



# Certificate of Analysis

Abbott GmbH  
Max-Planck Ring 2  
65205 Wiesbaden  
Germany

**Product Name:** Alinity i HAVAb IgG Reagent Kit (2 x 100 tests)  
**List Number:** 08P2622 **SCP/Revision:** 08P26-49 / 04B  
**Lot Number:** 37306BE00 **Assay Software Version:** 286\_002  
**Expiration Date:** 2023-02-04 **Test Date:** 2022-04-05  
**Lot Size:** 5195

Component Name	List Number	Lot Number	Production Date	Expiration Date
Alinity i HAVAB IgG Microparticle	8P26G01	37310BE00	2022-02-12	2023-02-12
Alinity i HAVAB IgG Conjugate	8P26H01	37311BE00	2022-02-04	2023-02-04
Alinity i HAVAB IgG Assay Diluent	8P26J01	37312BE00	2022-03-18	2023-03-18

Acceptance Criteria		Specifications	Result	Pass
Negative Control	Grand Mean S/CO	$\leq 0.32$	0.18	X
Positive Control	Grand Mean S/CO	1.65 – 2.62	2.16	X

This product has been manufactured, including packaging and quality control in full compliance with ISO 13485:2016 and GMP guidelines as applicable.

The specifications in this certificate reflect the internal Abbott release specifications. When performing the assay in a laboratory the specifications listed in the package insert apply.

Quality Assurance (QA):

J. Kroll

Date:

2022-04-07