



Certificate of Analysis

Product name

MSH2 (G219-1129) Mouse Monoclonal PAB US

Material No.

07862253001

Lot No.

G03097

Date of Manufacturing

2020-02-17

Expiry Date

2022-02-16

Parameter**Result****Unit**

Performance Test

Pass

Positive colorectal carcinoma and tonsil

The test batch must demonstrate specific staining in the nuclei of viable tumor cells and internal positive control cells (lymphocytes or fibroblasts or normal colonic epithelium) of 3.0 or higher on a 0-4 scale in colorectal carcinoma tissue.

The test batch must demonstrate specific stain intensity of 3.0 point or higher on a 0-4 scale in nuclei of the germinal center and shall mostly demonstrate specific stain intensity of 3.0 point in the mantle zone and interfollicular region of the tonsil.

The specific stain intensity must also be within 0.5 pt. of the reference batch for a passing result

The background intensity must be equal to or less than 0.5 point on a 0-4 scale.

The intensity of the negative reagent control slide must be 0.5 point or less on a 0-4 scale

Identity Test

Pass

Issue date 2020-03-04

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Ventana Medical Systems, Inc.
1910 Innovation Park Drive
Tucson, Arizona 85755
Phone: + 1 520 887 2155
<http://www.ventana.com>



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Parameter**Result****Unit**

Positive Staining: Unequivocal nuclear staining in 80% or greater of cells with greater than 0.5 stain intensity.

Negative Staining: Absence of unequivocal nuclear staining with an overall average stain intensity of less than or equal to 0.5.

The test batch must produce the same pos/neg results as the reference batch for a passing result.

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

Mia Cazares

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