



Certificate of Analysis

Product name

VENTANA CLDN18 (43-14A) Assay

Material No.

08504148001

Lot No.

K02360

Date of Manufacturing

2023-02-21

Expiry Date

2025-02-20

Parameter**Result****Unit**

Gyrolab Relative Activity Acceptability

Pass

The relative activity (%RA) value must be within 50% to 200% Relative Activity

Functional Staining

Pass

Tissue Type: CLDN18 qualified gastric or GEJ adenocarcinoma tissue and qualified gastric tissue with intestinal metaplasia.

For CLDN18 qualified gastric or GEJ adenocarcinoma tissue, the test and reference batch must demonstrate 40 to 80% tumor staining with specific stain intensity more than or equal to 2 (score 2-3), and the test batch specific stain intensity must be within 0.5 pt. of the reference batch. The % tumor staining must be within 10% between the test and reference batches.

For CLDN18 qualified gastric tissue with intestinal metaplasia, the test batch specific stain intensity is within 0.5 pt. of the reference batch. The normal gastric epithelia demonstrates a stain intensity of 3 and a stain intensity of 1 to 2 on intestinal metaplasia.

The test and reference batch background is 0.5 or less on both CLDN18 qualified tissues as described above.

Issue date 2023-03-09

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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 is 0.5 or less.

Functional Staining

Pass

Tissue Type: CLDN18 qualified gastric or GEJ adenocarcinoma tissue and qualified gastric tissue with intestinal metaplasia.

For CLDN18 qualified gastric or GEJ adenocarcinoma tissue, the test and reference batch must demonstrate 40 to 80% tumor staining with specific stain intensity more than or equal to 2 (score 2-3), and the test batch specific stain intensity must be within 0.5 pt. of the reference batch. The % tumor staining must be within 10% between the test and reference batches.

For CLDN18 qualified gastric tissue with intestinal metaplasia, the test batch specific stain intensity is within 0.5 pt. of the reference batch. The normal gastric epithelia demonstrates a stain intensity of 3 and a stain intensity of 1 to 2 on intestinal metaplasia.

The test and reference batch background is 0.5 or less on both CLDN18 qualified tissues as described above.

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Parameter**Result****Unit**

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

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

Joshua Burgette

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

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