



Certificate of Analysis

Product name

VENTANA MET (SP44) RxDx Assay PMA

Material No.

08866856001

Lot No.

N21548

Date of Manufacturing

2025-09-22

Expiry Date

2027-09-21

Parameter**Result****Unit**

Gyrolab Analytic Testing

Pass

The % Relative Activity (% RA) must be within specification

Functional Staining

Pass

Non-Small Cell Lung Carcinoma (NSCLC)
Normal Gallbladder

The test and reference batch of VENTANA MET (SP44) RxDx Assay must have a non-specific staining intensity of 0.5 or less on all NSCLC tissue.

Weak NSCLC specific staining intensity must be 0.5 or greater and less than or equal to 1.75. Moderate NSCLC specific staining intensity must be 1.75 or greater and less than or equal to 3.0.

The reference and test batch of VENTANA MET (SP44) RxDx Assay must give acceptable staining in normal gallbladder with a non-specific staining intensity of 0.5 or less. Specific staining intensity must be 1.5 or greater and less than or equal to 2.5.

The test batch specific stain intensity must be within 0.5 of the reference batch on all tissues for a passing result.

Issue date 2025-10-10

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Ventana Medical Systems, Inc.
1910 Innovation Park Drive
Tucson, Arizona 85755
Phone: + 1 800 227 2155
<http://www.ventana.com>



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Parameter**Result****Unit**

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

Visual Inspection

Pass

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

Visual Inspection

Pass

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

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

This lot meets our specification

Disposition by

Lupe Villarreal

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

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