Evaluating the use of Copan eNAT® and E&O VPSS transport media types for SARS-CoV-2 testing on the NeuMoDx™ random access RT-PCR platform

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Introduction
The COVID-19 pandemic, caused by the SARS-CoV-2 virus, has caused 15,953,685 confirmed cases and 153,196 confirmed deaths (up until 24/01/2022) in the United Kingdom alone (GOV.UK, 2022). Therefore, the need for quick and reliable molecular testing has risen exponentially.

The workload of all Molecular laboratories has increased. To ensure laboratories meet this new, unprecedented large screening capacity – high throughput diagnostic assays are needed.

To meet this demand, the Microbiology and Infection Control Laboratory of NHS Fife have introduced a NeuMoDx™ 96 molecular system; a fully automated, qualitative real-time RT-PCR system capable of the extraction and isolation of nucleic acids, as well as amplification and detection of target sequences by fluorescence-based PCR. The NeuMoDx™ 96 molecular system represents a completely new methodology and workflow.

The system was initially verified using Copan Universal Transport Medium (UTM) (BD™ Universal Viral Transport System (UVT) from nasopharyngeal, oropharyngeal, and nasal swabs (NeuMoDx™ SARS-CoV-2 Assay IFU, 2020).

Experiment 1

For experiment 1 (Figure 2), all 28 previously SARS-CoV-2 detected nasopharyngeal samples collected in eNAT® Copan were confirmed using the NeuMoDx™ SARS-CoV-2 assay. In addition, all 32 previously SARS-CoV-2 detected nasopharyngeal samples collected in eNAT® Copan were also confirmed.

The specific gene targets detected by both assays differ; however, the qualitative result will be evaluated.

The goal of Experiments 1 and 2 was to evaluate the laboratory’s current transport systems; Copan eNAT® and E&O VPSS; and to compare the sensitivity and specificity of each transport system to the gold standard protocols.

NeuMoDx™ analyser’s capability to continuously load and unload specimens in a non-batch format, allows for more samples to be tested as required, rather than delaying for a batch to be accrued, and continuous release of results allows for speedier patient management.

The entire process takes place on-board, compared with the current protocol. Once the analysis and specimen have been loaded, no operator intervention is required, releasing operators and reducing opportunity for error.

Reagents are ready to use, so training in fine volume liquid handling is not required; enabling the system to be operated by non-HCPC registered staff, releasing time for the molecular BMS, who is only required to perform result release.

Further Work

Further Work

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References


2. NeuMoDx™ SARS-CoV-2 Assay Instructions For Use (2020).

3. altona Diagnostics RealStar® SARS-CoV-2 Kit 1.0 by altona Diagnostics, on the QIAsymphony/RotorGene Q platform; and ‘N’ and ‘Nsp2’ detected by NeuMoDx™. However, the confirmed detection of SARS-CoV-2 without exception demonstrates the NeuMoDx™ compares favourably to the current methodology in detecting SARS-CoV-2 in nasopharyngeal samples in both collection systems.

As shown in Figure 4, calculated Sensitivity and Specificity of 100% compared well with the IFU, with both gene targets being detected in each previously confirmed detected sample. The estimated TAT is significantly shorter when run using the NeuMoDx™ over the laboratory’s gold standard test; with a difference of 145 minutes, allowing for further testing capacity (Figure 5).

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