



Certificate of Analysis

Product name

VENTANA MET (SP44) RxDx Assay

Material No.

08866856001

Lot No.

H18573Z

Date of Manufacturing

2021-08-04

Expiry Date

2023-08-03

Parameter**Result****Unit**

Visual Inspection

Pass

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

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

Final Acceptance Testing / Intensity

Pass

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

Visible bacterial colonies must be 100 or less CFU/mL

This lot meets our specification.

Disposition by

KEN EBLEN Ken Eble

Issue date

24 / JAN / 2024