# Comparison of the clinical sensitivity and specificity of two commercial RNA SARS-CoV-2 assays

The NeuMoDx molecular system demonstrates
100% specificity and 98.7% sensitivity
in detection of SARS-CoV-2 from nasopharyngeal swabs.

Keywords: COVID-19, diagnostic assay, NeuMoDx, RT-PCR, rapid testing, SARS-CoV-2.

## Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has spread globally since first identification in December of 2019 in Wuhan, China. In a race to manage the pandemic, researchers have developed a range of molecular diagnostic assays.

Automation of workflows has been instrumental in coping with the large number of tests necessary to support clinical needs, as well as providing fast-tracked rapid testing for highly urgent cases (Eigner et al., 2019).

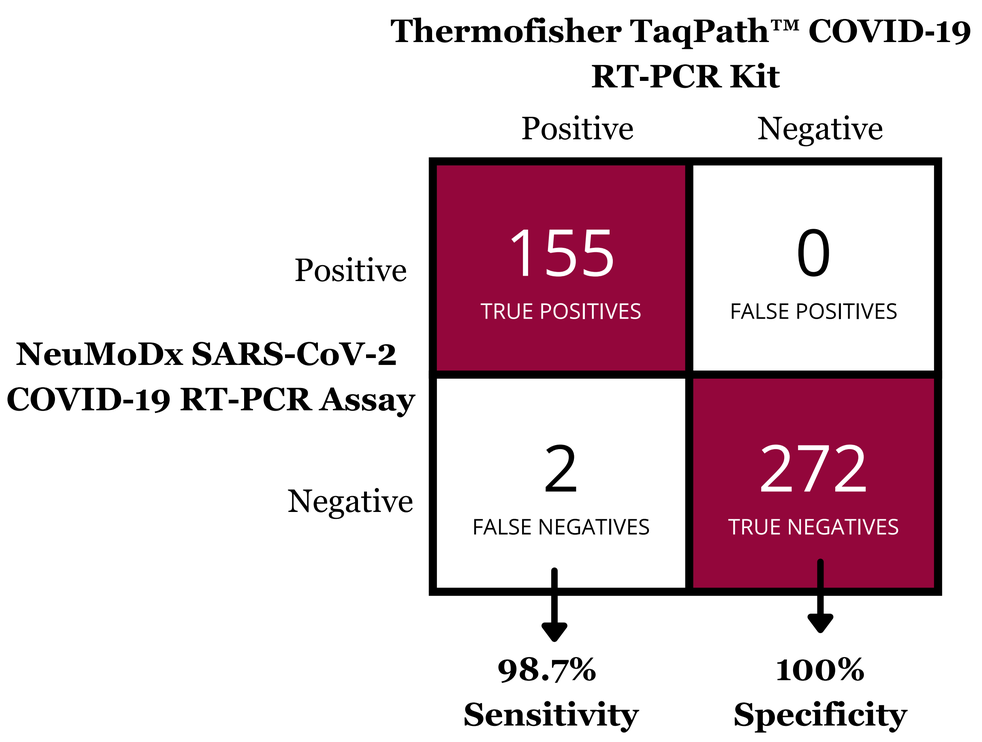
This study aimed to compare the performance of the NeuMoDx™ SARS-CoV-2 Assay with the ThermoFisher TaqPath™ COVID-19 CE-IVD RT-PCR Kit (reference method).

