



# Certificate of Analysis

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

**Product Name:** Alkaline Phosphatase2  
**List number:** 04T8320  
**Lot number:** 36902UD00  
**Reagent Lot Number:** 36902UD00  
**Expiry Date:** 2023-02-28

SCP / revision 4T830020/005

Component name	List Number	Lot Number	Production date	Expiry date
AlkP2 R1	04T83R	35602UD00	2021-11-30	2023-02-28
AlkP2 R2	04T83T	35605UD00	2021-12-02	2023-03-02

### Acceptance Table: Grand Mean Concentration via Calibration (U/L)

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	102.40	121.12	116.59	Acceptable
REF_Control_2	417.31	510.05	468.35	Acceptable
REF_GC3_L5	1932.33	2361.73	2195.03	Acceptable
REF_GC3_L6	3019.03	3689.93	3423.83	Acceptable


### Acceptance Table: Grand Mean Concentration via Factor (U/L)

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	102.40	121.12	115.08	Acceptable
REF_Control_2	417.31	510.05	462.26	Acceptable
REF_GC3_L5	1932.33	2361.73	2166.41	Acceptable
REF_GC3_L6	3019.03	3689.93	3379.20	Acceptable

This product has been manufactured, including packaging and quality control in full compliance with ISO 13485, IVD Regulation (EU) 2017/746 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:

  
 Printed name and signature

Date: 07 Dec 21