

Certificate of Analysis


Product name	AzureSeq 4 CE qPCR Kit for 200 Reactions
Reference number	AzureSeq 4-200 CE
LOT number	OMX4046 (22R05010, 22B32006, 22B33002, 21B31005, 22B40001, 22B41002, 22C06005)
Kit Assembling Date	2023-02-13
Expiration date	2023-07-08

Components

Product Code	Product name	Pass/Fail*
OA-ITMP-MM-100	2X InhibiTaq Multiplex HotStart MasterMix	Pass
OA-RTM-200	RT Mix	Pass
OA-CPPM4-100	CoVi PLUS Primer/Probe Mix 4	Pass
OA-NFW-350uL	Nuclease Free Water	Pass
OA-CVNC-150	CoVi Negative Control	Pass
OA-CVPC-150	CoVi Positive Control	Pass
OA-FABPC-150	Flu A/B Positive Control	Pass

*for acceptance criteria see second page.

Authorization for release

Name	A Némethi	Function	Manufacturing Quality Engineer
Signature		Sign date	2023-02-13

Acceptance Criteria

Component	Assay name / Specification	Passing Result	Result
OA-ITMP-MM-100	N1, N2 and RNase P qPCR amplification ITMP is tested for performance in multiplex qPCR reaction using primers specific to the SARS-Cov2 N1/N2 EUA Assays, and RNase P with 100 copies of synthetic RNA and 1 ng of UHRR. Successful amplification of synthetic RNA < 40 Ct and UHRR < 30 Ct	Pass	Pass
	Unspecific dsDNA nucleases HindIII digested Lambda DNA and dsRNA are incubated with 2x InhibiTaq Multiplex Master at a concentration of 1x at 37°C for 1 hours. No detectable degradation of DNA via agarose gel electrophoresis.	Pass	Pass
	N1/N2 EUA & RNase P Amplicon Contamination Components are used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. No amplification < 40 Ct (<2%) is detectable	Pass	Pass
	Shelf life	≥ 12 months	≥ 12 months
OA-RTM-200	Performance Test: RT Mix is used for performance in multiplex qPCR reactions using primers specific to th SARS-Cov2 N1/n2 EUA Assays. Inactivated virus spiked into negative swab sample + VTM@10cp/uL. ≥19/20 Replicates amplify <40ct.	Pass	Pass
	Covid RNase P, N1/N2 EUA Amplicon Contamination Assay: RT Mix ix used as the template in RT-qPCR reactions with InhibiTaq Multiplex Master Mix at 1x using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. 88 NTC showing amplification before 45Ct. Positive control amplification in the determined Ct range.	Pass	Pass
	Unspecific Endonucleases: HindIII digested Lambda-NDA and dsRNA are incubated with RT Mix at 37C for 1 hour. No degradation is observed via gel electrophoresis.	Pass	Pass
	N1 EUA, FluA and FluB Amplicon Contamination: RT Mix is used in multiplex qPCR reactions using primers specific to the SA of 72 reactions) RS-Cov2 N1 EUA Assay, FluA, FluB, and RNase P. No amplification <40ct (in ≤ is detectable)	Pass	Pass
OA-CPPM4-100	qPCR Amplification: Covi Primer/Probe Mix 4 is tested for performance in multiplex q PCR reactions using primers specific to the SARS-Cov2 N1 EUA Assays, and RNase P with 100 copies of synthetic RNA, 500 copies FluA and FluB Synthetic RNA and 1 ng of UHRR. Successful amplification of synthetic RNA <40 ct. FluA and FluB Synthetic RNA <40ct, and UHRR <30ct.	Pass	Pass
	SSRNAse: Single-Stranded RNA is incubated with Covi Primer/Probe Mix 4 at 37C or 2 hours. No degradation is observed by gel electrophoresis.	Pass	Pass
	Unspecific endonucleases: dsEndonuclease: HinIII digested Lambda-DNA and dsRNA are incubated with Covi Primer/Probe Mix 4 at 37C for 1 hour. No degradation is observed by gel electrophoresis.	Pass	Pass
	N1 EUA, FluA and FluB Amplicon Contamination: Covi Primer/Probe Mix 4 is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1 EUA Assay, FluA, FluB and RNase P. no amplification <40ct (2%) is detected.	Pass	Pass
OA-NFW-350uL	N1, N2 & RNase P qPCR Amplification Nuclease Free Water is tested for performance in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays, and RNase P with 100 copies of synthetic RNA and 1ng of UHRR. Successful amplification of synthetic RNA <40ct and UHRR <30ct	≤1 of NTC showing amplification before 45 Ct 4/4 positive controls amplification the specified Ct range	Pass
	TB Performance and Contamination Nuclease Free Water is used in a qPCR reaction to amplify DNA from Mycobacterium tuberculosis complex (TB). Nuclease Free Water is also used as	TBC Positive control: 8/8	Pass

	<p>NTC and tested for TB and internal amplification control plasmid (IAC) contamination</p> <p>ssRNase Single stranded RNA is incubated with CPPM at 37C for 2 hours. No degradation is observed by gel electrophoresis.</p> <p>Unspecific dsEndonucleases dsEndonuclease: HindIII digested Lambda-DNA is incubated with the components at 37°C for 1 hour. No degradation is observed by gel electrophoresis.</p> <p>N1, N2 EUA & RNase P Amplicon Contamination NFW is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. No amplification < 40 Ct (<2%) is detectable.</p> <p>Influenza A/B Amplicon Contamination NFW is used in multiplex qPCR reactions using primers specific to FluA/B template. No amplification < 40 Ct is detectable</p>	<p>IAC Positive Control ≥47/48 Positive ≤ 35 Ct TBC NTC: ≤ 1/88 positive ≤ 40 Ct IAC NTC: 1/40 positive ≤ 40 Ct</p> <p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Flu Positive Control: 6/6 Positive ≤32 Ct FluAB/Covid NTC: ≤ 1/72 Positive ≤ 40 Ct</p>	<p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>
OA-CVNC-150	<p>qPCR Amplification: CoVI NC is tested for performance in multiplex q PCR reactions using primers specific to the SARS-Cov2 N1/n2 EUA Assays, and RNase P with 100 copies of synthetic RNA, and 1 ng of UHRR. Successful amplification of synthetic RNA <40ct, and UHRR <30ct.</p> <p>ssRNase Single stranded RNA is incubated with CoVi NC at 37C for 2 hours. No degradation is observed.</p> <p>Unspecific dsEndonucleases dsEndonuclease: HindIII digested Lambda-DNA is incubated with CoVi NC at 37°C for 2 hours. No degradation is observed.</p> <p>N1, N2 EU Amplicon Contamination CoVi NC is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. No amplification < 40 Ct (<2%) is detectable.</p>	<p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>	<p>Pass</p> <p>Pass</p> <p>Pass</p> <p>Pass</p>
	<p>qPCR Amplification: CoVI PC is tested for performance in multiplex q PCR reactions using primers specific to the SARS-Cov2 N1/n2 EUA Assays, and RNase P with 100 copies of synthetic RNA, and 1 ng of UHRR. Successful amplification of synthetic RNA <40ct, and UHRR <30ct</p>	<p>Pass</p>	<p>Pass</p>
	<p>qPCR Amplification: Flu A/B Positive Control is tested for performance in multiplex qPCR reactions using primers specific to the Influenza A M1 and Influenza B NS2 gene. Successful amplification of all targets<34ct.</p>	<p>Pass</p>	<p>Pass</p>