



Certificate of Analysis

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

Product Name: ARCHITECT Urine NGAL Reagent Kit

List number: 1P37-25

Lot number: 36283UD00

Reagent Lot Number: 36283UD00

Expiry Date: 2023-06-30

SCP / revision

1P370025/006

Component name	List Number	Lot Number	Production date	Expiry date
ARCHITECT Urine NGAL Microparticles	1P37G	36279UD00	2021-12-30	2023-06-30
ARCHITECT Urine NGAL Conjugate	1P37H	36280UD00	2022-01-07	2023-07-07

Acceptance Table: Grand Mean Concentration ng/mL (n=30) over 2 instruments

Description	Lower Limit	Upper Limit	Value	Result
REF Control Low	16.8	23.2	19.9	Acceptable
REF Control Medium	168.0	232.0	187.5	Acceptable
REF Control High	1008.0	1321.0	1198.2	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 SOB CZYK Maciej Sobczyk
Printed name and signature

Date:

13 Feb 22