

# Certificate of Analysis

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

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

<b>Product Catalogue Number</b>	GA00C
<b>Pack Size</b>	50
<b>Date of Manufacture</b>	2022-02-02
<b>Product GTIN</b>	
<b>Date of expiry</b>	2022-08-02

### QC Test Parameters

<b>Analytical investigation</b>		
<b>Name</b>	<b>Results (mean**) - time of product detection (minutes)</b>	<b>Specification met?</b>
Control A (con. at x25 LOD*)	20	Yes
Control B	20	Yes
Neg. Control A/B	0	Yes
Inhibition Control	20	Yes
Neg. Inhibition Control	0	Yes
Control S	20	Yes
<b>Visual inspection of the part-products kit</b>		
<b>Name</b>	<b>Description</b>	<b>Specification met?</b>
Part-product volume	All volumes must be as indicated on the part-labels	
	0CM - 1780ul	Yes
	0CH - 137ul	Yes
	0CJ - 137ul	Yes

<b>Analytical investigation</b>		
	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
<b>Inspection of the manufacturing process involving epMotion 5073lc robot</b>		
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
<b>Inspection of the laboratory balance or other device used for reagent weighing</b>		
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
<b>Overall specification met?</b>		Yes

Notes:

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

\*\*Mean 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.Cierzniak	Production Specialist	03.02.2022

*Aneta Cierzniak*

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