

Certificate of Analysis

Genomtec® SARS-CoV-2 EvaGreen® RT-LAMP CE-IVD Duo Kit

Certificate Reference (batch number) 0000E.00010.000D3.00001

Product Catalogue Number	GA00B
Pack Size	50
Date of Manufacture	2021-03-04
Product GTIN	
Date of expiry	2021-06-04

QC Test Parameters

Analytical investigation		
Name	Results (mean**) - time of product detection (minutes)	Specification met?
Control A (con. at 5xLOD*)	14	Yes
Control B	12	Yes
Neg. Control A/B	0	Yes
Human Control	15	Yes
Neg. Human Control	0	Yes
Visual inspection of the part-products kit		
Name	Description	Specification met?
Part-product volume	All volumes must be as indicated on the part-labels	
	0BM - 1350ul	Yes
	0BH - 100ul	Yes
	0BJ - 100ul	Yes

[*RootItem.Category*]

Analytical investigation		
	OBC - 40ul	Yes
	0BD - 1000ul	Yes
Correctness of part-labels	Quality of label print and printed text	Yes
	Correct part label applied onto the corresponding part-product microtube	Yes
Inspection of the manufacturing process involving epMotion 5073lc robot		
Name	Description	Specification met?
Visual inspection of the following parameters:	The appropriate volume of pipetted reagents	Yes
	Correct application and dropping off tips by the pipettor	Yes
	Correct movement of the pipetting arm	Yes
	The sequence of procedures performed	Yes
Data log of the performed robot run is retained in QC file		Yes
Overall specification met?		Yes

Notes:

*The LOD is 20 genome equivalents / reaction (either S or N gene fragments targetted in the assay).

**Mean for three replicates.

We hereby confirm that the In-Vitro Diagnostic Device identified above has been manufactured in compliance to the current product specification.

Name	Position	Date
Aneta.Cierzniak	Production Specialist	08.03.2021

Aneta Cierzniak

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