



Certificate of Analysis

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

Product Name: Alinity i Urine NGAL Reagent Kit
List number: 09P2920
Lot number: 36284UD00
Reagent Lot Number: 36284UD00
Expiry Date: 2023-06-30

SCP / revision 9P290020/006

Component name	List Number	Lot Number	Production date	Expiry date
Alinity i Urine NGAL Microparticles	9P29G	36281UD00	2021-12-30	2023-06-30
Alinity i Urine NGAL Conjugate	9P29H	36282UD00	2022-01-07	2023-07-07

Acceptance Table: Grand Mean Reported Result

Description	Lower Limit	Upper Limit	Value	Result
REF Control Low (ng/mL)	16.80	23.20	20.10	Acceptable
REF Control Medium (ng/mL)	168.00	232.00	195.13	Acceptable
REF Control High (ng/mL)	1008.00	1321.00	1200.65	Acceptable
REF Panel Low (ng/mL)	75.77	112.68	101.72	Acceptable
REF Panel Medium (ng/mL)	186.19	279.28	245.51	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:

Margaret Greer
Printed name and signature

Date:

01 Feb 23