



Certificate of Analysis

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

Product Name: Architect Prolactin Calibrators

List number: 7K76-01
 Lot number: 38219UD00
 Expiry Date: 2023-03-01

SCP / revision 7K760001/009

Component name	List Number	Lot Number	Production date	Expiry date
Architect Prolactin Calibrator 1	7K76V	38217UD00	2022-03-01	2023-03-01
Architect Prolactin Calibrator 2	7K76W	38218UD00	2022-03-01	2023-03-01

Acceptance Table: Grand Mean Conc. (ng/mL) over 2 instruments

Description	Lower Limit	Upper Limit	Value	Result
REF Control Low (n=2)	7.0	8.8	8.1	Acceptable
REF Control Medium (n=2)	17.5	21.4	20.8	Acceptable
REF Control High (n=2)	35.6	44.4	42.4	Acceptable
REF Panel Low (n=2)	7.0	9.3	7.8	Acceptable
REF Panel Medium (n=2)	15.7	21.7	17.6	Acceptable
REF Panel High (n=2)	75.5	106.5	88.6	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:

CARMA FARRHC F ECOVERLY
Printed name and signature

06 Apr 22