

Certificate of Analysis

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

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

| | |
|---------------------------------|------------|
| Product Catalogue Number | GA00B |
| Pack Size | 50 |
| Date of Manufacture | 2022-08-16 |
| Product GTIN | |
| Date of expiry | 2023-02-16 |

QC Test Parameters

| Analytical investigation | | |
|--|--|--------------------|
| Name | Results (mean**) - time of product detection (minutes) | Specification met? |
| Control A (con. at 5xLOD*) | 25 | Yes |
| Control B | 20 | Yes |
| Neg. Control A/B | 0 | Yes |
| Inhibition Control | 18 | Yes |
| Neg. inhibition 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 |

| Analytical investigation | | |
|---|--|--------------------|
| | OBC - 40ul | Yes |
| | OBD - 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 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 | 16.08.2022 |

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