

Certificate of Analysis

**Product Name**

VENTANA ANTI-P63 (4A4)

Material No.

05867061001

Lot No.

H33778

Date of Manufacturing

02-DEC-2021

Expiry Date

2023/12/01

Parameter**Result****Unit**

Visual Inspection

Pass

Reagent must be clear of foreign material and particulate matter, and free of turbidity.

Functional Staining

Pass

Tonsil and Prostate Carcinoma Tissues

For specific stain intensity, the test batch and reference batch must score 3.0 or greater in squamous epithelial cells of the tonsil tissue and 3.0 or greater in normal cells of the prostate carcinoma tissue.

The neoplastic cells of the prostate carcinoma tissue are used as an intra-tissue control, and specific stain intensity must be less than or equal to 0.5.

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

The background intensity must be 0.5 or less on both tissues for the test batch and reference batch.

The background intensity of the negative reagent control on both tissues must be 0.5 or less.

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL.



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This lot meets all specifications

Disposition by

JOSHUA BURGETTE

Issue date

15/Dec/2021