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## CE-IVD Xpert® Test Overview

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

# GeneXpert® System: CE-IVD Test Overview

TEST NAME	INTENDED USE SUMMARY	# TESTS / KIT	TEST RUN TIME (MIN)	TARGETED GENE SEQUENCES	SAMPLE <sup>^</sup>	SAMPLE STORAGE CONDITION	MINIMUM SOFTWARE VERSION GENEXPERT®	MINIMUM SOFTWARE VERSION INFINITY
<b>Respiratory</b>								
<b>Xpert® Xpress CoV-2/Flu/RSV plus</b>	Detection and differentiation of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV)	10	36*	10	Nasopharyngeal or Anterior nasal swab	15–30 °C for up to 48 hours (VTM, saline/eNAT) 2–8 °C up to seven days (VTM/saline) and up to six days in eNAT	4.7b or higher	6.4b or higher
<b>Xpert Xpress CoV-2 plus</b>	Detection of SARS-CoV-2 in symptomatic and asymptomatic patients	10	30*	3	Nasopharyngeal or Anterior nasal swab <sup>†</sup>	15–30 °C for up to 48 hours (VTM, Saline/eNAT), (2–8 °C) up to seven days (VTM, Saline/eNAT)	4.7b or higher	6.4b or higher
<b>Xpert Xpress Strep A</b>	Detection of <i>Streptococcus pyogenes</i> from patients with symptoms of pharyngitis	10	24*	1	Throat swab, ESwab™	15–30 °C ≤2 days 2–8 °C ≤6 days	4.7b or higher	6.4b
<b>Xpert Xpress Flu/RSV</b>	Detection and differentiation of Flu A, Flu B, and RSV	10	30*	5	Nasopharyngeal or nasal swabs	Stability in Transport Reagent: 2–30 °C up to 24 hours Stability in Transport Reagent: 2–8 °C for up to 7 days	4.6a or higher	6.4b
<b>Healthcare-Associated Infections &amp; Other Infectious Diseases</b>								
<b>Xpert MRSA NxG</b>	Detection of MRSA directly from nasal swabs in patients at risk for nasal colonization	10 / 120	70*	3	Nasal (Rayon) swab, ESwab™	15–30 °C ≤24 hours 2–8 °C ≤7 days	4.3	6.1
<b>Xpert SA Nasal Complete</b>	Detection of <i>S.aureus</i> and MRSA from nasal swabs in patients at risk for nasal colonization and pre-surgical patients	10 / 120	65	3	Nasal swab	15–30 °C ≤24 hours; 5 days at 2–8 °C	2.1	6.1
<b>Xpert MRSA/SA Blood Culture</b>	Detection of MRSA and <i>S. aureus</i> in positive blood cultures	10	62	3	50 µL positive blood culture bottle	Immediately when culture positive; 2–8 °C, 15–30 °C ≤24 hours, 2–8 °C ≤3 days at 2–8 °C	N/A	5.3
<b>Xpert MRSA/SA SSTI</b>	Detection of MRSA and <i>S. aureus</i> skin and soft tissue infections	10	62	3	Skin/wound swab	15–30 °C ≤24 hours; 5 days at 2–8 °C	1.6	6.1
<b>Xpert Carba-R</b>	Detection and differentiation of KPC, NDM, VIM, IMP-1, and OXA-48	10 / 120	50	5	Pure colonies, rectal and perirectal swab specimens	Swabs in the transport tube: 15–28 °C <5 days Fresh isolates after an incubation of 18–24 hours at 35 °C	4.3	6.1
<b>Xpert Norovirus</b>	Identification and differentiation of Norovirus GI and GII	10	88*	2	Raw or unpreserved unformed stool specimen	2–8 °C ≤2 days	4.3	6.1
<b>Xpert EV</b>	Detection of enteroviruses in CSF	10	150	1	Cerebrospinal fluid	2–8 °C ≤3 days, -20 °C ≤3 days	1.6	N/A
<b>Xpert C. difficile BT</b>	Detection of <i>Clostridioides difficile</i> and its binary toxin plus the differentiation of the 027 strain	10	43	3	Swab from unformed stool specimens	20–30 °C <24 hours, 2–8 °C <5 days	4.3	6.1
<b>Xpert vanA/vanB</b>	Detection of vancomycin-resistance ( <i>vanA-vanB</i> ) genes	10	48	2	Rectal or peri-anal swab	2–8 °C <5 days	1.6b	6.1

