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EMERGENCY USE AUTHORIZATION (EUA) SUMMARY HEALTHQUEST ESOTERICS TAQPATH SARS-COV-2 ASSAY (HEALTHQUEST ESOTERICS)

For in vitro diagnostic use
Rx only
For use under Emergency Use Authorization (EUA) Only

(The HealthQuest Esoterics TaqPath SARS-CoV-2 Assay will be performed at HealthQuest Esoterics, a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory, per the laboratory procedures that were reviewed by the FDA under this EUA).

INTENDED USE

The HealthQuest Esoterics TaqPath SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swabs, as well as nasopharyngeal wash/aspirate or nasal aspirates, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider.

Testing is limited to HealthQuest Esoterics located in Irvine, CA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high-complexity tests.

Results are for the detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The HealthQuest Esoterics TaqPath SARS-CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The HealthQuest Esoterics TaqPath SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) test. The assay uses primers and probes that were developed and validated under the Emergency Use Authorization (EUA) for the ThermoFisher TaqPath COVID-19 Combo Kit and are designed to detect RNA from SARS-CoV-2 in respiratory specimens from patients as recommended for testing by public health authority guidelines.

Anterior nasal swabs, mid-turbinate nasal swabs, oropharyngeal (throat) swabs, nasopharyngeal swabs, nasopharyngeal wash/aspirate or nasal aspirate specimens, and BALs should be collected, transported and stored according to standard procedures. The swabs that were used for assay validation include Puritan PurFlock Ultra Collection swabs (Cat # 25-3317-U and 25-3606-U) transported using ClearPrep Specimen Transport Medium (Biomedical Solutions, Cat # CV12001). Other flocked swabs with plastic shafts in appropriate transport media discussed in the Clinical Laboratory Diagnostics Test FAQs (UTM, VTM, saline, PBS) are also acceptable for testing with the HealthQuest Esoterics assay. BAL specimens are collected in sterile containers without preservative matrix and subsequently transferred to the ClearPrep transport tube. Samples (swab/wash/aspirate/BAL) that cannot be processed immediately upon receipt can be stored at 4^{o}C for up to 72 hours prior to testing. If samples cannot be shipped right after collection or will not be processed within 72 hours of receipt, specimens should be stored at -70°C.

RNA extraction for all specimen types is performed using the Perkin Elmer Chemagic Viral DNA/RNA 300 Kit H96 on the Chemagic 360 extraction instrument with software version 6.3.0.3. The input sample volume is 300 µL and the elution volume is 50 µL. Samples are prepared for extraction and RT-PCR using the automated Janus G3 workstation (software 5.5.48) liquid handling system.

Reverse transcriptase-PCR (RT-PCR) is performed using the QuantStudio 12K Flex Real-Time PCR System with 10 µL of the extracted sample.

INSTRUMENT USED WITH THE TEST

The HealthQuest Esoterics TaqPath SARS-CoV-2 Assay is for use with the QuantStudio 12K Flex Real-Time PCR System with software version 1.3.

The HealthQuest Esoterics TaqPath SARS-CoV-2 Assay can be used with the following extraction and liquid handling instruments, respectively:

- Perkin Elmer Chemagic 360 extraction instrument with software version 6.3.0.3
- Janus G3 automated workstation with WinPREP software version 5.5.48

REAGENTS AND MATERIALS

Table 1. Reagents and materials required for use of the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay

Reagent	Manufacturer	Catalogue #
Chemagic Viral DNA/RNA 300 Kit H96 • Magnetic Beads • Lysis Buffer 1 • Binding Buffer 2 (added automatically) • Wash Buffer 3 (added automatically) • Wash Buffer 4 (added automatically) • Elution Buffer 5 • Poly(A) RNA • Proteinase K • Nuclease-free Water (not DEPC-Treated)	Perkin Elmer	CMG-1033-S*
TaqPath COVID-19 Combo Kit, 1000 reactions	Applied Biosystems by ThermoFisher Scientific	A47814
TaqPath 1-Step Multiplex Master Mix (No ROX)	Applied Biosystems by ThermoFisher Scientific	A28521
ABY Dye Spectral Calibration Plate for Multiplex qPCR, 384-well	Applied Biosystems by ThermoFisher Scientific	A24736
JUN Dye Spectral Calibration Plate for Multiplex qPCR, 384-well	Applied Biosystems by ThermoFisher Scientific	A24733
OpenArray 384-well Sample Plates[a]	Applied Biosystems by ThermoFisher Scientific	4406947
MicroAmp Adhesive Film Applicator	Applied Biosystems by ThermoFisher Scientific	4333183
MicroAmp Optical Adhesive Film	Applied Biosystems by ThermoFisher Scientific	4311971
MicroAmp Clear Adhesive Film	Applied Biosystems by ThermoFisher Scientific	4306311

