



# Certificate of Analysis

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

**Product Name:** ARCHITECT Prolactin Reagent Kit

List number: 7K76-35

Lot number: 37159UD01

Reagent Lot number: 37159UD00

Expiry Date: 2023-02-16

SCP / revision

7K760035/001

| Component name                     | List Number | Lot Number | Production date | Expiry date |
|------------------------------------|-------------|------------|-----------------|-------------|
| ARCHITECT Prolactin Microparticles | 7K76G       | 37157UD00  | 2022-03-03      | 2023-03-03  |
| ARCHITECT Prolactin Conjugate      | 7K76H       | 37158UD00  | 2022-02-16      | 2023-02-16  |

## Acceptance Table: Grand Mean Conc (ng/mL) over 3 instruments

| Description              | Lower Limit | Upper Limit | Value | Result     |
|--------------------------|-------------|-------------|-------|------------|
| REF Control Low (n=3)    | 7.0         | 9.0         | 8.1   | Acceptable |
| REF Control Medium (n=3) | 17.2        | 22.6        | 20.6  | Acceptable |
| REF Control High (n=3)   | 34.9        | 44.0        | 40.9  | Acceptable |
| REF Panel Low (n=3)      | 7.0         | 9.9         | 8.7   | Acceptable |
| REF Panel Medium (n=3)   | 14.2        | 20.0        | 18.5  | Acceptable |
| REF Panel High (n=3)     | 75.5        | 106.5       | 94.7  | 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:

*MACIEJ SOBIEZYK* *Maciej Sobiezyk*  
Printed name and signature

Date:

*15 Apr 22*