

Certificate of Analysis

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

Product Name: Aspartate Aminotransferase2
List number: 04S9020
Lot number: 30909UD00
Reagent Lot Number: 30909UD00
Expiry Date: 2022-12-27

SCP / revision 4S900020/002

Component name	List Number	Lot Number	Production date	Expiry date
AST2 R1	04S90R	31077UD00	2021-06-28	2022-12-28
AST2 R2	04S90T	31078UD00	2021-05-27	2022-11-27

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

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	40.06	45.72	42.07	Acceptable
REF_Control_2	202.08	232.50	211.17	Acceptable
REF_GC3_Lv5	870.76	1001.84	893.44	Acceptable
REF_GC3_Lv6	2915.95	3354.91	3031.98	Acceptable


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

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	40.06	45.72	42.72	Acceptable
REF_Control_2	202.08	232.50	213.42	Acceptable
REF_GC3_Lv5	870.76	1001.84	902.11	Acceptable
REF_GC3_Lv6	2915.95	3354.91	3061.05	Acceptable

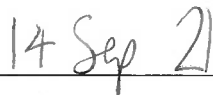
This product has been manufactured, including packaging and quality control in full compliance with ISO 13485, IVD Directive 98/79/EC and GMP guidelines as applicable.

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:


 14 Sep 21