*CMG-1033-S is a viral DNA/RNA extraction kit containing all components listed above.
[a] The Janus G3 liquid handling system combines 4 x 96 well plates used for extraction to one 384 well plate (4406947) which is subsequently used for RT-PCR on the QuantStudio 12K Flex.

CONTROLS TO BE USED WITH THE COVID-19 RT-PCR

The controls used with the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay are described in Table 2.

Table 2. Controls Used with the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay

Control Type	Purpose	Frequency of Testing
Positive Control	To monitor the integrity of the RT-PCR reagents and process	Two per run of RT-PCR
Negative Extraction Control (NEC)	To monitor for cross-contamination during RNA extraction and RT-PCR	Two negative extraction controls per batch of specimens and per run of RT-PCR
Internal (MS2 Phage) Control	To monitor the integrity of nucleic acid extraction and RT-PCR for each specimen	Added to each specimen and the Negative Control prior to extraction
No Template Control (NTC)	To monitor for contamination of extraction and assay reagents	Once per run of RT-PCR

The results from the controls are interpreted according to the criteria shown in Table 3. If the results obtained with the Positive, Extraction, and No Template Controls do not meet the criteria shown, the results from the entire batch of samples are considered invalid and repeat testing must be performed using new extracted material. If any of the above controls do not exhibit the expected performance as described, the assay may have been improperly set up and/or executed improperly, or reagent or equipment malfunction could have occurred. The run is invalidated and the entire assay including extraction and RT-PCR is repeated using residual clinical specimen contained within the transport medium. Given that the extraction procedure only uses 300 µL of sample material and the ClearPrep tube contains 3 mL of media, sufficient clinical sample should remain for re-extraction and RT-PCR.

INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted (Refer to Table 3 for a summary of control results).

1) ***TaqPath SARS-CoV-2 RT-PCR Test Controls – Positive, Negative, Extraction, and Internal:***

- **MS2 (Internal Positive Control);** MS2 in a sample indicates that PCR amplification occurred in the well. The presence of MS2 and no detectable SARS-CoV-2 during the analysis indicates that proper RNA extraction and amplification occurred, however, no SARS-CoV-2 is present. If SARS-CoV-2 is present in the specimen, amplification of the target RNA may reduce or abrogate MS2 amplification. In this case, the amplified SARS-CoV-2 indicates proper RNA extraction and amplification. Therefore, MS2 may or may not be detectable in a valid test on patient specimens.

- **External Positive Control;** The positive control must be positive for all three SARS-CoV-2 targets, i.e., the ORF1ab, the N Protein, and the S Protein genes and amplification must have a Ct <37 in order for the test result to be valid. The positive control does not contain MS2.

- **No Template Control (NTC);** The no template control only consists of DNase-RNase free water. The NTC must be negative (undetermined) for all assay targets in order for the test result to be valid.

- **Negative Extraction Control (NEC);** Although not supplied with the ThermoFisher TaqPath Combo Kit, HealthQuest Esoterics runs two negative extraction controls with each batch of samples. A characterized negative human specimen with a spike-in of MS2 control serves as the NECs. Results for the NECs should only show an amplification curve for MS2 with a Ct <37 and must be negative for all SARS-CoV-2 targets (Ct undetermined).

Table 3. Ct Values for Controls That Must be Observed to Obtain Valid Results

Control	Ct Value (Optical Channel)			
	N Gene (VIC)	S Gene (ABY)	ORF1ab (FAM)	MS2 Phage (JUN)
Negative Extraction Control	Undetermined >37	Undetermined >37	Undetermined >37	<37
Positive Control	<37	<37	<37	Undetermined [1] >37
No Template Control	Undetermined >37	Undetermined >37	Undetermined >37	Undetermined [1] >37
MS2 Internal Control	Any	Any	Any	<37

Undetermined/Negative (Ct > 37 or No Detectable Ct)

[1] The MS2 Phage Internal Control is not added to the Positive Control or No Template Control and no signal should be generated.

