



Document Number
Form 7.5-58-3

Title
Certificate of Analysis - Ventana

Authoring Site Rocklin, CA	Document Type – Subtype Procedural – Form	Document Security 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: V0003603
Storage Temperature: 2°C - 8°C
Expiration Date: 2025-03-31
Quality Release Date: 2022-10-27
Date of Manufacture: 2022-04-27

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	Pass	Pass
Intensity difference between sample and a reference must be less than or equal to 0.5		
IHC Staining	Pass	Pass
Background difference between sample and a reference must be less than or equal to 0.5		
IHC – Tissue	Tissue Type	Breast
Elisa Titer	0.20 – 2.00 µg/mL	0.88 µg/mL
Bioburden	Pass	Pass
Visible bacterial colonies must be less than 100 CFU/mL		
Source	Supernatant	Supernatant

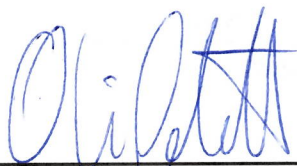
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Quality Assurance
Rocklin, California
US

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REVISION SHEET

Date	Version	Nature of Changes	Changed By
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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