

PATHWAY™ HER 2

Control Slides

Cat. #: S9100
Product Data
For *In Vitro* Diagnostic Use

Lot #:
Exp. Date:

INTENDED USE/ INDICATIONS FOR USE

PATHWAY™ Her 2 Control Slides consist of formalin-fixed, paraffin-embedded cultured human breast cell lines and are intended to be used as assayed semi-quantitative quality control material in conjunction with PATHWAY™ Her 2 (Cat. # 760-2694, and 760-2174) for use in monitoring the performance of the PATHWAY™ Her 2 immunohistochemical anti c-erbB-2/Her 2 staining process on a Ventana automated immunohistochemistry staining device.

CONTRAINDICATIONS

None Known.

SUMMARY AND EXPLANATION

To monitor the performance of the automated immunohistochemistry staining assays run with PATHWAY™ Her 2, established controls such as the PATHWAY™ Her 2 Control Slides, available as an accessory to PATHWAY™ Her 2 (Cat. # 760-2694, and 760-2174), should be processed and run with all clinical specimens. The set contains five each of three controls: Level 1 Control (negative), Level 2 Control (1+ staining in >10% of the cells), and Level 3 Control (3+ staining in 100% of the cells). The Control Slides are recommended for use as controls in monitoring the performance of PATHWAY™ Her 2 staining. The recommended frequency of use of the control set is once per assay run. Any deviation from the recommended frequency of Quality Control (QC) Testing must be validated by the user laboratory. QC requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements.

PRINCIPLES OF THE PROCEDURE

Good clinical laboratory procedure dictate that the controls be used with every assay run.

PATHWAY™ Her 2 Control Slides are prepared from cultured human breast cancer cell lines. Pellets of the cultured cells are suspended in a plasma/thrombin matrix, formalin-fixed and paraffin-embedded. 4 µm sections are cut and mounted onto silanized slides.

STORAGE

Store PATHWAY™ Her 2 Control Slides at 18°C to 25°C. **Caution:** Keep slides at designated temperature. Slides stored under other conditions may not perform as expected and may compromise reliability of results.

MATERIALS PROVIDED

1. S9100-1 Level 1 Control Slide. 5 each.
2. S9100-2 Level 2 Control Slide. 5 each
3. S9100-3 Level 3 Control Slide. 5 each

The Control Slides contain formalin-fixed, paraffin-embedded cell clots that have been derived from human breast cancer tissue cell lines. The clots have been cut into 4 µm sections and placed on silanized slides. The control slides have not been baked and should be baked along with the specimen slides at 65°C ± 5°C for two hours to overnight prior to use with Pathway™ Her 2 in a staining run.

MATERIALS REQUIRED BUT NOT PROVIDED

Refer to the PATHWAY™ Her 2 Package Insert for details.

SPECIMEN PREPARATION

Refer to the PATHWAY™ Her 2 Package Insert for details. The control slides have not been baked and should be baked along with the specimen slides at 65°C ± 5°C for two hours to overnight prior to use with Pathway™ Her 2 in a staining run.

PROCEDURE

Refer to the PATHWAY™ Her 2 Package Insert for details.

1. Slides are to be processed with the test specimens following the instructions found in the PATHWAY™ Her 2 Package Insert.
2. Scoring is to be performed following the instructions found in the PATHWAY™ Her 2 Package Insert. In addition photographs of expected staining results may be found in the "Scoring Guide for the Interpretation of Ventana PATHWAY™ Her 2 Staining of Breast Carcinomas".

- Control slides should be evaluated first to ensure the staining procedure produced valid results prior to proceeding to patient specimens.

If the indicated staining, especially the 1+ staining in greater than 10% of the cells, is not evident in the Level 2 cell line control, the staining of the tissues should be repeated.

STAINING SPECIFICATIONS

The human breast cell lines used in the PATHWAY™ Her 2 Control Slides have been extensively characterized as described in the table below:

Characterization of c-erbB-2 in Cell Line Controls

Control Slide:	Cell Line:	Gene Copy # (Avg.)	Receptor #	IHC Staining Intensity	% Cells Staining
Level 1	MDA-MB-468	2.5	8.45E+04	0	100%
Level 2	T-47D	4.8	1.13E+05	1+	>10%
Level 3	SK-BR-3	17	2.02E+05	3+	100%

The control slides were evaluated for gene copy number using Ventana INFORM™ Her-2/neu.

The procedure used for Scatchard analysis of the cells for receptor content was a saturation binding assay that utilized a monoclonal antibody specific for the external domain of c-erbB-2 antigen and a secondary antibody labeled with a fluorescent marker for visualization.

The procedure used for preparing the slides stained with PATHWAY™ Her 2 included pretreatment of the slides using microwave antigen enhancement in an acidic buffer. Slides were then stained using a protocol consisting of a 32 minute incubation of the primary antibody (PATHWAY™ Her 2 or negative IgG reagent), Ventana's Basic DAB detection kit and counterstaining with hematoxylin and bluing reagent.

For an assay run to be considered valid, the Control Slides must stain appropriately. The cell membrane should be evaluated as follows:

S9100-1 Level 1 Control Slides:
100% of the cells should be negative—no cell membrane staining.

S9100-2 Level 2 Control Slides:
>10% of the cells should exhibit 1+ (partial membrane) staining.

S9100-3 Level 3 Control Slides:
100% of the cells should exhibit 3+ staining (intense full ring membrane staining).

QC Approval/Date: _____

WARNINGS/PRECAUTIONS

- For In Vitro Diagnostic Use.
- Keep all control slides at designated temperature. Slides stored under other conditions may not perform as expected and may compromise reliability of results.
- Good clinical laboratory procedures should be observed when performing the test including, but not limited to, adherence to the procedures, equipment, and material specifications provided in the PATHWAY™ Her 2 Package Insert.
- Strict adherence to the provided scoring criteria is required to assure proper performance of the test.
- Use universal precautions when handling specimens of human origin.

PERFORMANCE CHARACTERISTICS

Refer to the PATHWAY™ Her 2 Package Insert for details.

LIMITATIONS

The Control Slides are to be used with Ventana PATHWAY™ Her 2 to monitor the performance of the automated immunohistochemistry staining assays. These cell lines may have been fixed or processed differently from the test specimen and as such provides control for all reagents and method steps except fixation and tissue processing.

BIBLIOGRAPHY

Refer to the PATHWAY™ Her 2 Package Insert.

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