Certificate of Analysis

Product name
VENTANA MET (SP44) RxDx Assay PMA

Material No.
08866856001

Lot No.	Date of Manufacturing	Expiry Date
P01161	2026-02-23	2028-02-18

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 2026-03-23

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		
Bioburden Visible bacterial colonies must be 100 or less CFU/mL	Pass	

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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