



Certificate of Analysis

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

Product Name: ARCHITECT Urine NGAL Calibrators
List number: 1P37-01 **SCP / revision** 1P370001/006
Lot number: 37361UD00
Expiry Date: 2023-07-26

Component name	List Number	Lot Number	Production date	Expiry date
ARCHITECT Urine NGAL Calibrator A	1P37A	36477UD00	2022-02-15	2023-08-15
ARCHITECT Urine NGAL Calibrator B	1P37B	36478UD00	2022-02-08	2023-08-08
ARCHITECT Urine NGAL Calibrator C	1P37C	36479UD00	2022-02-08	2023-08-08
ARCHITECT Urine NGAL Calibrator D	1P37D	36480UD00	2022-02-08	2023-08-08
ARCHITECT Urine NGAL Calibrator E	1P37E	36481UD00	2022-02-08	2023-08-08
ARCHITECT Urine NGAL Calibrator F	1P37F	36482UD00	2022-01-26	2023-07-26

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

Description	Lower Limit	Upper Limit	Value	Result
REF Control Low	16.8	23.2	20.3	Acceptable
REF Control Medium	168.0	232.0	192.5	Acceptable
REF Control High	1008.0	1303.2	1200.0	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:

MACIEJ SOJBCZYK Marij Sah
Printed name and signature

Date:

04 Mar 22