2) ***Examination and Interpretation of Patient Specimen Results:***

Assessment of clinical specimen test results should be performed after the positive, extraction, and NTC controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted. Please see the table below (Table 4) for guidance on interpretation and reporting of results.

Table 4. Result Interpretation for Patient Samples

ORF1ab (FAM)	N gene (VIC)	S gene (ABY)	MS2 (JUN)	Status	Result	Action
NEG	NEG	NEG	NEG	Invalid	N/A	Repeat extraction and RT-PCR using residual specimen. If the repeat result remains invalid, consider collecting a new specimen.
NEG	NEG	NEG	POS	Valid	SARS-CoV-2 Not detected	Report results to healthcare provider. Consider testing for other viruses.
Only one SARS-CoV-2 target = POS			POS or NEG	Valid	Positive SARS-CoV-2	Report results to healthcare provider and appropriate public health authorities.
Two or more SARS-CoV-2 targets = POS			POS or NEG	Valid	Positive SARS-CoV-2	Report results to healthcare provider and appropriate public health authorities.

NEG; Undetermined (Ct > 37 or No Detectable Ct)
POS; Ct < 37

PERFORMANCE EVALUATION

1) Analytical Sensitivity

The LoD of the HealthQuest Esoterics TaqPath SARS-CoV-2 assay was determined using targeted fragments of SARS-CoV-2 viral RNA (ORF1ab, S, and N transcripts) (Thermo Fisher; TaqPath COVID-19 Positive Control, Cat # A47814) at several concentrations that was diluted in SARS-CoV-2 negative, pooled nasopharyngeal swab matrix. An initial estimate of the LoD with the Applied Biosystems QuantStudio 12K Flex was obtained by testing three replicates at each of six different target levels: 100, 50, 40, 30, 20, and 10 copies/µL. The lowest level at which all three replicates were positive for all three SARS-CoV-2 targets was 10 copies/µL (Table 5). The estimated LoD was confirmed by testing additional extraction replicates at the same target level and at 20 copies/µL. All 30 replicates produced the expected results for each SARS-CoV-2 target at 20 copies/µL, and the LoD was therefore confirmed to be 20 copies/µL (Table 6).

Table 5. Preliminary LoD Determination Results

Concentration (copies/µL)	ORF1ab		N Gene		S Gene		MS2 (IC)	
	Detection Rate (%)	Mean Ct (SD)	Detection Rate (%)	Mean Ct (SD)	Detection Rate (%)	Mean Ct (SD)	Detection Rate (%)	Mean Ct (SD)
100	3/3 (100)	26.6 (2.4)	3/3 (100)	26.1 (0.1)	3/3(100)	25.4 (0.2)	3/3 (100)	26.7 (0.4)
50	3/3 (100)	26.7 (0.1)	3/3 (100)	26.9 (0.1)	3/3 (100)	26.2 (0.1)	3/3 (100)	27.6 (0.4)
40	3/3 (100)	27.3 (0.1)	3/3 (100)	27.3 (0.1)	3/3 (100)	26.0 (0.6)	3/3 (100)	27.4 (0.5)
30	3/3 (100)	27.5 (0.3)	3/3 (100)	27.8 (0.2)	3/3 (100)	26.9 (0.2)	3/3 (100)	28.7 (2.5)
20	3/3 (100)	28.2 (0.2)	3/3 (100)	27.9 (0.2)	3/3 (100)	28.0 (0.2)	3/3 (100)	28.4 (0.2)
10	3/3 (100)	29.2 (0.3)	3/3 (100)	28.3 (0.3)	3/3 (100)	28.6 (0.2)	3/3 (100)	29.2 (0.3)
Negative	0 (0)	NA	0 (0)	NA	0 (0)	NA	10/10 (100)	29.1 (0.3)

Table 6. Confirmatory LoD Study Results for Nasopharyngeal Swab Specimens

Concentration (copies/µL)	ORF1ab		N Gene		S Gene		MS2 (IC)	
	Detection Rate (%)	Mean Ct (SD)	Detection Rate (%)	Mean Ct (SD)	Detection Rate (%)	Mean Ct (SD)	Detection Rate (%)	Mean Ct (SD)
20	30/30 (100)	27.3 (0.3)	30/30 (100)	28.1 (0.3)	30/30 (100)	27.3 (0.3)	30/30 (100)	27.1 (0.4)
10	8/10 (80)	30.2 (1.1)	8/10 (80)	31.4 (2.0)	8/10 (80)	30.3 (1.4)	10/10 (100)	27.6 (0.8)

