



Certificate of Analysis

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

Product Name: ARCHITECT Urine NGAL Controls

List number: 1P37-10

Lot number: 35094UD00

Expiry Date: 2023-05-29

SCP / revision

1P370010/005

Component name	List Number	Lot Number	Production date	Expiry date
ARCHITECT Urine NGAL Control Low	1P37L	35088UD00	2021-12-01	2023-06-01
ARCHITECT Urine NGAL Control Medium	1P37M	35089UD00	2021-11-29	2023-05-29
ARCHITECT Urine NGAL Control High	1P37N	35090UD00	2021-11-29	2023-05-29

Acceptance Table: Mean S/C Concentration Ratio

Description	Lower Limit	Upper Limit	Value	Result
Control Low	0.90	1.10	0.97	Acceptable
Control Medium	0.90	1.10	1.00	Acceptable
Control High	0.90	1.09	0.99	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 SOBICZYK Maij Sath
Printed name and signature

Date:

09 Jan 22