

## Product Information

Product Name:	<b>PlexPCR<sup>®</sup> SARS-CoV-2</b>
Catalogue Number:	<b>1301384</b>
Product Description:	The <b>PlexPCR<sup>®</sup> SARS-CoV-2</b> kit is an in vitro diagnostic real-time PCR test for the qualitative detection of the RdRp and ORF1ab genes on the LightCycler <sup>®</sup> 480II instrument.
Lot Number:	23030068
Manufacture Date:	2023-11-09
Expiry Date:	2024-07-31
Storage Conditions:	<b>-15°C to -25°C</b>

## Test method:

**PlexPCR<sup>®</sup> SARS-CoV-2** kit was tested with reference material containing the RdRp and ORF1ab genes using the LightCycler<sup>®</sup> 480 II instrument with thermal cycling conditions stated in the IFU. The amplifications were analysed using the **PlexPCR<sup>®</sup> 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	<b>PASS</b>
ORF1ab – 50 copies/rxn	90% detection for ORF1ab assay	<b>PASS</b>
Internal Control RNA	Average Cq within specified range	<b>PASS</b>
No Template Control	No observable amplification	<b>PASS</b>

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:

QA Approval	 <u>Regine Citra</u> <small>Regine Citra (Nov 16, 2023 09:00 GMT+11)</small>
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