



Certificate of Analysis

Product name

VENTANA PTEN (SP218)

Material No.

07970200001

Lot No.

J28539

Date of Manufacturing

2022-11-17

Expiry Date

2024-11-16

Parameter**Result****Unit**

Final Acceptance Testing

Pass

PTEN Positive and PTEN Negative tissue

The test batch must score greater than or equal to 1.0 in normal internal control staining elements of qualified prostate adenocarcinoma

The test batch must score 0.0 for the specific cytoplasmic staining on greater than or equal to 50% of the viable malignant cells of qualified PTEN Loss prostate adenocarcinoma

The test batch must score greater than or equal to 1.0 for the specific cytoplasmic staining on greater than 50% of the viable malignant cells of qualified PTEN Intact prostate adenocarcinoma

The specific stain intensity must be within 0.5 pt. of the reference batch for all tissues

The background intensity must be less than or equal to 0.5

The intensity of the negative reagent control slide must be less than 0.5

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Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

Visual Inspection

Pass

Reagent must be clear, and free of turbidity.

Reagent must be free of foreign material and substantially free of intrinsic particulate matter.

This lot meets our specification

Disposition by

Ken Eblen

This certificate is a computer printout and has therefore not been signed by hand.

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