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<b>TB &amp; Emerging Infectious Diseases</b>								
Xpert MTB/RIF	Detection of <i>Mycobacterium tuberculosis</i> complex and Rifampin-resistance associated mutations	10 / 50	105	5	Sputum sample or concentrated sediment	≤35 °C ≤ 3 days; 2–8 °C for 7 additional days	4.3	6.0
Xpert MTB/RIF Ultra	Detection of <i>Mycobacterium tuberculosis</i> complex and Rifampin-resistance associated mutations	10 / 50	80	6	Sputum sample or concentrated sediment	≤35 °C up to 3 days; 2–8 °C for 4 to 10 days	4.7b or higher	6.4b
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	10	90	8	Sputum sample, concentrated sediment or MGIT culture	Unprocessed Sputum: 2–35 °C up to 7 days Sputum Sediment: 2–8 °C up to 7 days Specimen treated with sample reagent ≤35 °C up to 2.5 hrs, 2–8 °C up to 4 hrs	6.2 or higher	N/A
Xpert Ebola	Detection of Ebola Zaire virus	10 / 50	94	2	Venous whole blood, peripheral blood from fingerstick, buccal swab†	Reagent-treated blood samples: 2–8 °C ≤3 days; ≤28 °C ≤48 hours; ≤35 °C ≤24 hours; Reagent-treated buccal swab samples: 2–8 °C ≤72 hours; ≤28 °C ≤24 hours	4.4a	6.2
<b>Blood Virology, Women's Health, &amp; Sexual Health</b>								
Xpert CT/NG	Detection and differentiation of genomic DNA from <i>Chlamydia trachomatis</i> (CT) and/or <i>Neisseria gonorrhoeae</i> (NG)	10 / 120	88	3	Urine or swab (vaginal/ endocervical swab or pharyngeal or rectal swab)	Urine in validated transport tube — M: 2–30 °C ≤45 days; F: 2–30 °C ≤3 days; 2–15 °C ≤45 days Swab — M/F: 2–30 °C ≤60 days	4.3	6.0
Xpert HPV	Detection of high risk Human Papillomavirus (HPV) — identifies types HPV 16 and HPV 18/45; reports 11 other high risk types in a pooled result	10	56	5	Cervical specimens collected with PreservCyt solution	2–30 °C ≤6 months	4.3	6.1
Xpert GBS	Detection of <i>Group B Streptococcus</i> (GBS)	10	56	1	Both vaginal and rectal swab	Room temperature ≤24 hours; 2–8 °C ≤6 days	N/A	N/A
Xpert Xpress GBS	Detection of <i>Group B Streptococcus</i> (GBS)	10	42*	2	Both vaginal and rectal swab	Room temperature ≤24 hours; 2–8 °C ≤6 days		
Xpert TV	Detection of <i>Trichomonas vaginalis</i> (TV)	10	64*	1	Urine or vaginal/endocervical swab	Urine in validated transport tube: 2–8 °C ≤28 days (F/M); 15–30 °C ≤14 days (F/M) Swabs: 2–30 °C ≤60 days	4.3	N/A

# GeneXpert® System: CE-IVD Test Overview *(continued)*

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<b>Blood Virology, Women's Health, &amp; Sexual Health</b>								
<b>ResistancePlus® MG FleXible#</b>	Detection of <i>M. genitalium</i> and macrolide resistance	10	131	1	Male: urine, urethral and rectal swabs Female: urine, cervical, endocervical, vaginal and high vaginal swabs and rectal swabs	Urine (M/F) in Roche 06466281190: 2–8 °C ≤90 days or 15–30 °C ≤90 days URINE/A Female: 2–15 °C ≤45 days, 2–30 °C ≤3 days URINE/A Male: 2–30 °C ≤45 days Vaginal & cervical swab in SWAB/A: 2–30 °C ≤60 days M/F rectal swab in SWAB/G: 2–30 °C ≤60 days Vaginal, cervical, urethral (M/F) & rectal (M/F) swab in: Copan 306 C: 2–25 °C ≤48 hours or ≤ -70 °C ≥48 hours; Roche 06466281190: 2–8 °C ≤90 days or 15–30 °C ≤90 days	4.7b	6.4b
<b>Xpert HBV Viral Load</b>	Detection and quantitation of Hepatitis B Virus (HBV)	10	57	1	Plasma Serum	EDTA anticoagulated blood can be conserved 24 hours between 15–35 °C or 3 days between 2–8 °C; 2–8 °C, 7 days	4.7b	6.4b
<b>Xpert HCV Viral Load</b>	Detection and quantitation of Hepatitis C Virus (HCV)	10	105	1	Plasma Serum	EDTA anticoagulated blood can be conserved 24 hours between 15–35 °C or 3 days between 2–8 °C; -70 to -18 °C ≤6 weeks	4.7b	6.4b
<b>Xpert HCV VL Fingerstick</b>	Detection and quantitation of Hepatitis C Virus (HCV)	10	57	1	EDTA whole capillary blood — fingerstick EDTA whole venous blood — venipuncture	EDTA capillary blood: 5–35 °C ≤15 minutes; EDTA venous blood: -20 °C ≤6 months; 2–8 °C ≤3 days; ≤35 °C ≤24 hours	4.7b	6.4b
<b>Xpert HIV-1 Qual</b>	Detection of Human Immunodeficiency Virus Type 1 (HIV-1)	10	93	2	EDTA whole blood / Dried blood spot	EDTA whole blood 31–35 °C ≤8 hours; 15–30 °C ≤24 hours, 2–8 °C ≤3 days DBS: 31–35 °C ≤8 weeks; 2–25 °C ≤12 weeks; -15 °C ≤12 weeks	4.7b	6.4b
<b>Xpert HIV-1 Qual XC</b>	Detection of Human Immunodeficiency Virus Type 1 (HIV-1)	10	79 / 91	3	EDTA whole venous blood — venipuncture EDTA whole capillary blood — fingerstick / Heel stick DBS	EDTA venous whole blood 2–8 °C for up to 96 hours or at 2–35 °C for up to 24 hours EDTA capillary whole blood 2–35 °C for up to 60 minutes DBS: 2–25 °C or frozen at -15 °C or colder for up to 16 weeks, or 2–35 °C for up to 8 weeks	4.7b	6.4b
<b>Xpert HIV-1 Viral Load</b>	Detection and quantification of Human Immunodeficiency Virus Type 1 (HIV-1)	10	91	3	Plasma	EDTA anticoagulated blood can be conserved 24 hours between 15–35 °C or 3 days between 2–8 °C; -70 to -18 °C ≤6 weeks	4.7b	6.4b
<b>Xpert HIV-1 Viral Load XC</b>	Detection and quantification of Human Immunodeficiency Virus Type 1 (HIV-1)	10	90	3	Plasma	EDTA whole blood 2–30 °C for up to 24 hours; Plasma 2–35 °C for up to 24 hours, at 2–8 °C for up to 7 days or frozen (≤ -18 °C and ≤ -70 °C) for up to 6 weeks	4.7b	6.4b

