



CE-IVD Test Overview

Assay Name	Intended Use	Hands-On Time (Min)	Assay Run Time (Min)	ROBAL*	Targeted Gene Sequences	Kit Storage Condition	Sample	Sample Storage Condition	Minimum Software Version Required	Modules Version Required	Launch date/ CE mark
HEALTHCARE ASSOCIATED INFECTIONS											
Xpert® MRSA	Screening for MRSA	2'	69'	YES	1	RT*	Nasal swab	15-30°C < 24 hours; 5 days at 2 to 8°C	1.6	4 color	Oct. 2006
Xpert® SA Nasal Complete	Pre-surgical screening for <i>S. aureus</i> and MRSA	2'	71'	YES	3	RT	Nasal swab	15-28°C < 24 hours; 5 days at 2 to 8°C	2.1	4 color	Mar. 2009
Xpert® MRSA/SA BC	Diagnose <i>S. aureus</i> infections from positive blood cultures	2'	66'	YES	3	RT	50 µL from blood culture bottle	Immediately when culture positive; 4 hours at 2 to 8°C	1.6	4 color	Dec. 2007
Xpert® MRSA/SA SSTI	Diagnose <i>S. aureus</i> infections directly from wounds and ulcers	2'	66'	YES	3	RT	Skin/wound swab	15-30°C < 24 hours; 5 days at 2 to 8°C	1.6	4 color	Dec. 2007
Xpert® <i>C. difficile</i>	Diagnose <i>C. difficile</i> disease and determination of Q27 strain	2'	47'	YES	3	RT	Swab from unformed stool	-20°C < 5 days	2.1	4 color	Nov. 2008
Xpert® <i>vanA/vanB</i>	VRE screening	2'	47'	NO	2	RT	Rectal or peri-anal swab	5 days at 2°C to 8°C	1.6	4 color	Oct. 2008
CRITICAL INFECTIOUS DISEASE											
Xpert® MTB/RIF	Diagnose <i>M. tuberculosis</i> and its Rifampicin resistance	2'	110'	YES	5	RT	Fresh sputum or induced sputum	RT < 72 hours; 2°C-8°C 4 to 10 days	4.0	6 color	Apr. 2009
Xpert® Flu	Determination of Flu A and B infection, identification of 2009 H1N1	2'	77'	YES but one reagent to add	3	RT	Nasals aspirates or nasopharyngeal swab in 3 ml UTM	2°C-8°C < 72 hours	2.1	6 color	Dec. 2010
Xpert® EV	Diagnose Enteroviral meningitis	5'	151'	NO	1	RT	Cerebrospinal Fluid	2 to 8°C < 72 hours -20°C > 72 hours	1.6	4 color	Jun. 2006
ONCOLOGY/GENETICS											
Xpert® BCR-ABL Monitor	Rapid testing for improved CML patient management	5'	92'	NO	2	RT	200 µL whole blood (EDTA, sodium citrate or PAXgeneR RNA tubes)	2-8°C < 48 hours	4.3	4 color	Jun. 2006
Xpert® FII & FV	Diagnose factor II and factor V Leiden genetic variations associated with thrombophilia	2'	32'	YES	4	RT	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	4 color	Mar. 2012
WOMEN'S HEALTH											
Xpert® GBS	Making rapid intrapartum testing for <i>Streptococcus</i> Group B	2'	52' for a negative result, 36' to 66' for positive*	YES	1	RT	Vaginal+anal swab	15-30°C < 24 hours; 6 days at 2 to 8°C	1.6	4 color	Mar. 2006
Xpert® CT	Diagnose <i>Chlamydia trachomatis</i> (CT)	2'	95'	YES	1	RT	Urine - vaginal or endocervical swab	Urine: 2°C-15°C < 45 days (F/M); 2°C-30°C < 3 days (F); 2°C-30°C < 30 days (M). Swab: 2°C-30°C < 60 days	4.3+ New motherboard modules	6 color	Jun. 2012
Xpert® CT/NG	Diagnose <i>Chlamydia trachomatis</i> (CT) and <i>Neisseria gonorrhoeae</i> (NG)	2'	95'	YES	3	RT	Urine - vaginal or endocervical swab	Urine: 2°C-15°C < 45 days (F/M); 2°C-30°C < 3 days (F); 2°C-30°C < 30 days (M). Swab: 2°C-30°C < 60 days	4.3+ New motherboard modules	6 color	Jun. 2012

*ROBAL (Reagents on board all line); EAT: Early assay termination; RT: Room Temperature