



Certificate of Analysis

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

Product Name: Alinity i Prolactin Reagent Kit

List number: 07P6620

Lot number: 35293UD00

Reagent Lot number: 35293UD00

Expiry Date: 2022-12-29

SCP / revision

7P660020/004

Component name	List Number	Lot Number	Production date	Expiry date
Alinity i Prolactin Microparticles	7P66G	35291UD00	2021-12-29	2022-12-29
Alinity i Prolactin Conjugate	7P66H	35292UD00	2022-01-07	2023-01-07

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

Description	Lower Limit	Upper Limit	Value	Result
REF Control Low	7.00	8.80	8.33	Acceptable
REF Control Medium	17.40	22.00	20.77	Acceptable
REF Control High	35.20	43.49	40.79	Acceptable
REF Panel Low	7.2	10.1	8.4	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:

Caroline Hayes C. Hayes
Printed name and signature

Date:

07 Feb 2022

