



Certificate of Analysis

Product name

CD117(EP10) Rabbit Monoclonal PAB

Material No.

08763909001

Lot No.

N10170

Date of Manufacturing

2025-05-27

Expiry Date

2027-05-26

Parameter**Result****Unit**

Functional Staining

Pass

For all tissues, anti-CD117 (EP10) Rabbit Monoclonal Primary Antibody should demonstrate cytoplasmic and/or membrane staining in the cells expected to be positive (neoplastic cells, stromal mast cells, or interstitial cells of Cajal). Punctate perinuclear Golgi staining in tumor may also be present.

One CD117 positive GIST reference and test tissue must have stain intensity of 2.5 - 3 within the tumor cells.

Seminoma reference tissue used should range from 1.5 - 2.5 in average stain intensity of tumor cells. The test tissue must stain with 0.5 points of the reference.

One normal appendix (reference and test tissue) should have stain intensity in both interstitial cells of Cajal in the muscularis propria and mast cells in muscularis propria, lamina propria and submucosa of 2 - 3. Weak cytoplasmic and/or membrane staining of mucosal glandular cells, if present, must be less than or equal to 0.75 in both test and reference (average overall intensity of all glandular cells).

Background staining must be less than or equal to 0.5. In addition, stain intensity of specific cell/cell components expected to be negative (smooth muscle and lymphocytes) must be less than or equal to 0.5.

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Ventana Medical Systems, Inc.
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Tucson, Arizona 85755
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<http://www.ventana.com>



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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

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

Antonio Reyes

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

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