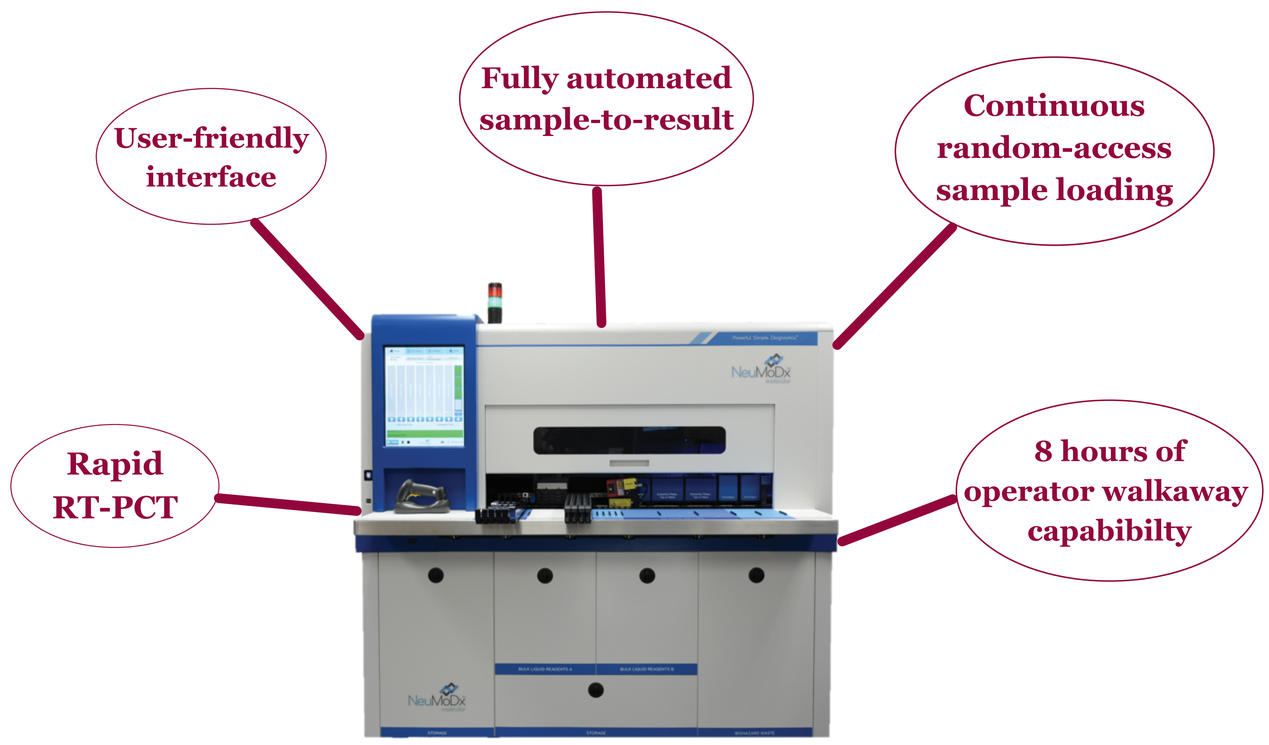
## Methods

Overall, 450 blinded nasopharyngeal swabs, previously tested using the ThermoFisher TaqPath COVID-19 CE-IVD RT-PCR Kit (A48067), were provided by the UK Biocentre (Milton Keynes, UK); 175 were positive and 275 were negative for SARS-CoV-2 RNA.

Samples were stored at –70°C, then transported to the Harefield laboratory (Uxbridge, UK) for testing using the NeuMoDx Assay (NeuMoDx SARS-CoV-2 test strip 300800). The manufacturer's method (NeuMoDx Molecular, 2021) was used without modification.

Samples that were positive at the reference method LoD were excluded in a secondary analysis; with the remaining results presented here.




## Results

By retrospective statistical analysis of all valid results, the NeuMoDx Assay had a clinical specificity of 100% (95% confidence interval [CI]: 98.65–100.00) and a clinical sensitivity of 98.73% (95% CI: 95.47–99.85). Additionally, the NeuMoDx 96 Molecular System provided turnaround times of 80 minutes and a throughput of 144 samples every 8 hours in a routine diagnostic setting (NeuMoDx Molecular, 2021).

## Conclusions

The NeuMoDx SARS-CoV-2 Assay demonstrated similar analytical and clinical performance to the ThermoFisher TaqPath COVID-19 CE-IVD RT-PCR Kit. The two discordant results could be accounted for by the freeze-thaw cycle or transcription errors. The NeuMoDx 96 Molecular System is well suited for automating medium-throughput routine SARS-CoV-2 testing or as an addition to high-throughput systems to allow fast-tracking for highly urgent clinical samples.

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**References:**

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**Acknowledgements:**

We would like to thank the UK Biocentre (Milton Keynes, UK) for sample collection and reference method performance, as well as QIAGEN for supporting the project.