



Certificate of Analysis

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

Product Name: Alkaline Phosphatase2
List number: 04S8720
Lot number: 36900UD00
Reagent Lot Number: 36900UD00
Expiry Date: 2023-02-28

SCP / revision 4S870020/002

Component name	List Number	Lot Number	Production date	Expiry date
AlkP2 R1	04S87R	35588UD00	2021-11-30	2023-02-28
AlkP2 R2	04S87T	35589UD00	2021-12-02	2023-03-02

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

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	101.73	120.33	155.26	Acceptable
REF_Control_2	417.45	510.21	476.64	Acceptable
REF_GC3_Lv5	1866.63	2281.43	2162.55	Acceptable
REF_GC3_Lv6	2967.15	3626.51	3441.97	Acceptable

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

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	101.73	120.33	110.59	Acceptable
REF_Control_2	417.45	510.21	457.42	Acceptable
REF_GC3_Lv5	1866.63	2281.43	2075.15	Acceptable
REF_GC3_Lv6	2967.15	3626.51	3302.29	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:

MACEJ SOPICZYK Jy 5/11
Printed name and signature

Date:

13 Dec 21