



Certificate of Analysis

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

Product Name: Architect Prolactin Reagent Kit

List number: 7K76-25

Lot number: 39524UD00

Reagent Lot number: 39524UD00

Expiry Date: 2023-02-16

SCP / revision

7K760025/009

Component name	List Number	Lot Number	Production date	Expiry date
Architect Prolactin Microparticles	7K76G	39522UD00	2022-03-03	2023-03-03
Architect Prolactin Conjugate	7K76H	39523UD00	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	20.4	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)	15.7	22.2	19.7	Acceptable
REF Panel High (n=3)	75.5	106.5	93.3	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:

MAIEJ SORCZYK Maij Sorkczyk
Printed name and signature

Date:

04 Apr 22