



Certificate of Analysis

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

Product Name: Alanine Aminotransferase2
List number: 04T8420
Lot number: 30919UD00
Reagent Lot Number: 30919UD00
Expiry Date: 2022-12-23

SCP / revision 4T840020/008

Component name	List Number	Lot Number	Production date	Expiry date
ALT2 R1	04T84R	31326UD00	2021-06-23	2022-12-23
ALT2 R2	04T84T	31327UD00	2021-06-24	2022-12-24

Acceptance Table: CAL Grand Mean Concentration (U/L)

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	22.33	32.33	26.99	Acceptable
REF_Control_2	85.07	103.97	96.11	Acceptable
REF_GC3_Lv5	859.46	1050.45	902.81	Acceptable
REF_GC3_Lv6	2149.82	2627.56	2194.69	Acceptable

Acceptance Table: ENZ Grand Mean Concentration (U/L)

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	22.33	32.33	27.59	Acceptable
REF_Control_2	85.07	103.97	98.26	Acceptable
REF_GC3_Lv5	859.46	1050.45	922.91	Acceptable
REF_GC3_Lv6	2149.82	2627.56	2243.56	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:


Printed name and signature

Date:

