



# Certificate of Analysis

**Product name**

VENTANA DLL3 (SP347) Assay

**Material No.**

08416931001

**Lot No.**

J28623

**Date of Manufacturing**

2022-11-10

**Expiry Date**

2023-11-09

**Parameter****Result****Unit**

Final Acceptance Testing

Pass

Small cell lung cancer (SCLC)

The test and reference batches must demonstrate heterogeneous staining with average specific stain intensity greater than or equal to 2 and greater than 35% tumor cell staining on the SCLC tissue with mid to high % DLL3 staining.

The test and reference batches must demonstrate less than 15% DLL3 tumor cell staining on the SCLC tissue with low % DLL3 staining.

The test batch must demonstrate DLL3 (SP347) stain intensity within 0.5pt of the reference batch on the SCLC tissue with mid to high % DLL3 staining and the SCLC tissue with low % DLL3 staining.

The test batch of DLL3 (SP347) shall demonstrate acceptable background staining of 0.5pt or less.

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

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

**Issue date** 2022-12-14

Page 1 of 2



# Certificate of Analysis

**Product name**

VENTANA DLL3 (SP347) Assay

**Material No.**

08416931001

**Lot No.**

J28623

**Date of Manufacturing**

2022-11-10

**Expiry Date**

2023-11-09

**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

This lot meets our specification

**Disposition by**

Nic Hau

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

**Issue date** 2022-12-14

Page 2 of 2

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