Certificate of Analysis

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

Product Name: Architect Prolactin Controls

List number: 7K76-10
Lot number: 36183UD00
Expiry Date: 2023-01-05

Cruz Bella Rose Navarro

Digitally signed by Cruz Bella Rose Navarro
DN: c=VN, st=THÀNH PHỐ HÀ NỘI, o=Văn phòng đại diện ABBOTT LABORATORIES GMBH tại thành phố Hà Nội, title=Trưởng Đại Diện, cn=Cruz Bella Rose Navarro, 0.9.2342.19200300.100.1.1=MST:P5954425A
Date: 2022.05.05 15:07:30 +07'00'

SCP / revision 7K760010/005

Component name	List Number	Lot Number	Production date	Expiry date
Architect Prolactin Control Low	7K76L	36180UD00	2022-01-05	2023-01-05
Architect Prolactin Control Medium	7K76M	36181UD00	2022-01-05	2023-01-05
Architect Prolactin Control High	7K76N	36182UD00	2022-01-05	2023-01-05

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

Description	Lower Limit	Upper Limit	Value	Result
SMP Control Low (n=2)	7.4	9.0	7.9	Acceptable
SMP Control Medium (n=2)	17.5	22.5	20.7	Acceptable
SMP Control High (n=2)	36.2	44.1	41.0	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: CARMEL FARRELL
Printed name and signature

Date: 31 Jan 22

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