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

Daniel Baird, Alana Muir, Lisa Logan, Dr. Mairiead MacLennan

Department of Medical Microbiology & Infection Control
Victoria Hospital, Hayfield Road, Kirkcaldy, Fife, KY2 5AG

Keywords: PCR, SARS-CoV-2, COVID-19, NeuMoDx™, eNAT®, VPSS

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-RT®) and BD™ Universal Viral Transport System (UVT) from nasopharyngeal, oropharyngeal, and nasal swabs (NeuMoDx™ SARS-CoV-2 Assay IFU, 2020).

The aim of this study was to evaluate and validate the laboratory's current transport systems; Copan eNAT® and E&O VPSS; and to compare to the currently validated and UKAS accredited gold standard process using RealStar® SARS-CoV-2 RT-PCR Kit 1.0 by altona Diagnostics, on the QIAsymphony and Rotor-Gene Q analysers (RealStar® SARS-CoV-2 IFU, 2021).

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

Methods

Experiment 1

Stored[1] SARS-CoV-2 Detected nasopharyngeal samples collected in both eNAT® Copan and E&O VPSS media.

↓

Samples tested to confirm that the NeuMoDx™ SARS-CoV-2 assay would detect the virus if collected in currently used laboratory consumables.

↓

Compare NeuMoDx™ result with original to ensure qualitative result is the same, and similar sensitivity and specificity are seen.

Experiment 2

SARS-CoV-2 nasopharyngeal samples, collected in both eNAT® Copan and E&O VPSS media, received for COVID-19 PCR testing.

↓

Samples first tested using laboratory's gold standard protocols[2] for COVID-19 PCR testing.

↓

Samples then tested using the NeuMoDx™ SARS-CoV-2 assay.

↓

Compare NeuMoDx™ result with gold-standard result to ensure qualitative result is confirmed and similar sensitivity and specificity are seen.

Figure 1: Methods used for all experiments in the study. [1.]Detected SARS-CoV-2 nasopharyngeal samples (stored at -80°C). [2.]Gold standard protocols involve using RealStar® SARS-CoV-2 RT-PCR Kit 1.0 by altona Diagnostics on the QIAsymphony and Rotor-Gene Q analysers OR using SARS-CoV-2 Respiratory Panel by QIAGEN on the QIAstat-Dx analyser.

Experiment 1 consisted of 28 previously confirmed detected SARS-CoV-2 nasopharyngeal samples collected in eNAT® Copan medium; and 32 previously confirmed detected SARS-CoV-2 nasopharyngeal samples collected in E&O VPSS medium.

Experiment 2 consisted of 64 SARS-CoV-2 nasopharyngeal samples collected in eNAT® Copan medium, and 120 SARS-CoV-2 nasopharyngeal samples collected in E&O VPSS medium.