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<b>Oncology &amp; Genetics</b>								
<b>Xpert Bladder Cancer Detection</b>	Molecular detection of the presence of bladder cancer in patients with hematuria	10	90	5	Voided Urine	Preserved Urine: 2–28 °C ≤7 days	4.7b or higher	6.4b and higher
<b>Xpert Bladder Cancer Monitor</b>	Qualitative monitoring for recurrence in patients previously diagnosed with bladder cancer	10	90	5	Voided Urine	Preserved Urine: 2–28 °C ≤7 days	4.7b or higher	6.4b and higher
<b>Xpert Breast Cancer STRAT4</b>	Semi-quantitative measurement of ESR1, PGR, ERBB2, and MKi67 from FFPE invasive breast cancer tissue	10	70	5	FFPE tissue specimens	FFPE Lysate: -80 °C, long term Scroll, in 1.5 mL tube: 2–8 °C, 14 days Slide Section: 2–8 °C, 28 days Macrodissected section(s), in 1.5 mL tube: 2–8 °C, 14 days	4.7b or higher	6.4b and higher
<b>Xpert BCR-ABL Ultra</b>	Sensitive, standardized and easy to use quantitative monitoring of BCR-ABL mRNA for chronic myeloid leukemia (CML) patients	10	105	2	4 mL whole blood	EDTA: 4 °C, 72 hours	5.1 or higher	6.6 or higher
<b>Xpert BCR-ABL Ultra p190</b>	Quantitation of BCR-ABL1 and ABL1 mRNA transcripts in peripheral blood specimens of diagnosed t(9;22) positive Chronic Myeloid Leukemia (CML) patients expressing BCR-ABL1 fusion transcripts type e13a2 and/or e14a2	10	103	2	4 ml whole blood (EDTA)	EDTA: 2–8 °C for 72 hours	6.2 or higher	N/A
<b>Xpert NPM1 Mutation</b>	Quantification of mutant NPM1 mRNA transcripts (types A, B and D in exon 12) in peripheral blood specimens from patients with acute myeloid leukemia (AML)	10	139	2	4 ml whole blood (EDTA)	EDTA: 2–8 °C for 72 hours	6.2 or higher	N/A
<b>Xpert FII &amp; FV</b>	Diagnostic genotyping test to identify risk factors for thrombosis	10	30	4	50 µL whole blood (EDTA or sodium citrate)	22–28 °C <24 hours; 2–8 °C <15 days; frozen up to 3 months	4.0	6.6

CE-IVD. Medical Devices for *In Vitro* Diagnosis. May not be available in all countries. Store all kits at room temperature except Xpert® Norovirus and Xpert® BCR-ABL Ultra (store at 2-8°C).

Xpert® tests are molecular biology tests intended for use by healthcare professionals with the GeneXpert® Systems. Carefully read the instructions in the package insert and in the systems user manual.

\* Early Assay Termination (EAT) is available for positive results.

<sup>^</sup> Please refer to the package insert for validated collection tools and/or transport media.

# Manufactured by SpeeDx and exclusively distributed by Cepheid.

† Follow WHO guidelines for transport of Ebola specimens.

‡ Asymptomatic Screening Available for sample type. Performance of Xpert **Xpress** CoV-2 **plus** for asymptomatic screening population has only been established in anterior nasal swab specimens. Specimen types other than anterior nasal swab have not been assessed and performance characteristics are unknown.

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