Certificate of Analysis

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

Certificate Reference (batch number) 0000C.00010.000D3.0000

Product Catalogue Number	GA00C
Pack Size	50
Date of Manufacture	2021-09-30
Product GTIN	
Date of expiry	2022-03-30

QC Test Parameters

Analytical investigation		
Name	**Results (mean**) - time of product detection (minutes)**	**Specification met?**
Control A (con. at x25 LOD*)	18	Yes
Control B	15	Yes
Neg. Control A/B	0	Yes
Inhibition Control	17	Yes
Neg. Inhibition Control	0	Yes
Control S	18	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	
	0CM - 1780ul	Yes
	0CH - 137ul	Yes

Analytical investigation		
	0CJ - 137ul	Yes
	0CC - 40ul	Yes
	0CL - 11ml	Yes
	0DL - 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	No
	Correct application and dropping off tips by the pipettor	No
	Correct movement of the pipetting arm	No
	The sequence of procedures performed	No
Data log of the performed robot run is retained in QC file		No
Inspection of the laboratory balance or other device used for reagent weighing		
Is the balance calibrated prior to use?		Yes
Reagent's average weight in three repeats does not exceed 95% CI (as evidenced by three pictures of the weighted reagent)		Yes
Overall specification met?		Yes

Notes:

For technical reasons, a Multipette E3x (Eppendorf, IN0055) was used in the production instead of a epMotion 5073lc robot

*The contrived heat-inactivated SARS-CoV-2 virus in the saliva sample produces final concentration at 50 copies / reaction.

**Mean for for at least two 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.Ciezniak	Production Specialist	01.10.2021

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