Ct values represent those with valid positive results (Ct < 37)

2) Analytical Specificity

In Silico Inclusivity

The HealthQuest Esoterics TaqPath SARS-CoV-2 Assay is a modification of the previously authorized ThermoFisher Applied Biosystems TaqPath COVID-19 Combo Kit. The assay targets specific genomic regions of the SARS-CoV-2 nucleocapsid (N) gene, spike (S) gene, and ORF1ab region. Inclusivity was demonstrated under the original ThermoFisher EUA and a right of reference to use their inclusivity data was provided to HealthQuest Esoterics on

June 2, 2020. Briefly, the primers and probes were mapped to 185 complete SARS-CoV-2 genomes that were available in the GenBank and GISAID (Global Initiative on Sharing All Influenza Data) databases as of March 5, 2020. For all primers and probes, there was 100% homology to each of the SARS-CoV-2 sequences analyzed, with one exception; a single base mismatch (95.6% homology) with the reverse primer for ORF1ab in sequence EPI_ISL_407084 (BetaCoronavirus/Japan/AI/I-004/2020). The mismatch is located at the 5′ end of the primer and is not expected to affect test performance.

In Silico Cross-Reactivity

The analytical specificity of the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay was demonstrated *in silico* under the original EUA for the ThermoFisher Applied Biosystems TaqPath COVID-19 Combo Kit. As stated previously, a right of reference to use ThermoFisher's exclusivity data was given to HealthQuest Esoterics. The analysis included evaluation of the primer and probe homology with the 43 organisms and viruses listed in Table 7.

Among the tested organisms, *Neisseria elongata* showed homology for the forward and reverse primers and probe for the N gene. The forward primer showed ≥80% homology while the reverse primer and probe showed 36% homology. The N gene reverse primer and probe show low homology; therefore, the risk of the non-specific amplification is low. Blast analysis showed ≥80% homology for one assay component (forward primer, reverse primer, or probe) for select isolates. Despite ≥80% homology of one assay component for select isolates, there is no anticipated amplification because hybridization of the forward and reverse primers and probe are necessary to generate a signal. ThermoFisher also indicated that there were multiple instances where different assay components had ≥80% homology to different isolates of the same species. For example, *Bacillus anthracis* strain AFS029987 had ≥80% homology to the ORF1ab forward primer while strain MCCC 1A01412 had ≥80% homology to the ORF1ab reverse primer.

Based on this analysis, significant amplification of non-target sequences that could result in cross-reaction (false-positive results) or interference (false-negative results) were considered unlikely to occur.

Table 7. Organisms and Viruses Evaluated for Potential Cross-Reaction and/or Interference with the Applied Biosystems TaqPath COVID-19 Combo Kit

Viruses	Bacteria
Adenovirus	*Bacillus anthracis*
Enterovirus	*Bordetella pertussis*
Human coronavirus 229E	*Chlamydophila pneumoniae*
Human coronavirus HKU1	*Chlamydophila psittaci*
Human coronavirus NL63	*Corynebacterium diphtheriae*
Human coronavirus OC43	*Coxiella burnetii*
Human Metapneumovirus (hMPV)	*Haemophilus influenzae*
Influenza A, B and C	*Legionella* (non-pneumophila)
MERS-coronavirus	*Legionella pneumophila*
Parainfluenza 1-4	*Leptospira* sp.
Parechovirus	*Moraxella catarrhalis*

Viruses	Bacteria
Respiratory Syncytial Virus A and B	*Mycobacterium tuberculosis*
Rhinovirus/Enterovirus	*Mycoplasma pneumoniae*
SARS-coronavirus	*Neisseria elongata* and *Neisseria meningitidis*
Yeast/Fungus	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus*
Pneumocystis jirovecii	*Staphylococcus epidermidis*
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Streptococcus salivarius

3) Clinical Evaluation

Testing of Real Clinical Patient Samples

Performance of the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay was evaluated using clinical nasopharyngeal swab specimens that were previously tested at the Orange County Health Department using the CDC's 2019-CoV Real-Time RT-PCR Diagnostic Panel (EUA200001). All positive and negative clinical samples were extracted using the Chemagic Viral DNA/RNA Kit on the Chemagic automated instrument and evaluated with the HealthQuest Esoterics TaqPath Assay on the QuantStudio 12K Flex Real-Time PCR System.

