



Certificate of Analysis

Abbott GmbH
Max-Planck Ring 2
65205 Wiesbaden
Germany

Product Name: Alinity i HAVAb IgG Reagent Kit (2 x 500 tests)
List Number: 08P2632 **SCP/Revision:** 08P26-49 / 04B
Lot Number: 37307BE00 **Assay Software Version:** 286_002
Expiration Date: 2023-02-04 **Test Date:** 2022-04-05
Lot Size: 455

Component Name	List Number	Lot Number	Production Date	Expiration Date
Alinity i HAVAB IgG Microparticle	8P26G05	37313BE00	2022-02-12	2023-02-12
Alinity i HAVAB IgG Conjugate	8P26H05	37314BE00	2022-02-04	2023-02-04
Alinity i HAVAB IgG Assay Diluent	8P26J05	37315BE00	2022-03-18	2023-03-18

Acceptance Criteria		Specifications	Result	Pass
Negative Control	Grand Mean S/CO	≤ 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): N. Schubert N. Leht Date: 06. Apr. 2022