



Certificate of Analysis

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

Product Name: Microalbumin
List number: 08P0424
Lot number: 74093UD00
Reagent Lot Number: 74093UD00
Expiry Date: 2026-12-16

SCP / revision 8P040024/005

Component name	List Number	Lot Number	Production date	Expiry date
uAlb R1	08P04R	74091UD00	2024-12-17	2026-12-17
uAlb R2	08P04T	74092UD00	2024-12-16	2026-12-16

Acceptance Table: Mean Concentration (µg/mL)

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_L_1	27.00	33.00	29.95	Acceptable
REF_Control_N_2	81.90	98.10	89.29	Acceptable
REF_Control_3	13.4	17.4	14.4	Acceptable
REF_Control_4	143.7	177.3	152.5	Acceptable
REF_Control_LH*	360.00	440.00	398.86	Acceptable

*Mean REF_Control_LH concentration acceptance criteria is $\pm 10.00\%$ from the REF_Control_LH expected value of 400 µg/mL as per SCP 8P040024

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:

Christy Pious C. Pious
Printed name and signature

Date: 21 Mar 2025

