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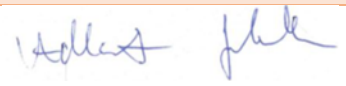
Certificate of Analysis

Product name	AzureSeq CE qPCR Kit SARS-CoV-2 for 200 Reactions
Reference number	AzureSeq-200 CE
LOT number	OMX3743 (22R05010, 22U06004, 22B30003, 22B32006)
Kit Assembling Date	2022-10-07
Expiration date	2023-08-18

Components

Product Code	Product name	Pass/Fail*
OA-ITMP-MM-100	2X InhibiTaq Multiplex HotStart MasterMix	Pass
OA-RT-200	RTScript Reverse Transcriptase, 200U/µL	Pass
OA-CPPM-100uL	CoVi Primer/Probe Mix 3	Pass
OA-NFW-350uL	Nuclease Free Water	Pass

*for acceptance criteria see second page.

Authorization for release			
Name	**G Adlovits**	**Function**	**RAQS Manager**
Signature		**Sign date**	**2022-10-11**

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Acceptance Criteria

Component	Assay name / Specification	Passing Result	Result
OA-ITMP-MM-100	**N1, N2 and RNase P qPCR amplification** 2X InhibiTaq™ Multiplex HotStart MasterMix is tested for performance in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays, and RNase P with 500 copies of synthetic RNA and 5 ng of UHRR. Successful amplification of synthetic RNA < 3 cT and UHRR < 30 cT.	Pass	Pass
	Unspecific dsEndonucleases HindIII digested Lambda DNA and dsRNA are incubated with 2x InhibiTaq™ Multiplex otStart qPCR MasterMix at a concentration of 1x at 37°C for 1 hour. No detectable degradation is observed via gel electrophoresis.	Pass	Pass
	N1/N2 EUA & RNase P Amplicon Contamination 2X InhibiTaq™ Multiplex HotStart MasterMix is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. No amplification < 45 cT (<2% of reactions) is detectable	Pass	Pass
	Shelf life	Corresponds	Corresponds
OA-RT-200	**DNase and RNase Activity** 100U of RTScript™ RT is tested for nuclease degradation in reactions containing a dsDNA or dsRNA substrate. After incubation for 1 hour at 37°C there is no detectable degradation of DNA or RNA substrate as determined by agarose gel electrophoresis.	Pass	Pass
	N1, N2 UA and RNase P Amplicon Contamination RTScript™ Reverse Transcriptase is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNAse P. No amplficaion <45 cT (<2%) is detectable for NTCs. Successful amplification o 6/6 positive controls containing synthetic COVID RNA and UHRR within Empirical specified cT ranges.	Pass	Pass
	E. coli DNA Contamination 100U of RTScript™ Reverse Transcriptase is used as the template in qPCR reactions using primers specific to E.coli DNA. No E.coli DNA is detected before 40 cycles.	Pass	Pass
	Nicking Activity pBR322 supercoiled plasmid DNA is incubated with 100 Units of RTScript™ Reverse Transcriptase at 37°C for 4 hours. No detectable nicking activity as determined by gel electrophoresis.	Pass	Pass
	Activity One unit is defined as the amount of enzyme required to catalyze the incorporation of 1 nmol of dTTP into an acid-insoluble form in 10 minutes at 37°C. The result is 200U/µL ± 15%	Pass	Pass
	Functionality RTScript™ Reverse Transcriptase is tested for performance in a 20 µL RT-qPCR assay. cT values are within 1 Ct of control enzyme for each serial dilution of template	Pass	Pass
	Single Stranded Exonuclease ssDNA probes are incubated with 100U of RTScript™ Reverse Transcriptase for 4 hours at 37°C. qPCR results display no probe degradation after incubation.	Pass	Pass
	Human gDNA Contamination 100U of RTScript™ Reverse Trancriptase is used as the template in qPCR reactions using primers specific to Human gDNA. No Human gDNA is detected before 45 cycles.	Pass	Pass
	Protein Purity ≥95% as determined by SDS-PAGE	Pass	Pass
	ssRNAse Single Stranded MS-II RNA is incubated with 100 Units of RTScript™ Reverse Transcriptase at 37°C for 2 hours. No degradation is observed by gel electrophoresis.	Pass	Pass
OA-CPPM-100uL	**N1, N2 and RNAse P qPCR Amplification** CPPM 3 is tested for performance in multiplex qPCR reaction using primers specific to the SARS-Cov2 N1/N2 EUA Assays, and RNase P with 500 copies of synthetic RNA and 5 ng of UHRR. Successful amplification of synthetic RNA < 35 ct and UHRR < 30 ct.	Pass	Pass
	ssRNase Single Stranded RNA is incubated with CPPM 3 at 37°C for 2 hours. No degradation is observed by gel electrophoresis.	Pass	Pass
	Unspecific Endonucleases dsEndonuclease: HindIII digested Lambda-DNA and dsRNA is incubated with CPPM 3 at 37°C for 1 hour. No degradation is observed by gel electrophoresis.	Pass	Pass
	N1/N2 EUA & RNAse P Amplicon Contamination CoVI Prier/Probe Mix 3 is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. No amplification <45 Ct (<2% of reactions) is detectable	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 500 copies	Pass	Pass

	of synthetic RNA and 5ng of UHRR. Successful amplification of synthetic RNA <35Ct and UHRR <30ct		
	ssRNase Single stranded RNA is incubated with Nuclease Free Water at 37C for 2 hours. No degradation is observed by gel electrophoresis.	Pass	Pass
	Unspecific Endonucleases dsEndonuclease: HindIII digested Lambda-DNA and dsRNA are incubated with Nuclease Free Water at 37°C for 1 hour. No degradation is observed by gel electrophoresis.	Pass	Pass
	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 < 45 Ct (<2% of reactions) is detectable.	Pass	Pass
	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 (in <2% of reactions).	Pass	Pass