



Xpert®
Breast
Cancer
STRAT4



Xpert® Breast Cancer STRAT4

Standardized breast cancer ESR1/PGR/ERBB2/MKi67
mRNA biomarker assessment in less than two hours

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



Cepheid®
A better way.



Used in conjunction with GeneXpert® technology, Xpert® Breast Cancer STRAT4 simplifies breast cancer biomarker assessment through semi-automated sample preparation, automated RNA isolation, reverse transcription, and amplification by real-time PCR detection. The entire process happens within a patented cartridge-based system.



The Need

Breast cancer biomarker ER/PR/HER2/Ki-67 results need to be dependable and objective

- Clinicians need more reliable ER/PR/HER2/Ki-67 assessment in FFPE tumor tissues.
- 5% of HER2 IHC results are equivocal based upon guideline recommended classifications.¹
- Resolving HER2 IHC2+ equivocal results with FISH is challenging.¹⁻⁴
- Technical and observer variability can lead to approximately 20% rate of inaccurate ER and PR results.⁵
- Ki-67 IHC scores deviate due to a lack of standardization.⁶



The Solution

Xpert® Breast Cancer STRAT4 paves the way for standardized, precise and reliable ESR1/PGR/ERBB2/MKi67 mRNA assessment in less than 2 hours

- Xpert Breast Cancer STRAT4 delivers semi-quantitative determination of ESR1/PGR/ERBB2/MKi67 mRNA levels in FFPE invasive breast cancer sections
 - The CYFIP1* reference gene is used for sample normalization
 - Two integrated assay controls and one Sample Adequacy Control (SAC) in each test
 - Software report allows for objective and easy result interpretation
 - External FFPE controls[#] available for identifying errors, shifts, trends, and operator variabilities



The Impact

Xpert® Breast Cancer STRAT4 standardizes reproducible ESR1/PGR/ERBB2/MKi67 assessment

- Clear and accurate results empower oncologists.
- Enables flexibility, simplicity and random access for a streamlined workflow 24/7.
- Easy and fast test implementation.
- Internal controls meet quality management requirements.
- Robust test and workflow that doesn't require a PCR laboratory.

* CYFIP1: Cytoplasmic FMR1 interacting protein 1

For Research Use Only. Not for use in diagnostic procedure. Not reviewed by any regulatory body.



Performance

Xpert Breast Cancer STRAT4 results are highly concordant with ER/PR/Ki67 IHC and IHC/FISH (HER2)⁷

Xpert Breast Cancer STRAT4 vs. IHC

	PPA	NPA	OPA
ESR1/ER	97.2%	100%	97.5%
PGR/PR	89%	92.9%	89.8%
ERBB2/HER2 (Xpert vs 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%

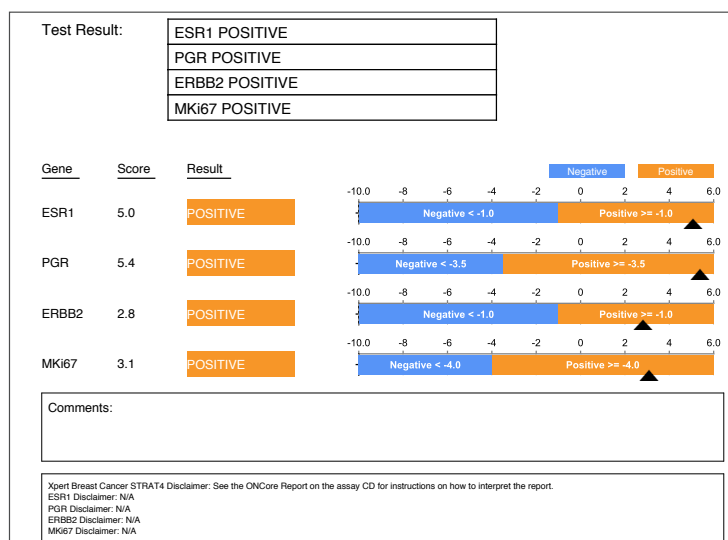
Positivity detection cutoffs of Xpert Breast Cancer STRAT4 for ESR1, PGR, ERBB2 were established to maximize concordance with IHC or IHC/ISH for each marker according to standard assay cutoffs according to ASCO-CAP, St. Gallen Consensus, and ESMO Guidelines.^{1,5,8,9}



Result Report

Software delivers binary test results and normalized gene expression scores:

- ESR1 positive correlates with IHC results $\geq 1\%$ ER positive cells
- PGR positive correlates with IHC results $\geq 1\%$ PR positive cells
- ERBB2 positive correlates with HER2 IHC 3+ and IHC 2+/FISH amplified
- MKi67 positive correlates with $> 20\%$ positive Ki67 stained cells





Workflow

Xpert® Breast Cancer STRAT4 is easy to perform and provides results in less than 2 hours



One H&E stained FFPE section is used to confirm invasive tumor area. This area is removed (scraped) from an unstained 4 µm section and placed into a lysis tube.



Add FFPE lysis reagents, add Proteinase K and heat for 30 min at 80°C. Add ethanol and vortex.



Add the lysate to GX cartridge.



Insert cartridge and start test (run time 70 minutes).

Ordering Information

CATALOG NUMBER

Xpert® FFPE Lysis Kit (10 tests)	GXFFPE-LYSIS-CE-10*
Xpert® Breast Cancer STRAT4 (10 tests)	GXBSTRAT4-CE-10*
Xpert® Breast Cancer STRAT4 FFPE Controls^ (1 set)	BCSTRAT4-BU1#
Xpert® Breast Cancer STRAT4 StartPAK containing Xpert® FFPE Lysis Kit and Xpert® Breast Cancer STRAT4 (20 tests each)	GXBCSTRAT4-SPAK1*
Xpert® Breast Cancer STRAT4 FFPE Controls (5 sets)	BCSTRAT4-BU2#

* CE-IVD. *In Vitro* Medical Device. Not available in all countries. Not available in the United States.
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^ Limited to one per customer.

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8. Coates AS et al. Tailoring therapies-improving the management of early breast cancer: St Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2015. *Ann Oncol.* 2015; 26:1533-46.
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