



# Certificate of Analysis



## AzureSeq CE qPCR Kit SARS-CoV-2 for 200 Reactions

Product name	AzureSeq CE qPCR Kit SARS-CoV-2 for 200 Reactions
Reference number	AzureSeq-200 CE
LOT number	OMX1840
Kit Assembling Date	2021.03.02.
Expiration date	2022.09.30.
Below data are based on the following documents:	20R05006; 20U06011; 20B30009; 20B32008

## AzureSeq-200 CE Components

Product Code	Product name	Pass/Fail*
OA-ITMP-MM-100	2X InhibiTaq Multiplex HotStart MasterMix	Pass
OA-RT-200	RTScript Reverse Transcriptase, 200U/uL	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>T. Deák</b>	Function	Laboratory Quality Coordinator
Signature		Sign date	2021.03.10
Name	<b>G. Adlovits</b>	Function	RAQS Manager
Signature		Sign date	2021.03.10

TITLE: AZURESEQ-200 CE\_v2

DOCUMENT NO. COA-01- AZURESEQ-200 CE

ISSUED: 2021-02-11

VERSION: 2

STATUS: CURRENT



# Acceptance Criteria

Component	Assay name / Specification	Passing Result	Result
OA-ITMP-MM-100	<b>qPCR Amplification</b> 2X InhibitTaq Multiplex Master Mix 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	Corresponds	Corresponds
	<b>Unspecific dsDNA nucleases</b> HindIII digested Lambda DNA is incubated with 2x InhibiTag Multiplex Master at a concentration of 1x at 37C for 16 hours. No detectable degradation of DNA via agarose gel electrophoresis.	Pass	Pass
	<b>N1/N2 EU amplicon Concentration:</b> 2X InhibitTaq Multiplex Master is used in multiplex qPCR reactions using primers specific to the SARA-Cov2 N1/N2 EUA Assay and RNase P. No amplification <40ct (<2%) is detectable.	Pass	Pass
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 37C there is no detectable degradation of DNA or RNA substrate as determined by agarose gel electrophoresis.	Not Detected	Not Detected
	<b>Nicking Activity</b> pBR322 supercoiled plasmid DNA is incubated with 100 Units of RTScript at 37C for 4 hours. No detectable nicking activity as determined by agarose gel electrophoresis.	Not Detected	Not Detected
	<b>Activity</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 37C. The test result is 200U/uL ± 15%	Corresponds	Corresponds
	<b>Performance Test</b> TScript Reverse Transcriptase is tested for performance in a 20uL RT-qPCR assay. Ct values are within 1Ct of control enzyme for each serial dilution of template	Corresponds	Corresponds
	<b>Single Stranded Exonuclease Assay</b> ssDNS probes are incubated with 100U of RTScript Reverse Transcriptase for 4 hours at 37C.	Not Detected	Not Detected
	<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>Shelf life</b>	≥ 12 months	≥ 12 months
OA-CPPM-100uL OA-NFW-350uL	<b>qPCR amplification</b> Components are tested for performance in multiplex qPCR reaction using primers specific to the SARS-Cov2 N1/N2 EUA Assays, and RNase P with copies of synthetic RNA and 1ng of UHRR. Successful amplification of synthetic RNA <40ct and UHRR <30ct.	Pass	Pass
	<b>ssRNase</b> Single stranded RNA is incubated with the components at 37C for 2 hours. No degradation is observed.	Pass	Pass
	<b>Unspecific Endonucleases</b> dsEndonuclease: HindIII digested Lambda-DNA is incubated with the components at 37C for 1 hour. No degradation is observed.	Pass	Pass
	<b>N1/N2 EU Amplicon concentration</b> Components are used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNase P. No amplification <40ct (<2%) is detectable	Pass	Pass