For the 34 negative clinical nasopharyngeal swab samples, the negative percent agreement (NPA) between the HealthQuest Esoterics assay and the authorized assay used as a comparator was 100%. Similarly, for the 35 clinical NP positive samples that were evaluated, 35/35 tested positive (100% PPA) using the HealthQuest Esoterics assay. Qualitative results of the clinical evaluation are shown in Table 8.

Table 8. Summary of Qualitative Clinical Study Results

		EUA Authorized Comparator Assay		
		Positive	**Negative**	**Total**
HealthQuest Esoterics TaqPath SARS-CoV-2 Assay	**Positive**	35	0	35
	Negative	0	34	34
	Total	35	34	69
Positive Agreement		100.00% (35/35); 90.11-100.00% [1]		
Negative Agreement		100.00% (34/34); 89.85-100.00%		

[1]Two-sided 95% score confidence intervals

Contrived Clinical Evaluation

A total of 75 contrived positive samples were prepared by spiking known concentrations of extracted SARS-CoV-2 targeted RNA fragments (ThermoFisher; TaqPath COVID-19 Positive Control), relative to the assay's LoD, into negatively screened nasopharyngeal swab matrix. All matrices were screened negative prior to spiking with the HealthQuest Esoterics TaqPath Assay. In addition, 34 negative clinical matrix samples were also tested. Samples were blinded and randomized for testing and RNA was extracted using the Chemagic Viral DNA/RNA 300 Kit H96 on the Chemagic extraction instrument. Testing was performed in one RT-PCR run on the QuantStudio 12K Flex with two

positive controls, two negative extraction controls, and one NTC. Results of the study are summarized below (Table 9).

Table 9. Clinical Evaluation Using Contrived Samples

Copies/ µL	Replicates	Analysis	Target (Optical Channel)			
			N Gene	S Gene	ORF1ab	MS2
0	34	Positive (%)	0 (0)	0 (0)	0 (0)	34 (100)
		Mean Ct (SD, %CV)	N/A	N/A	N/A	28.9 (2.0, 7.0)
10	3	Positive (%)	3 (100)	3 (100)	3 (100)	3 (100)
		Mean Ct (SD, %CV)	29.1 (0.2. 0.8)	28.2 (0.1, 0.4)	28.6 (0.2, 0.6)	27.0 (0.3,1.1)
20	30	Positive (%)	30 (100)	30 (100)	30 (100)	30 (100)
		Mean Ct (SD, %CV)	28.4 (0.2, 0.6)	27.4 (0.3, 1.1)	27.8 (0.3, 1.1)	26.9 (0.6, 2.1)
30	18	Positive (%)	18 (100)	18 (100)	18 (100)	18 (100)
		Mean Ct (SD, %CV)	27.9 (0.7, 2.4)	26.8 (0.7, 2.7)	27.0 (0.4, 1.6)	27.5 (1.9, 6.9)
40	18	Positive (%)	18 (100)	18 (100)	18 (100)	18 (100)
		Mean Ct (SD, %CV)	27.6 (0.5, 1.8)	26.6 (0.2, 0.7)	26.9 (0.2, 0.7)	27.6 (0.4, 1.5)
50	3	Positive (%)	3 (100)	3 (100)	3 (100)	3 (100)
		Mean Ct (SD, %CV)	26.9 (0.1, 0.5)	26.0 (0.1, 0.4)	26.4 (0.1, 0.3)	28.8 (0.7, 2.3)
100	3	Positive (%)	3 (100)	3 (100)	3 (100)	3 (100)
		Mean Ct (SD, %CV)	26.3 (0.1, 0.5)	25.2 (0.1, 0.3)	25.2 (0.3, 0.2)	32.0 (0.8, 2.6)

Clinical Confirmation

The first 5 positive and first 5 negative nasopharyngeal specimens as determined by HealthQuest Esoterics using the TaqPath SARS-CoV-2 Assay were also tested by Vitae Laboratories utilizing the 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC EUA authorized assay). There was 100% (5/5) positive and negative agreement for the specimens tested. These results are acceptable and support use of the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay for testing clinical specimens.

WARNINGS:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The extraction method and instrument used were Chemagic 360 for extraction and a QuantStudio 12k flex for RT-PCR. The results are summarized in the following Table.

Table 10. Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal Swab	$1.8x10^4$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND: Not detected