


## Certificate of Analysis

Product name	AzureSeq CE qPCR Kit SARS-CoV-2 for 200 Reactions
Reference number	AzureSeq-200 CE
LOT number	OMX3102 (22R05002, 21U06010, 22B30001, 22B32001)
Kit Assembling Date	2022-02-22
Expiration date	2023-01-18

## Components

Product Code	Product name	Pass/Fail*
OA-ITMP-MM-100	2X InhibiTaQ Multiplex HotStart MasterMix	Pass
OA-RT-200	RTScript Reverse Transcriptase, 200U/ $\mu$ L	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	2022-02-23

# Acceptance Criteria

Component	Assay name / Specification	Passing Result	Result
OA-ITMP-MM-100	<b>N1, N2 and RNase P qPCR amplification</b> 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
	<b>Unspecific dsDNA nucleases</b> HindIII digested Lambda DNA and dsRNA are incubated with 2x InhibiTag Multiplex Master at a concentration of 1x at 37°C for 1 hours. No detectable degradation of DNA via agarose gel electrophoresis.	Pass	Pass
	<b>N1/N2 EUA &amp; RNase P Amplicon Contamination</b> 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
	<b>Shelf life</b>	≥ 12 months	≥ 12 months
OA-RT-200	<b>DNase and RNase Activity</b> 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 RTScript Reverse Transcriptase at 37°C for 1 hour. No degradation is observed by gel electrophoresis.	Pass	Pass
	<b>RNase P, N1 and N2 COVID Contamination Assay</b> RTScript 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
	<b>E. coli DNA Contamination Assay</b> Not detectable before 40 cycles in qPCR Assay for E-coli DNA in presence of 100 Units of RTScript Reserve Transcriptase	Pass	Pass
	<b>Nicking Activity Assay</b> 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
	<b>Activity Assay</b> 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
	<b>Performance Test</b> 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
	<b>Single Stranded Exonuclease Assay</b> ssDNS probes are incubated with 100U of RTScript Reverse Transcriptase for 4 hours at 37°C. Results observed via qPCR analysis.	Pass	Pass
	<b>Human gDNA Contamination Assay</b> 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
	<b>Protein Purity</b> ≥95% as determined by SDS-PAGE		Pass
	<b>Shelf life</b>	≥ 12 months	≥ 12 months
OA-CPPM-100uL	<b>N1, N2 and RNase P qPCR amplification</b> 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
	<b>ssRNase</b> Single stranded RNA is incubated with CPPM at 37°C for 2 hours. No degradation is observed by gel electrophoresis.	Pass	Pass
	<b>Unspecific Endonucleases</b> dsEndonuclease: HindIII digested Lambda-DNA is incubated with CPPM at 37°C for 1 hour. No degradation is observed by gel electrophoresis.	Pass	Pass
	<b>N1/N2 EUA &amp; RNase P Amplicon Contamination</b> 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	<b>N1, N2 &amp; RNase P qPCR Amplification</b> 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
	<b>TB Performance and Contamination</b>	TBC Positive control: 8/8	Pass

	<p>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</p>	<p>IAC Positive Control <math>\geq 47/48</math> Positive <math>\leq 35</math> Ct TBC NTC: <math>\leq 1/88</math> positive <math>\leq 40</math> Ct IAC NTC: <math>1/40</math> positive <math>\leq 40</math> Ct</p>	
	<p><b>ssRNase</b> Single stranded RNA is incubated with CPPM at 37C for 2 hours. No degradation is observed by gel electrophoresis.</p>	<p>Pass</p>	<p>Pass</p>
	<p><b>Unspecific dsEndonucleases</b> 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>Pass</p>	<p>Pass</p>
	<p><b>N1, N2 EUA &amp; RNase P Amplicon Contamination</b> NFW is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. No amplification <math>&lt; 40</math> Ct (<math>&lt; 2\%</math>) is detectable.</p>	<p>Pass</p>	<p>Pass</p>
	<p><b>Influenza A/B Amplicon Contamination</b> NFW is used in multiplex qPCR reactions using primers specific to FluA/B template. No amplification <math>&lt; 40</math> Ct is detectable</p>	<p>Flu Positive Control: <math>6/6</math> Positive <math>\leq 32</math> Ct FluAB/Covid NTC: <math>\leq 1/72</math> Positive <math>\leq 40</math> Ct</p>	<p>Pass</p>