Cepheid®
A better way.

Standardized Breast Cancer ESR1/PGR/ERBB2/MKi67 mRNA Biomarker Assessment in Less Than Two Hours

Xpert® Breast Cancer STRAT4

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

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
- Five percent 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.

Coverage, plus
Accuracy, plus
Peace of mind

That's the **PCR***plus* advantage.
From Cepheid.

Performance

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

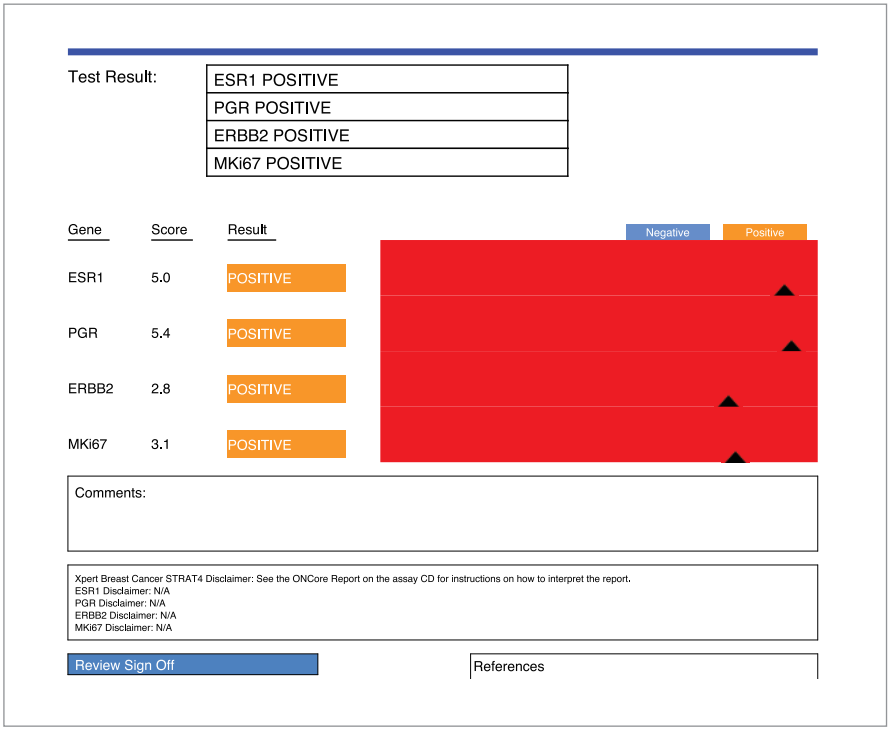
Xpert Breast Cancer STRAT4 vs. IHC	PPA	NPA	OPA
ESR1/ER	97.2%	100%	97.5%
PGR/PR	89%	92.9%	89.8%
ERBB2/HER2 (Xpert vs IHC)	100%	92.4%	93.3%
ERBB2/HER2 (Xpert vs FISH)	100%	92.0%	93.3%
ERBB2/HER2 (Xpert vs IHC+FISH)	100%	91.2%	92.4%
MKi67/Ki67	88.7%	100%	90.5%

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 ≥ 1% ER positive cells
- PGR positive correlates with IHC results ≥ 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

1

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.

2

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

3

Add the lysate to cartridge.

4

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

PN0060-02

Catalog Information

Xpert FFPE Lysis Kit	10 tests	GXFFPE-LYSIS-CE-10*
Xpert Breast Cancer STRAT4	10 tests	GXBCSTRAT4-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#

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^ Limited to one per customer.

CORPORATE HEADQUARTERS
904 Caribbean Drive
Sunnyvale, CA 94089 USA
TOLL FREE **+1.888.336.2743**
PHONE **+1.408.541.4191**
FAX **+1.408.541.4192**

EUROPEAN HEADQUARTERS
Vira Solelh
81470 Maurens-Scopont France
PHONE **+33.563.82.53.00**
FAX **+33.563.82.53.01**
EMAIL **cepheid@cepheideurope.fr**

www.**Cepheidinternational**.com

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