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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	OMX2927(21R05009; 21U06001; 21B30011; 21B32005)
Kit Assembling Date	2021.12.20
Expiration date	2022.11.04

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	**B Kosiba**	**Function**	**Quality Engineer**
Signature		**Sign date**	2021.12.20

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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-RT-200	**DNase and RNase Activity** 100U of RTScript RT is tested for nuclease degradation in reactions containing a DNA or RNA 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. MS-II RNA is incubated with 200U of RTSript Reverse Transcriptase at 37°C for 1 hour. No degradation is observed by gel electrophoresis.	Pass	Pass
	RNase P, N1 and N2 COVID Contamination Assay RTSript Reverse Transcriptase is used as the template in RT-qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays, and RNase P. 95 NTCs and 1 positive control are run each assay.	≤ 1 of 95 NTC showing amplification before 40 Ct 1/1 positive control amplifies before 40 Ct	Pass
	E. coli DNA Contamination Assay Not detectable before 40 cycles in qPCR Assay for E-coli DNA in presence of 100 Units of RTSript Reserve Transcriptase	Pass	Pass
	Nicking Activity Assay pBR322 supercoiled plasmid DNA is incubated with 100 Units of RTScript at 37°C for 4 hours. No detectable nicking activity as determined by agarose gel electrophoresis.	Pass	Pass
	Activity Assay One unit is defined as the amount of enzyme required to catalyse the incorporation of 1 nmol of dTTP into an acid-insoluble form in 10 minutes at 37°C. The test result is 200U/µL ± 15%	Pass	Pass
	Performance Test TScript 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 Assay ssDNS probes are incubated with 100U of RTScript Reverse Transcriptase for 4 hours at 37°C. Results observed via qPCR analysis.	Pass	Pass
	Human gDNA Contamination Assay 100U of RTScript Reverse Transcriptase 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
	Shelf life	≥ 12 months	≥ 12 months
OA-CPPM-100uL	**N1, N2 and RNAse P qPCR amplification** CPPM 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
	ssRNase Single stranded RNA is incubated with CPPM at 37°C for 2 hours. No degradation is observed by gel electrophoresis.	Pass	Pass
	Unspecific Endonucleases dsEndonuclease: HindIII digested Lambda-DNA is incubated with CPPM at 37°C for 1 hour. No degradation is observed by 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
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	TBC Positive control: 8/8	Pass

	Nuclease Free Water is used in a qPCR reaction to amplify DNA from Mycobacterium tuberculosis complex (TB). Nuclease Free Water is also used as NTC and tested for TB and internal amplification control plasmid (IAC) contamination	IAC Positive Control ≥47/48 Positive ≤ 35 Ct TBC NTC: ≤ 1/88 positive ≤ 40 Ct IAC NTC: 1/40 positive ≤ 40 Ct	
	ssRNase Single stranded RNA is incubated with CPPM at 37C for 2 hours. No degradation is observed by gel electrophoresis.	Pass	Pass
	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.	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 < 40 Ct (<2%) 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	Flu Positive Control: 6/6 Positive ≤32 Ct FluAB/Covid NTC: ≤ 1/72 Positive ≤ 40 Ct	Pass