

Xpert® Breast Cancer STRAT4

Standardized breast cancer mRNA biomarker assessment in less than two hours



The Need

Breast cancer in women is the leading cancer worldwide, with approximately 2.3 million new breast cancer cases every year.¹ Earlier diagnosis of breast cancer in a localized stage improves the 5-year relative survival rate across breast cancer subtypes.²

The European Society for Medical Oncology (ESMO) breast cancer treatment guidelines recommend testing for predictive biomarkers such as ER, PR, HER2, and Ki67 in all primary breast carcinomas to determine the treatment choice.³

Standard testing methods, such as Immunohistochemistry (IHC) and in situ hybridization (ISH), are subject to variability based on technical performance as well as subjective interpretation of results.⁴

The Impact

- Fast, clear, and accurate results by STRAT4 can help laboratories in diverse settings address various challenges with IHC/ISH testing to aid in the clinical evaluation of patients.⁶
- May facilitate a cost-efficient, quick, easy, and quality solution in labs facing challenges with IHC.⁷⁻⁹
- Enables decentralized testing that doesn't require a PCR laboratory to support breast cancer testing in low- and middle-income countries.^{6,7,9}

The Solution

The Xpert Breast Cancer STRAT4 is intended for assessment of ESR1/PGR/ERBB2/MKi67 mRNA in invasive breast cancer tissues obtained from patients and prepared as Formalin-Fixed Paraffin Embedded (FFPE) specimens, and as an aid in clinical evaluation in conjunction with other laboratory data.⁵

The test provides essential information on a tumor's estrogen receptor, progesterone receptor, HER2 and proliferation marker status based on demonstrated concordance with standard IHC/ISH tests.⁵

The STRAT4 test delivers standardized, reproducible, and reliable semi-quantitative determination of biomarker status in less than two hours with a report that allows for objective and easy result interpretation.⁵

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Xpert® Breast Cancer STRAT4

Product Reference Sheet — CE-IVD

Test Reagent Kit	Xpert Breast Cancer STRAT4		
Catalog Number	CE-IVD GXBCSTRAT4-CE-10		
Technology	Semiquantitative Real-time RT-PCR		
Targets	Four mRNA targets <i>ESR1</i> , <i>PGR</i> , <i>ERBB2</i> , <i>MKi67</i>		
Batch or On-Demand	On-demand		
Minimum Batch Size	1		
Sample Type	FFPE tissue sections or scrolls		
Sample Volume	520 µL of FFPE lysate		
Sample Extraction	Automated/integrated (following offboard lysis procedure)		
Off-board Sample Preparation Time	Approximately 50 minutes (includes hands-on time and a 30 minute incubation step)		
Assay Run Time	Approximately 70 minutes		
Internal Assay Controls	Sample Adequacy Control/ Reference Gene CYFIP1 mRNA	Probe Function/ Detection Control Probe Check Control (PCC)	RT-PCR Control CIC

Xpert Breast Cancer STRAT4 Performance vs. IHC/FISH

N=200 breast cancer specimens

	Positive Percent Agreement	Negative Percent Agreement	Overall Percent Agreement
ESR1/ER	97.2%	100%	97.5%
PGR/PR	89.0%	92.9%	89.8%
ERBB2/HER2 IHC*	100%	92.4%	93.3%
ERBB2/HER2 (Xpert vs FISH)	100%	92.0%	93.3%
ERBB2/HER2 (Xpert vs. IHC+FISH)^	100%	91.2%	92.4%
MKi67/Ki67#	88.7%	100%	90.5%

System & Software	GeneXpert Dx System GeneXpert Dx software version 4.7b or higher	GeneXpert Infinity Xpertise software version 6.4b or higher
Sample Stability	Up to 1 week when prepared lysates in Xpert® FFPE Lysis kit tubes are stored at 2–8 °C Up to 4 weeks when prepared lysates in Xpert® FFPE Lysis kit tubes are stored at ≤ -20 °C For long term storage, store at -80 °C	
Kit Storage	2–28 °C	
Additional Required Materials	Xpert FFPE Lysis Kit	Catalog Number: GXFFPE-LYSIS-CE-10
Commercial Controls	Refer to Instructions for Use (IFU) or Contact Cepheid Technical Support	

* Excludes IHC 2+ (reflexed to FISH), Negative includes 0-1+, Positive includes IHC 3+

^ All IHC 2+ cases were reflexed to FISH

Intermediate IHC (10%–20%, inclusive) were excluded

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

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