Results

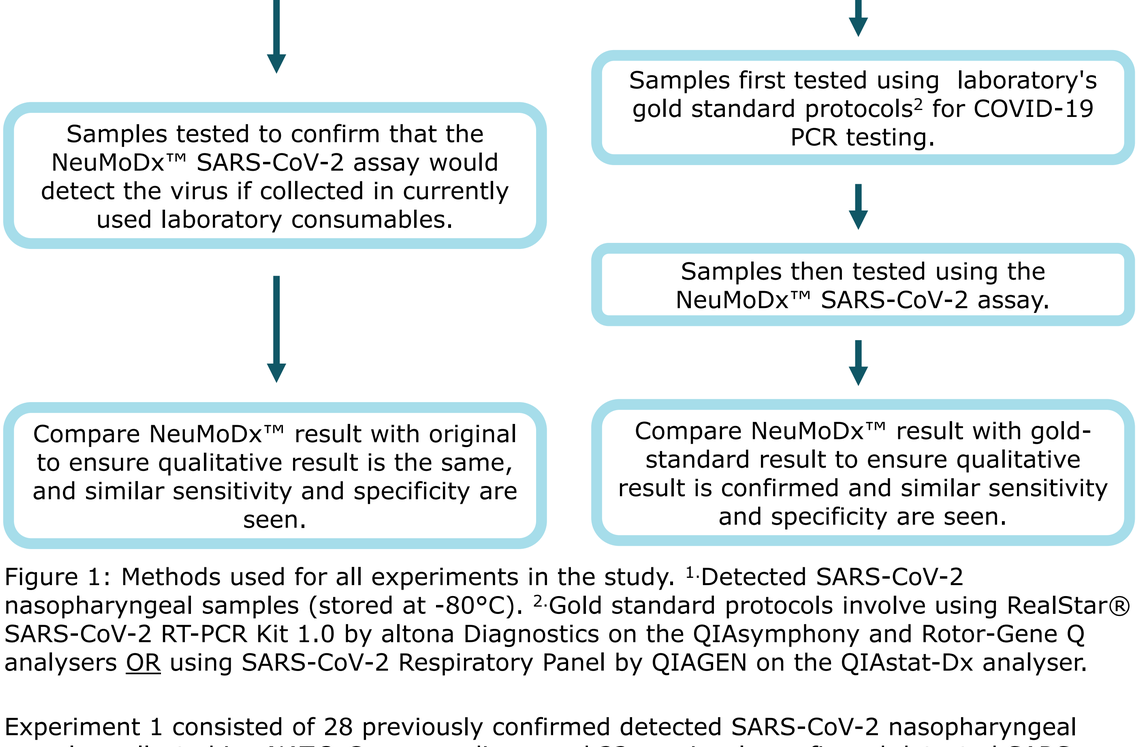

Figure 2: Graph detailing Experiment 1 results confirming the detection of SARS-CoV-2 in both eNAT® Copan and E&O VPSS transport media.

	NeuMoDx Protocol (N + Nsp2) / Gold Standard Protocol			
Gold Standard Protocol	**DET/DET**	**DET/NOD**	**NOD/DET**	**NOD/NOD**
QIAsymphony/Rotor-Gene Q (eNAT® Copan) (S + E)	30	0	0	34
QIAsymphony/Rotor-Gene Q (E&O VPSS) (S + E)	43	0	0	77

Figure 3: Table detailing Experiment 2 results comparing detection of SARS-CoV-2 in each transport media on both protocols.

Statistic	Value	95% C.I.
Sensitivity	100.00%	97.62% to 100.00%
Specificity	100.00%	96.97% to 100.00%

Figure 4: Table detailing statistical analysis of Experiments 1 and 2.

Analyser(s)	Turnaround Time	% Change
QS/RGQ	234 minutes	0%
NeuMoDx™	89 minutes	**-62.2%**

Figure 5: Table detailing turnaround time (TAT) and the percentage change in TAT from testing between protocols.

Discussion

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.

For experiment 2 (Figure 3), the comparison between two distinct platform/assay combinations is not direct because the principles and genes detected differ: 'S' and 'E' detected with the QIAsymphony/Rotor-Gene 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).

The 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 onboard, compared with the current protocol. Once the analyser and specimens 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.

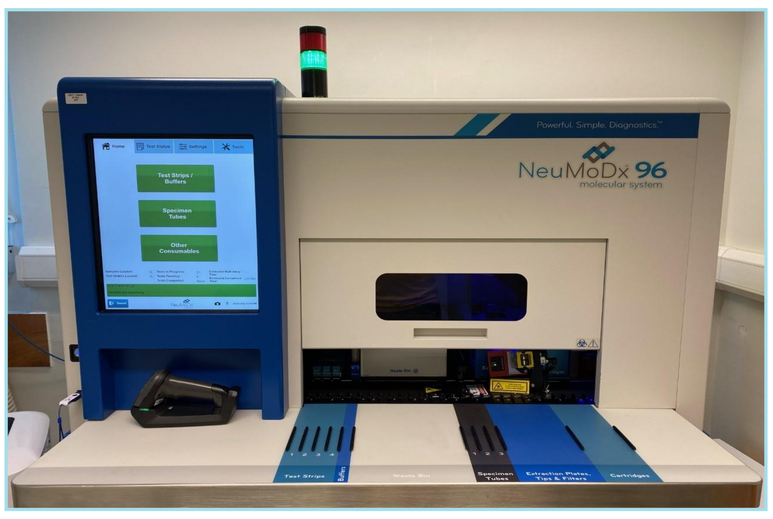

Figure 6: NeuMoDx™ 96 Molecular System, situated in Medical Microbiology and Infection Control, NHS Fife.

Further Work

Identify SARS-CoV-2 nasopharyngeal samples with high Ct values to evaluate the difference, if any, between all platforms in use to determine qualitative result comparison.

The laboratory receives nasopharyngeal aspirate (NPA) and endotracheal secretions (ETS) samples for COVID-19 PCR testing. Further verification of these specimen types will be undertaken.

A new formulation of E&O VPSS (named MSS) has been introduced. Verification of this collection medium is required prior to use for the collection of SARS-CoV-2 nasopharyngeal samples.

Acknowledgements

The authors gratefully appreciate the contributions by all colleagues at Microbiology and Infection Control, NHS Fife, to this work.

QIAGEN

References

1. GOV.UK, 2022. *Coronavirus (COVID-19) in the UK*. [online] Available at: <https://coronavirus.data.gov.uk/> [Accessed 24 January 2022].
2. NeuMoDx™ SARS-CoV-2 Assay Instructions For Use (2020).
3. altona Diagnostics RealStar® SARS-CoV-2 RT-PCR Kit 1.0 Instructions For Use (2021).