



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: GCDFP-15 (EP1582Y) Rabbit Monoclonal Antibody
Product Number: 760-4386
Roche Number: 05463530001
Batch Number: V0003018
Storage Temperature: 2°C - 8°C
Expiration Date: 2023-12-31
Quality Release Date: 2022-01-04
Date of Manufacture: 2021-02-05

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 Intensity difference between sample and a reference must be less than or equal to 0.5	Pass	Pass
IHC Staining 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	0.01 – 1.00 µg/mL	0.32 µg/mL
Bioburden Visible bacterial colonies must be less than 100 CFU/mL	Pass	Pass
Source	Supernatant	Supernatant

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 04 JAN 2022

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

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