



# Certificate of Analysis

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

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

List number: 08P4532

Lot number: 37612UD00

Reagent Lot Number: 37612UD00

Expiry Date: 2023-05-22

SCP / revision

8P450032/003

| Component name                      | List Number | Lot Number | Production date | Expiry date |
|-------------------------------------|-------------|------------|-----------------|-------------|
| Alinity i Vit D 25OH Microparticles | 8P45G       | 37609UD00  | 2022-02-23      | 2023-05-23  |
| Alinity i Vit D 25OH Conjugate      | 8P45H       | 37610UD00  | 2022-02-22      | 2023-05-22  |
| Alinity i Vit D 25OH Assay Diluent  | 8P45J       | 37611UD00  | 2022-02-23      | 2023-05-23  |

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

| Description        | Lower Limit | Upper Limit | Value | Result     |
|--------------------|-------------|-------------|-------|------------|
| REF Control Low    | 18.0        | 22.0        | 20.5  | Acceptable |
| REF Control Medium | 36.0        | 44.0        | 40.1  | Acceptable |
| REF Control High   | 67.5        | 82.5        | 76.7  | 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:

Date:

Caroline Hayes C. Hayes  
Printed name and signature

24 MAR 2022