

Certificate of Analysis

Article Name: WID®-easy PCR Kit
 Catalogue Number: OE00103
 Batch Code: SOLA-0005
 Disclaimer: For *in vitro* diagnostic use.
 Expiry Date: 2025-06-30

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_Comparison of labeled end product	The correct label was used and attached properly.	Yes
OE-018-03_Performance of Primer Mix A in Positive Control	Mean ZSCAN12 Ct-Values are in the range of 26.5 to 27.5.	in spec
OE-018-03_Performance of Primer Mix A in Reference Sample 1 (15 copies)	Mean ZSCAN12 Ct-Values are in the range of 33.5 to 35.4.	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_Performance of Primer Mix A in Standard 1	Mean ZSCAN12 Ct-Values are in the range of 21.2 to 22.2.	in spec
OE-018-03_Performance of Primer Mix A in Standard 2	Mean ZSCAN12 Ct-Values are in the range of 24.5 to 25.5.	in spec
OE-018-03_Performance of Primer Mix A in Standard 3	Mean ZSCAN12 Ct-Values are in the range of 27.8 to 28.9.	in spec
OE-018-03_Performance of Primer Mix A in Standard 4	Mean ZSCAN12 Ct-Values are in the range of to 31.2 to 32.2.	in spec
OE-018-03_Slope of Standard curve in Primer Mix A_ZSCAN12	Slope is in the range of -3.4 to -3.3.	in spec
OE-018-03_Comparison of labeled end product Primer Mix B	The correct label was used and attached properly.	Yes
OE-018-03_Performance of Primer Mix B in Positive Control	Mean GYPC Ct-Values are in the range of 24.3 to 25.8. Mean COL2A1 Ct-Values are in the range of 27.3 to 28.8.	in spec
OE-018-03_Performance of Primer Mix B Reference Sample 1 (15 copies)	Mean GYPC Ct-Values are in the range of 31.4 to 33.4.	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 B in Standard 1	Mean GYPC Ct-Values are in the range of 18.9 to 20.4. Mean COL2A1 Ct-Values are in the range of 21.8 to 22.8.	in spec
OE-018-03_Performance of Primer Mix B in Standard 2	Mean GYPC Ct-Values are in the range of 22.1 to 23.6. Mean COL2A1 Ct-Values are in the range of 25.3 to 26.5.	in spec
OE-018-03_Performance of Primer Mix B in Standard 3	Mean GYPC Ct-Values are in the range of 25.4 to 26.9. Mean COL2A1 Ct-Values are in the range of 28.6 to 30.3.	in spec
OE-018-03_Performance of Primer Mix B in Standard 4	Mean GYPC Ct-Values are in the range of 28.9 to 30.4. Mean COL2A1 Ct-Values are in the range of 32.0 to 34.3.	in spec
OE-018-03_Slope of Standard curve in Primer Mix B_GYPC	Slope is in the range of -3.4 to -3,3.	in spec
OE-018-03_Slope of Standard curve in Primer Mix B_COL2A1	Slope is in the range of -3.9 to -3.4.	in spec

DETERMINATION OF RELEASE: PASS

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

Release Date: 2024-12-16




Prof. Dr. med. M. Widschwendter
 Geschäftsführer

Dr. P. Kayatz
 Geschäftsführer










CoA_OE00103_WID®-easy PCR Kit_SOLA-0005-Sola Logo

Final Audit Report

2024-12-19

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