNA in human lesion swab specimens in approximately 36 minutes	10	GXMPX-10
	Xpert HCV^	Detection of hepatitis C RNA directly from fingerstick capillary whole blood at the point of care in as soon as 41 minutes [§]	10	GXHCV-10
Sexual & Women's Health	Xpert CT/NG	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> infections in around 90 minutes	10	GXCT/NG-10
	Xpert TV	Detection of <i>Trichomonas vaginalis</i> in male and female specimens in around 40 minutes [§]	10	GXTV-10
	Xpert Xpress GBS	Intrapartum detection for Group B <i>Streptococcus</i> (GBS) during labor/delivery in approximately 30 minutes [‡]	10	XPRSGBS-10
	Xpert GBS LB XC	On-demand GBS molecular testing for antepartum screening with positive results in around 42 minutes	10	GXGBSLBXC-10
	Xpert Xpress MVP	Detection and differentiation of organisms associated with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis (TV) within an hour.	10	XPRSMVP-10
Oncology & Genetics	Xpert BCR-ABL Ultra	Sensitive and quantitative monitoring of BCR::ABL p210 transcript levels in patients with Chronic Myelogenous Leukemia (CML) in under 2.5 hours.	10	GXBCRABL-US-10
	Xpert Factor II & Factor V	Identification of genetic risk factors for thrombosis in around 30 minutes	10	GXFIIIFV-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 for emergency use 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. Xpert Mpox has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not for any other viruses or pathogens. Xpert Ebola has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014). 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, monkeypox virus, including non-variola Orthopoxvirus, and/or Ebola virus 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 approximately 30 minutes.

§ With early assay termination (EAT) for positive results.

^ In Vitro diagnostic device for use on the GeneXpert® Xpress system in Moderate Complexity or CLIA waived settings.

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