



# Certificate of Analysis

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

**Product Name:** Lactate Dehydrogenase2  
**List number:** 04T9920  
**Lot number:** 34915UD00  
**Reagent Lot Number:** 34915UD00  
**Expiry Date:** 2022-10-27

SCP / revision 4T990020/002

Component name	List Number	Lot Number	Production date	Expiry date
LDH2 R1	04T99R	34357UD00	2021-10-27	2022-10-27
LDH2 R2	04T99T	34358UD00	2021-10-27	2022-10-27

### Acceptance Table: CALGrand Mean Concentration (U/L)

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	124.86	150.86	135.42	Acceptable
REF_Control_2	338.15	391.01	357.95	Acceptable
REF_GC3_Lv5	1802.66	2159.22	1997.52	Acceptable
REF_GC3_Lv6	3135.99	3756.29	3444.71	Acceptable

### Acceptance Table: ENZGrand Mean Concentration (U/L)

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	124.86	150.86	135.72	Acceptable
REF_Control_2	338.15	391.01	358.71	Acceptable
REF_GC3_Lv5	1802.66	2159.22	2001.72	Acceptable
REF_GC3_Lv6	3135.99	3756.29	3451.89	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 SOBICZYK *Macej Sobicz*  
Printed name and signature

Date:

21 Nov 21