OMIXON BIOCOMPUTING LTD.
H-1117 BUDAPEST, KAPOSVÁR u 14-18.
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# Certificate of Analysis

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|---|---|
| Product name | AzureSeq 4 CE qPCR Kit for 200 Reactions |
| Reference number | AzureSeq 4-200 CE |
| LOT number | OMX3895 (22R05010, 22B32006, 22B33001, 21B31005, 22B40001, 22B41002, 22C06005) |
| Kit Assembling Date | 2022-11-30 |
| Expiration date | 2023-03-23 |

# Components

| Product Code | Product name | Pass/Fail* |
|---|---|---|
| **OA-ITMP-MM-100** | 2X InhibiTaq Multiplex HotStart MasterMix | Pass |
| **OA-RTM-200** | RT Mix | Pass |
| **OA-CPPM4-100** | CoVi PLUS Primer/Probe Mix 4 | Pass |
| **OA-NFW-350uL** | Nuclease Free Water | Pass |
| **OA-CVNC-150** | CoVi Negative Control | Pass |
| **OA-CVPC-150** | CoVi Positive Control | Pass |
| **OA-FABPC-150** | Flu A/B Positive Control | Pass |

*for acceptance criteria see second page.

| Authorization for release | | | |
|---|---|---|---|
| Name | **A Németi** | **Function** | **Manufacturing Quality Engineer** |
| Signature |  | **Sign date** | **2022-12-05** |

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# Acceptance Criteria

| Component | Assay name / Specification | Passing Result | Result |
|---|---|---|---|
| OA-ITMP-MM-100 | **N1, N2 and RNase P qPCR amplification**<br>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**<br>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**<br>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-RTM-200 | **Performance Test:**<br>RT Mix is used for performance in multiplex qPCR reactions using primers specific to th SARS-Cov2 N1/n2 EUA Assays. Inactivated virus spiked into negative swab sample + VTM@10cp/uL. ≥19/20 Replicates amplify <40ct. | Pass | Pass |
| | **Covid RNAse P, N1/N2 EUA Amplicon Contamination Assay:**<br>RT Mix ix used as the template in RT-qPCR reactions with InhibiTaq Multiplex Master Mix at 1x using primers specific to the SARS-Cov2 N1/N2 EUA Assays and RNAse P. 88 NTC showing amplification before 45Ct. Positive control amplification in the determined Ct range. | Pass | Pass |
| | **Unspecific Endonucleases:**<br>HindIII digested Lambda-NDA and dsRNA are incubated with RT Mix at 37C for 1 hour. No degradation is observed via gel electrophoresis. | Pass | Pass |
| | **N1 EUA, FluA and FluB Amplicon Contamination:**<br>RT Mix is used in multiplex qPCR reactions using primers specific to the SA of 72 reactions) RS-Cov2 N1 EUA Assay, FluA, FluB, and RNAse P. No amplification <40ct (in ≤ is detectable) | Pass | Pass |
| OA-CPPM4-100 | **qPCR Amplification:**<br>Covi Primer/Probe Mix 4 is tested for performance in multiplex q PCR reactions using primers specific to the SARS-Cov2 N1 EUA Assays, and RNAse P with 100 copies of synthetic RNA, 500 copies FluA and FluB Synthetic RNA and 1 ng of UHRR. Successful amplification of synthetic RNA <40 ct. FluA and FluB Synthetic RNA <40ct, and UHRR <30ct. | Pass | Pass |
| | **SSRNAse:**<br>Single-Stranded RNA is incubated with Covi Primer/Probe Mix 4 at 37C or 2 hours. No degradation is observed by gel electrophoresis. | Pass | Pass |
| | **Unspecific endonucleases:**<br>dsEndonuclease: HinIII digested Lambda-DNA and dsRNA are incubated with Covi Primer/Probe Mix 4 at 37C for 1 hour. No degradation is observed by gel electrophoresis. | Pass | Pass |
| | **N1 EUA, FluA and FluB Amplicon Contamination:**<br>Covi Primer/Probe Mix 4 is used in multiplex qPCR reactions using primers specific to the SARS-Cov2 N1 EUA Assay, FluA, FluB and RNAse P. no amplification <40ct (2%) is detected. | Pass | Pass |
| OA-NFW-350uL | **N1, N2 & RNAse P qPCR Amplification**<br>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<br>4/4 positive controls amplification the specified Ct range | Pass |
| | **TB Performance and Contamination**<br>Nuclease Free Water is used in a qPCR reaction to amplify DNA from Mycobacterium tuberculosis complex (TB). Nuclease Free Water is also used as | TBC Positive control: 8/8 | Pass |

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|---|---|---|---|
| | 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 |
| **OA-CVNC-150** | **qPCR Amplification:** CoVI NC is tested for performance in multiplex q PCR reactions 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 <40ct, and UHRR <30ct. | Pass | Pass |
| | **ssRNase** Single stranded RNA is incubated with CoVi NC at 37C for 2 hours. No degradation is observed. | Pass | Pass |
| | **Unspecific dsEndonucleases** dsEndonuclease: HindIII digested Lambda-DNA is incubated with CoVi NC at 37°C for 2 hours. No degradation is observed. | Pass | Pass |
| | **N1, N2 EU Amplicon Contamination** CoVi NC 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 |
| **OA-CVPC-150** | **qPCR Amplification:** CoVI PC is tested for performance in multiplex q PCR reactions 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 <40ct, and UHRR <30ct | Pass | Pass |
| **OA-FABPC-150** | **qPCR Amplification:** Flu A/B Positive Control is tested for performance in multiplex qPCR reactions using primers specific to the Influenza A M1 and Influenza B NS2 gene. Successful amplification of all targets<34ct. | Pass | Pass |