

Product Information

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:	24020029
Manufacture Date:	2024/04/24
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:

QA Approval	 <small>Regine Citra (May 1, 2024 15:03 GMT+10)</small>
-------------	---