Poster 6

Bedfordshire Hospitals NHS Foundation Trust

Validation of the Sigma MM™Medium for the detection of SARS-CoV-2.

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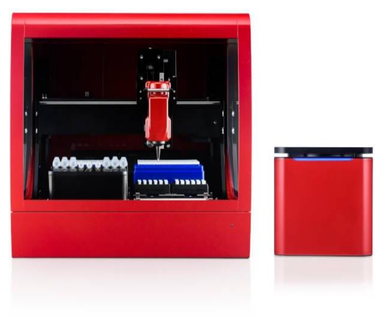
Introduction

With the emergence of SARS-CoV-2 in 2019, Sigma MM™ came to the forefront of Covid-19 testing because of its key performance characteristics. This media deactivates SARS-CoV-2 in 1 minute from samples taken direct from the patient. This media does this while retaining the ability to do PCR testing from the sample on multiple platforms and the ability to sequence and type using this deactivated primary sample. Sigma MM™ helped facilitate the key implementation of SARS-CoV-2 testing within the A&E department which allowed the Covid-19 PCR results to be available within 25 minutes using the Roche® Liat®. This allowed for safe testing of Covid-19 samples in a point of care setting without the use of a safety cabinet or a category 3 facility. In addition to this, confirmatory testing could be performed within the laboratory on platforms such as the GeneXpert®, the Mic-4® using the ViaSure® kit and the Biofire® film array.

Multi-platform Approach The use of multiple analysers with Sigma MM™ demonstrated its versatile use and provided the laboratory with resilience and a flexible approach to patient management.



Method

A cohort of 20 patients who had tested positive for SARS-CoV-2 were swabbed in duplicate using Sigma MM™ and Virocult® Transport media . These duplicate swabs were then tested on the Roche Liat®, Biofire® film array, GeneXpert® and the Mic-4® using the ViaSure® kits. 10 negative patients were also tested using duplicate swabs and 10 blank duplicate swabs were also tested. Patients who had a primary positive result were re-swabbed on the same day using the Sigma MM™ de-activating medium.

Results

From the 20 patients swabbed, both the Sigma MM™ and the Virocult® swabs tested positive on all the platforms. The 20 negative swabs all produced negative results indicating no cross-reactivity with the media. The results, demonstrated that both Virocult® and Sigma MM™ swabs were capable of recovering SARS-CoV-2 via PCR on multiple platforms without any cross reactivity or invalid results. The results for the SARS-CoV-2 positive cohort patients with Sigma MM™ are shown in Table 1.

Table 1 shows the results from multiple platforms for the detection of SAR-CoV-2 from Sigma MM™.

Patient	Primary Patient result Using Virocult and ViaSure SAR-CoV-2	Cepheid GeneXpert SAR-CoV-2 Sigma MM Result	Viasure SAR-CoV-2 Sigma MM Result	Roche Liat SAR-CoV-2 Sigma MM Result	BioFire SAR-CoV-2 Sigma MM Result
1	Detected	Detected	Detected	Detected	Detected
2	Detected	Detected	Detected	Detected	Detected
3	Detected	Detected	Detected	Detected	Detected
4	Detected	Detected	Detected	Detected	Detected
5	Detected	Detected	Detected	Detected	Detected
6	Detected	Detected	Detected	Detected	Detected
7	Detected	Detected	Detected	Detected	Detected
8	Detected	Detected	Detected	Detected	Detected
9	Detected	Detected	Detected	Detected	Detected
10	Detected	Detected	Detected	Detected	Detected
11	Detected	Detected	Detected	Detected	Detected
12	Detected	Detected	Detected	Detected	Detected
13	Detected	Detected	Detected	Detected	Detected
14	Detected	Detected	Detected	Detected	Detected
15	Detected	Detected	Detected	Detected	Detected
16	Detected	Detected	Detected	Detected	Detected
17	Detected	Detected	Detected	Detected	Detected
18	Detected	Detected	Detected	Detected	Detected
19	Detected	Detected	Detected	Detected	Detected
20	Detected	Detected	Detected	Detected	Detected

POCT Application

The impact on patient pathways as a result of the Implementation of Sigma MM™ was significant allowing point of care testing to help triage patients based on the results of rapid near patient PCR tests within 25 minutes of sampling. This was key when patients admitted from A&E were segregated in to Green, Amber or Red pathways. This infection control process reduced the risk for patients and allowed the efficient and safe flow of patients through A&E. The application of Sigma MM™ also contributed to effective patient management where patient segregation was not possible such as pediatric's, Rapid POCT testing allowed early detection of SAR-CoV-2 and effective management of patients.

Conclusion

The results show both the Sigma MM™ and Virocult® were able to detect SARS-CoV-2 in patient samples. The negative results demonstrated no cross-reactivity with the media and PCR chemistry across all platforms. The ability to use Sigma MM™ in A&E and paediatrics has been a significant aspect of providing safe and effective patient management due to the effective use of the deactivating medium.

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