



# Certificate of Analysis

Abbott Ireland Diagnostics Division,  
Lisnamuck,  
Longford,  
Co. Longford,  
Ireland

**Product Name:** Alinity i 25-OH Vitamin D Reagent Kit

List number: 08P4522

SCP / revision

8P450022/003

Lot number: 37241UD00

Reagent Lot Number: 37241UD00

Expiry Date: 2023-04-27

Component name	List Number	Lot Number	Production date	Expiry date
Alinity i Vit D 25OH Microparticles	8P45G	37236UD00	2022-01-27	2023-04-27
Alinity i Vit D 25OH Conjugate	8P45H	37237UD00	2022-01-27	2023-04-27
Alinity i Vit D 25OH Assay Diluent	8P45J	37239UD00	2022-01-31	2023-04-30

### Acceptance Table: Mean Reported Results (ng/mL)

Description	Lower Limit	Upper Limit	Value	Result
REF Control Low	18.0	22.0	20.3	Acceptable
REF Control Medium	36.0	44.0	40.4	Acceptable
REF Control High	67.5	82.5	76.0	Acceptable

This product has been manufactured, including packaging and quality control in full compliance with ISO 13485, IVD Directive 98/79/EC and GMP guidelines as applicable.

Note: 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:

*Martinus Evers* *Lotman* Date: 10 Feb 23  
Printed name and signature