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	OMX1404(20R05004; 20U06008; 20B30006; 20B32005)
Kit Assembling Date	2020.10.15
Expiration date	2021.09.09

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	**Dr. G. Tölgyesi**	**Function**	**Head of Assay**
Signature		**Sign date**	**2020.10.15**
Name	**G. Adlovits**	**Function**	**RAQS Manager**
Signature		**Sign date**	**2020.10.15**

Acceptance Criteria

Component	Assay name / Specification	Passing Result	Result
OA-ITMP-MM-100	**qPCR Amplification** 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
	Unspecific dsDNA nucleases HindIII digested Lambda DNA is incubated with 2x InhibiTaq Multiplex Master at a concentration of 1x at 37C for 16 hours. No detectable degradation of DNA via agarose gel electrophoresis.	Pass	Pass
	N1/N2 EU amplicon Concentration: 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	**DNasa 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 37C there is no detectable degradation of DNA or RNA substrate as determined by agarose gel electrophoresis.	Not Detected	Not Detected
	Nicking Activity 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
	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 37C. The test result is 200U/uL ± 15%	Corresponds	Corresponds
	Performance Test TScript Revers 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
	Single Stranded Exonuclease Assay ssDNS probes are incubated with 100U of RTScript Reverse Transcriptase for 4 hours at 37C.	Not Detected	Not Detected
	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
	Shelf life	≥ 12 months	≥ 12 months
OA-CPPM-100uL OA-NFW-350uL	**qPCR amplification** 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 os synthetic RNA <40ct and UHRR <30ct.	Pass	Pass
	ssRNAse Single stranded RNA is incubated with the componentsat 37C for 2 hours. No degradation is observed.	Pass	Pass
	Unspecific Endonucleases dsEndonuclease: HindIII digested Lambda-DNA is incubated with the conponentsat 37C for 1 hour. No degradation is observed.	Pass	Pass
	N1/N2 EU Amplicon concentration Compoents 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