



Certificate of Analysis

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

Product Name: Alinity i Prolactin Calibrators

List number: 07P6601

Lot number: 36051UD00

Expiry Date: 2023-01-17

SCP / revision

7P660001/003

Component name	List Number	Lot Number	Production date	Expiry date
Alinity i Prolactin CAL 1	7P66V	36049UD00	2022-01-17	2023-01-17
Alinity i Prolactin CAL 2	7P66W	36050UD00	2022-01-24	2023-01-24

Acceptance Table: Grand Mean Reported Result (ng/mL) (SMP Calibration Curve)

Description	Lower Limit	Upper Limit	Value	Result
Control Low (Target = 8ng/mL)	7.10	8.80	8.16	Acceptable
Control Medium (Target = 20ng/mL)	17.50	20.92	20.34	Acceptable
Control High (Target = 40ng/mL)	35.60	43.80	40.68	Acceptable
Panel Low (Target = 8ng/mL)	6.6	8.8	8.2	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 SOBIECH Maj Sa/h
Printed name and signature

Date:

14 Feb 22