



Certificate of Analysis

Product name

VENTANA PTEN (SP218)

Material No.

07970200001

Lot No.

E04146

Date of Manufacturing

2018-02-19

Expiry Date

2020-02-18

Parameter**Result****Unit**

Functional Staining

Pass

PTEN Positive and PTEN Negative tissue.

The test batch must score 2 or greater on normal pancreas control tissue

The test batch must score less than 1 for the specific staining on the qualified PTEN negative prostate carcinoma

The specific stain intensity must be within 0.5 pt. of the reference batch for PTEN positive tissue

The background intensity must be 0.5 or less

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

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

Issue date 2018-03-14

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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

Whitney Croft

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

Issue date 2018-03-14

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