



# Certificate of Analysis

**Product name**

PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONO

**Material No.**

05278368001

**Lot No.**

K11348

**Date of Manufacturing**

2023-06-20

**Expiry Date**

2024-11-30

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

Visual Inspection

Pass

Reagent must be clear of foreign material and particulate matter, and free of turbidity.

Functional Staining

Pass

Breast Carcinoma Tissue

Gastric Carcinoma Tissue

Qualified 4 in 1 Cell Line Controls

The specific staining of the test batch must be acceptable on all tissues and cell line cores.

The test batch background intensity must not exceed 0.5 pt. on any tissue or cell line core.

All tissues and cell line cores stained with the negative control reagent must be negative for specific staining.

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

This lot meets our specification

**Disposition by****Issue date** 2023-07-06

Page 1 of 2

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



# Certificate of Analysis

**Product name**

PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONO

**Material No.**

05278368001

**Lot No.**

K11348

**Date of Manufacturing**

2023-06-20

**Expiry Date**

2024-11-30

Antonio Reyes

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

**Issue date** 2023-07-06

Page 2 of 2

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