



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:** V0003519  
**Storage Temperature:** 2°C - 8°C  
**Expiration Date:** 2025-07-31  
**Quality Release Date:** 2022-09-27  
**Date of Manufacture:** 2022-08-04

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	0.28 µg/mL
Bioburden Visible bacterial colonies must be less than 100 CFU/mL	Pass	Pass
Source	Supernatant	Supernatant

**NOTICE:** This document is proprietary and its contents are the exclusive property of Merck KGaA and its affiliates. This document may not be reproduced in any form whatsoever, without prior written permission from Quality Assurance Department of the life science business of Merck.  
 Template Document Number: 20460388, 1.0



Document Number

Form 7.5-58-3

Title

Certificate of Analysis - Ventana

29 SEP 2022

Quality Assurance  
Rocklin, California  
US

Cell Marque™ (a Sigma-Aldrich Company) warrants, that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. For further inquiries, please contact Technical/Customer Service. Purchase must determine the suitability of the product for its particular use. See website or packaging slip for additional terms and conditions of sale.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact [misbranding@sial.com](mailto:misbranding@sial.com)

**NOTICE:** This document is proprietary and its contents are the exclusive property of Merck KGaA and its affiliates. This document may not be reproduced in any form whatsoever, without prior written permission from Quality Assurance Department of the life science business of Merck.

Template Document Number: 20460388, 1.0



Document Number  
Form 7.5-58-3

Title  
Certificate of Analysis - Ventana

### 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

**NOTICE:** This document is proprietary and its contents are the exclusive property of Merck KGaA and its affiliates. This document may not be reproduced in any form whatsoever, without prior written permission from Quality Assurance Department of the life science business of Merck.

Template Document Number: 20460388, 1.0

