

Certificate of Analysis

Article Name: **WID®-easy PCR Kit**

Catalogue Number: OE00083

Batch Code: SOLA-0002

Disclaimer: For research use only. Not for use in diagnostic procedures.

Expiry Date: 2024-04-30

This product has been subjected to quality control and was tested in completion according to the assigned methods. All required specifications are met and therefore, the product is released for use.

Test	Specification	Result
OE-018-03_Performance of Primer Mix A in Positive Control	All Ct-Values are in the range of 26.8 to 27.8.	in spec
OE-018-03_Performance of Primer Mix B in Positive Control	GYPC Ct-Values are in the range of 23.95 to 25.13. COL2A1 Ct-Values are in the range of 25.51 to 28.08.	in spec
OE-018-03_Performance of Primer Mix A in Reference Sample 1 (15 copies)	All Ct-Values are in the range of 33.59 to 35.72.	in spec
OE-018-03_Performance of Primer Mix B Reference Sample 1 (15 copies)	GYPC Ct-Values are in the range of 30.29 to 33.05.	in spec
OE-018-03_Absence of template in Primer Mix A_NTC	No Ct-Values below 43 are detected.	in spec
OE-018-03_Absence of template in Primer Mix B_NTC	No Ct-Values below 43 are detected.	in spec
OE-018-03_Performance of Primer Mix A in Standard 1	All Ct-Values are in the range of 20.76 to 22.39.	in spec
OE-018-03_Performance of Primer Mix B in Standard 1	GYPC Ct-Values are in the range of 18.38 to 19.38. COL2A1 Ct-Values are in the range of 19.96 to 22.22.	in spec
OE-018-03_Performance of Primer Mix A in Standard 2	All Ct-Values are in the range of 24.80 to 25.48.	in spec
OE-018-03_Performance of Primer Mix B in Standard 2	GYPC Ct-Values are in the range of 21.76 to 22.73. COL2A1 Ct-Values are in the range of 23.00 to 25.77.	in spec

OE-018-03_Performance of Primer Mix A in Standard 3	All Ct-Values are in the range of 28.07 to 28.82.	in spec
OE-018-03_Performance of Primer Mix B in Standard 3	GYPC Ct-Values are in the range 25.20 to 26.13. COL2A1 Ct-Values are in the range of 26.66 to 29.39.	in spec
OE-018-03_Performance of Primer Mix A in Standard 4	All Ct-Values are in the range of 31.27 to 32.26.	in spec
OE-018-03_Performance of Primer Mix B in Standard 4	GYPC Ct-Values are in the range of 28.43 to 29.82. COL2A1 Ct-Values are in the range of 30.63 to 33.08.	in spec
OE-018-03_Slope of Standard curve in Primer Mix A_ZSCAN12	Slope is in the range of -3.45 to -3.24.	in spec
OE-018-03_Slope of Standard curve in Primer Mix B_GYPC	GYPC Slope is in the range of -3.70 to -2.95.	in spec
OE-018-03_Slope of Standard curve in Primer Mix B_COL2A1	COL2A1 Slope is in the range of -3.84 to -3.23.	in spec

DETERMINATION OF RELEASE: PASS

Storage: This product shall be stored protected from light between -25 °C to -15 °C.

Release Date: 2023-11-30




Prof. Dr. med. M Widschwendter

Dr. P. Kayatz

Geschäftsführer

Geschäftsführer










CoA_OE00083_WID®-easy PCR Kit_SOLA-0002 - Sola

Final Audit Report

2023-11-30

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