

# Certificate of Analysis

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

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

<b>Product Catalogue Number</b>	GA00B
<b>Pack Size</b>	50
<b>Date of Manufacture</b>	2020-12-16
<b>Product GTIN</b>	
<b>Date of expiry</b>	2021-03-16

### 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 2xLOD*)	18	Yes
Control B	13	Yes
Neg. Control A/B	0	Yes
Inhibition Control	14	Yes
Neg. Inhibition Control	0	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	
	0BM - 1350ul	Yes
	0BH - 100ul	Yes
	0BJ - 100ul	Yes

Analytical investigation		
	0BC - 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
<b>Overall specification met?</b>		Yes

Notes:

\*The LOD is 20 genome equivalents / reaction (either S or N gene fragments targeted 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	2020-12-16

*Aneta Cierzniak*

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