

**Document Number**  
Form 7.5-58-3



**Title**  
Certificate of Analysis - Ventana

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

### Certificate of Analysis

**Product Name:** CD16 (SP175) Rabbit Monoclonal Primary Antibody  
**Product Number:** 760-4863  
**Roche Number:** 07047681001  
**Batch Number:** V0002414  
**Storage Temperature:** 2°C - 8°C  
**Expiration Date:** 2023-03-31  
**Quality Release Date:** 2020-12-10  
**Date of Manufacture:** 2020-04-16

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	Tonsil
Elisa Titer	1 – 10 µg/mL	3 µg/mL
Bioburden Visible bacterial colonies must be less than 100 CFU/mL	Pass	Pass
Source	Supernatant	Supernatant

*Patrick Stralber* 12/10/2020

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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

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