



## 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 Xpert® 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 <i>Streptococcus</i> 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 <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> 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 <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
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 <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> infections in around 90 minutes	10 120	GXCT/NG-10 GXCT/NG-120
	Xpert TV	Detection of <i>Trichomonas vaginalis</i> in male and female specimens in around 40 minutes‡	10	GXTV-10
	Xpert GBS	Intrapartum screening for Group B <i>Streptococcus</i> during labor/delivery in less than one hour	10	GXGBS-100N-10
	Xpert GBS LB XC	On-demand GBS molecular testing for antepartum screening with positive results in around 40 minutes	10 120	GXGBSLBXC-10 GXGBSLBXC-120
	Xpert Xpress MVP	Detection and differentiation of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomoniasis (TV) within an hour	10	XPRSMVP-10 XPRSMVP-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	GXFIIIV-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.

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

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

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