

Product Information

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| Product Name: | PlexPCR[®] SARS-CoV-2 |
| Catalogue Number: | 1301384 |
| Product Description: | The PlexPCR[®] SARS-CoV-2 kit is an in vitro diagnostic real-time PCR test for the qualitative detection of the RdRp and ORF1ab genes on the LightCycler [®] 480II instrument. |
| Lot Number: | 24030033 |
| Manufacture Date: | 2024-05-10 |
| Expiry Date: | 2025-04-30 |
| Storage Conditions: | -15°C to -25°C |

Test method:

PlexPCR[®] SARS-CoV-2 kit was tested with reference material containing the RdRp and ORF1ab genes using the LightCycler[®] 480 II instrument with thermal cycling conditions stated in the IFU. The amplifications were analysed using the **PlexPCR[®] SARS-CoV-2 (LC480)** software for the interpretation of the results.

Results:

| Test Samples | Specification | Result |
|------------------------|-----------------------------------|-------------|
| RdRp – 50 copies/rxn | 90% detection for RdRp assay | PASS |
| ORF1ab – 50 copies/rxn | 90% detection for ORF1ab assay | PASS |
| Internal Control RNA | Average Cq within specified range | PASS |
| No Template Control | No observable amplification | PASS |

The Finished products were tested according to standard Quality Control methods. The results were verified against the design specifications, acceptance criteria and reviewed and approved by the Quality Department.

Quality Assurance Signature and Date:

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| QA Approval |  <u>Regine Citra</u> <small>Regine Citra (May 15, 2024 16:01 GMT+10)</small> |
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