



Certificate of Analysis

Product name

VENTANA MET (SP44) RxDx Assay

Material No.

08866856001

Lot No. H18571Z**Date of Manufacturing:** 08-Jul-2021**Expiry Date** 2023-07-07

Parameter	Result	Unit
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Visual Inspection	Pass	
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Reagent must be free of foreign material and substantially free of particulate matter

Reagent must be clear and free of turbidity

Gyrolab Analytic Testing	Pass	
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The relative activity (%RA) value must meet the criteria outlined in OP4100-479.

Final Acceptance Testing / Intensity	Pass	
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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/strong 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.

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

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

This lot meets our specification.

Disposition by

ANTONIO REYES

Issue date

23-Aug-2021