



# Certificate of Analysis

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

**Product Name:** Lactate Dehydrogenase2  
**List number:** 04T0320  
**Lot number:** 34913UD00 **SCP / revision** 4T030020/002  
**Reagent Lot Number:** 34913UD00  
**Expiry Date:** 2022-10-27

Component name	List Number	Lot Number	Production date	Expiry date
LDH2 R1	04T03R	34352UD00	2021-10-27	2022-10-27
LDH2 R2	04T03T	34353UD00	2021-10-27	2022-10-27

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

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	125.28	151.28	133.70	Acceptable
REF_Control_2	338.21	391.09	352.02	Acceptable
REF_GC3_Lv5	1799.06	2154.92	1970.55	Acceptable
REF_GC3_Lv6	3114.13	3730.11	3420.36	Acceptable

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

Description	Lower Limit	Upper Limit	Value	Result
REF_Control_1	125.28	151.28	136.85	Acceptable
REF_Control_2	338.21	391.09	360.08	Acceptable
REF_GC3_Lv5	1799.06	2154.92	2016.17	Acceptable
REF_GC3_Lv6	3114.13	3730.11	3499.00	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:

MACIEJ SORCZYŃSKI Maj sał  
Printed name and signature

Date:

20 Nov 21