



Document Number  
Form 7.5-58-3

Title  
Certificate of Analysis - Ventana

| Authoring Site   | Document Type – Subtype | Document Security |
|--|-------------------------|-------------------|
| Rocklin, CA  | Procedural – Form       | N/A               |
| Referenced Documents                                   |                         | Special Notes     |
| 1. WI 7.5-58 Releasing Finished Goods Inventory in SAP |                         | N/A               |

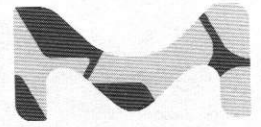
## Certificate of Analysis

**Product Name:** E-Cadherin (EP700Y) Rabbit Monoclonal Antibody  
**Product Number:** 760-4440  
**Roche Number:** 05973872001  
**Batch Number:** V0003063  
**Storage Temperature:** 2°C - 8°C  
**Expiration Date:** 2024-10-31  
**Quality Release Date:** 2022-01-19  
**Date of Manufacture:** 2021-11-29

| Test   | Specification                    | Result                           |
|--|----------------------------------|----------------------------------|
| Appearance (Turbidity)   | Free of Visible Foreign Material | Free of Visible Foreign Material |
| Appearance (Color)   | Green Transparent                | Green Transparent                |
| Appearance (Form)  | Liquid                           | Liquid                           |
| IHC Staining<br>Intensity difference between sample and a reference must be less than or equal to 0.5  | Pass                             | Pass                             |
| IHC Staining<br>Background difference between sample and a reference must be less than or equal to 0.5 | Pass                             | Pass                             |
| IHC – Tissue   | Tissue Type                      | Breast                           |
| Elisa Titer  | 0.20 – 2.00 µg/mL                | 0.96 µg/mL                       |
| Bioburden<br>Visible bacterial colonies must be less than 100 CFU/mL                                   | Pass                             | Pass                             |
| Source   | Supernatant                      | Supernatant                      |

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*J. H. Harris* 24 JAN 2022

Quality Assurance  
Rocklin, California  
US

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**REVISION SHEET**

| <b>Date</b> | <b>Version</b> | <b>Nature of Changes</b>  | <b>Changed By</b> |
|-------------|----------------|---|-------------------|
| 12/5/18     | 1.0            | Initial Release   | Chris Kaneshiro   |
| 1/24/19     | 2.0            | Add IHC background staining pass criteria   | Chris Kaneshiro   |
| 24Nov2021   | 3.0            | Administrative change to update periodic review property from 1 year to 3 years and updated to most current template. | Wesley Levin      |

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