



# Certificate of Analysis

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

**Product Name:** Architect Prolactin Reagent Kit

List number: 7K76-30

Lot number: 37159UD00

Reagent Lot number: 37159UD00

Expiry Date: 2023-02-16

SCP / revision

7K760030/004

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 SOBIECZYK Maciej  
Printed name and signature

Date:

15 Apr 22