



Certificate of Analysis

Product name

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

Material No.

05278368001

Lot No.

G03395M

Date of Manufacturing

2020-02-25

Expiry Date

2021-08-19

Parameter**Result****Unit**

Final Acceptance Testing

Pass

Breast Carcinoma Tissue, Gastric Carcinoma Tissue, and 4 in 1 Cell Lines.

The specific staining of the test batch must be acceptable on all tissues and cell line cores using both the iView DAB IHC and the ultraView DAB IHC detection kits.

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

Visual Inspection

Pass

Reagent must be free of foreign material and substantially free of particulate matter

Reagent must be clear and free of turbidity

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

Issue date 2020-03-23

Page 1 of 2



Certificate of Analysis

Product name

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

Material No.

05278368001

Lot No.

G03395M

Date of Manufacturing

2020-02-25

Expiry Date

2021-08-19

This lot meets our specification

Disposition by

Amanda Cabrera

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

Issue date 2020-03-23

Page 2 of 2

Ventana Medical Systems, Inc.
1910 Innovation Park Drive
Tucson, Arizona 85755
Phone: + 1 520 887 2155
<http://www.ventana.com>