



## CE-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.

CE-IVD. In Vitro Diagnostic Medical Device. Not available in all countries.

# CE-IVD Xpert® Test Menu

			Number of Tests	Catalog Number
Respiratory	Xpert® Xpress CoV-2/Flu/RSV <i>plus</i> *	Rapid detection and differentiation of SARS-CoV-2, Flu A, Flu B, and RSV, with the addition of a 3rd gene target for SARS-CoV-2, in approximately 36 minutes	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 three gene targets in as soon as 20 minutes <sup>#</sup>	10	XP3SARS-COV2-10
	Xpert Xpress Strep A*	Rapid detection of Group A <i>Streptococcus</i> DNA in as soon as 18 minutes <sup>#</sup>	10	XPRSTREPA-CE-10
	Xpert Xpress Flu/RSV*	Rapid detection and differentiation of Flu A, Flu B, and RSV in as soon as 20 minutes <sup>†</sup>	10	XPRSFLU/RSV-CE-10
Healthcare- Associated Infections & Critical Infections	Xpert MRSA NxG*	Active MRSA surveillance testing in around 45 minutes <sup>#</sup>	10 120	GXM RSA-NXG-CE-10 GXM RSA-NXG-CE-120
	Xpert SA Nasal Complete*	Pre-surgical testing of <i>S. aureus</i> and MRSA in about an hour	10 120	GXSACOMP-CE-10 GXSACOMP-120
	Xpert MRSA/SA BC*	Detection of MRSA and <i>S. aureus</i> in positive blood cultures in about an hour	10	GXM RSA/SABC-CE-10
	Xpert MRSA/SA SSTI*	Detection of MRSA and <i>S. aureus</i> skin and soft tissue infections in about an hour	10	GXM RSA/SA-SSTI-CE
	Xpert Carba-R*	Detection and differentiation of KPC, NDM, VIM, IMP, and OXA-48 in 50 minutes	10 120	GXCARBAP-CE-10 GXCARBAP-CE-120
	Xpert Norovirus*	Identification and differentiation of Norovirus GI and GII in less than 1 hour <sup>#</sup>	10	GXNOV-CE-10
	Xpert <i>C. difficile</i> BT*	Detection of <i>Clostridioides difficile</i> infection with an independent call-out of binary toxin and differentiation of the 027 strain in around 45 minutes	10	GXCDIFFBT-CE-10
	Xpert vanA/vanB*	Rapid VRE screening for active outbreak prevention and control in around 45 minutes	10	GXVANA/B-CE-10
TB, Virology, & Emerging Infectious Diseases	Xpert MTB/RIF Ultra*	Detection of <i>Mycobacterium tuberculosis</i> complex and Rifampin-resistance associated mutations in less than 80 minutes	10 50	GXMTB/RIF-ULTRA-10 GXMTB/RIF-ULTRA-50
	Xpert MTB/XDR*	Detection of <i>Mycobacterium tuberculosis</i> complex and mutations associated with drug resistance towards Isoniazid, Fluoroquinolones, Second-Line Injectable Drugs and Ethionamide in less than 90 minutes, leveraging 10-color GeneXpert technology	10	GXMTB/XDR-10
	Xpert Ebola*	Detection of Ebola Zaire virus in around 90 minutes	10 50	GXEBOA-CE-10 GXEBOA-CE-50
	Xpert HBV Viral Load <sup>^</sup>	Detection and quantitation of Hepatitis B virus (HBV) in less than one hour	10	GXHBV-VL-CE-10
	Xpert HCV Viral Load <sup>^</sup>	Detection and quantitation of Hepatitis C virus (HCV) in 105 minutes	10	GXHCV-VL-CE-10
	Xpert HCV VL Fingerstick <sup>^</sup>	Detection and quantitation of Hepatitis C virus (HCV) in about an hour	10	GXHCV-FS-CE-10
	Xpert HIV-1 Qual XC <sup>^</sup>	Detection of Human Immunodeficiency Virus Type 1 (HIV-1) in around 90 minutes	10	GXHIV-QA-XC-CE-10
	Xpert HIV-1 Viral Load XC <sup>^</sup>	Detection and quantification of Human Immunodeficiency Virus type 1 (HIV-1) in around 90 minutes	10	GXHIV-VL-XC-CE-10
Sexual & Women's Health	Xpert CT/NG <sup>^</sup>	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> infections in about 90 minutes	10 120	GXCT/NGX-CE-10 GXCT/NGX-CE-120
	Xpert HPV v2	Detection of high risk Human Papillomavirus (HPV) — Identifies types HPV 16 and HPV 18/45; reports 11 other high risk types in pooled results in less than one hour	10	GXHPV2-CE-10
	Xpert Xpress GBS*	Intrapartum detection for Group B <i>Streptococcus</i> (GBS) during labor/delivery in approximately 30 minutes <sup>#</sup>	10	XPRSGBS-CE-10
	Xpert TV*	Detection of <i>Trichomonas vaginalis</i> in male and female specimens in around one hour <sup>#</sup>	10	GXTV-CE-10
	ResistancePlus® MG Flexible <sup>‡</sup>	Detection of <i>M. genitalium</i> and macrolide resistance in around two hours	10	S2A-2000410
Oncology & Human Genetics	Xpert BCR-ABL Ultra*	Standardized measurement of BCR-ABL p210 transcript levels for individuals with Chronic Myeloid Leukemia (CML) in under 2 hours	10	GXBCRABL-10
	Xpert BCR-ABL Ultra p190*	Quantitative monitoring of BCR-ABL p190 mRNA transcript levels for individuals with Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) in approximately 2.5 hours	10	GXBCRABLP190-CE-10
	Xpert NPM1 Mutation*	Quantitative monitoring of NPM1 mRNA transcript levels for individuals with Acute Myeloid Leukemia (AML) in approximately 3 hours	10	GXNPM1-CE-10
	Xpert Bladder Cancer Detection*	Detection of the presence of bladder cancer in patients with hematuria in around 90 minutes	10	GXBLAD-CD-CE-10
	Xpert Bladder Cancer Monitor*	Qualitative monitoring for recurrence in patients previously diagnosed with bladder cancer in around 90 minutes	10	GXBLAD-CM-CE-10
	Xpert Breast Cancer STRAT4*	Semi-quantitative measurement of ESR1, PGR, ERBB2, and MKi67 from FFPE invasive breast cancer tissue in 70 minutes	10	GXBCSTRAT4-CE-10
	Xpert FII & FV*	Identification of genetic risk factors for thrombosis in around 30 minutes	10	GXFII FV-10

\* This product is not under Notified Body oversight.

<sup>^</sup> This product is under Notified Body oversight.

<sup>#</sup> With Early Assay Termination (EAT) for positive results.

<sup>†</sup> With early assay termination for positive Flu or for positive RSV only. Reporting negatives and combined Flu and RSV results in 30 minutes.

<sup>‡</sup> Exclusively distributed by Cepheid under the Flexible by GeneXpert® system program.

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CE 2797 IVD

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