Establishment of "hot labs" for molecular detection of SARS-CoV-2 in a near patient testing environment.

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Summary

We describe the implementation of rapid point of care testing platforms for SARS-CoV-2 testing, the Roche Cobas LIAT, and the Diagnostics for the Real World SAMBA II systems, and their application, performance and impact of their use in near patient testing "hot labs" in major teaching hospitals across Birmingham.

Background

In order to safely triage patients presenting to emergency departments and acute medical units for possible symptomatic and asymptomatic infection with SARS-CoV-2, testing at the point of entry to the hospital was deemed necessary to improve turnaround as recommended by PHE [1]. Dedicated laboratory space was created in close proximity to the ward based teams involved in the patient admission process, crewed by trained laboratory technical staff, and supported by the main laboratories within the trust.

Results

Over the course of 9 months 95403 specimens were tested through the Near Patient testing laboratories set up in the emergency departments and acute medical units of Good Hope Hospital, Heartlands Hospital and the Queen Elizabeth Hospital in Birmingham.

All of these specimens were subsequently sent to Microbiology departments at Heartlands Hospital and Queen Elizabeth Hospital for post-implementation monitoring and confirmation of results.

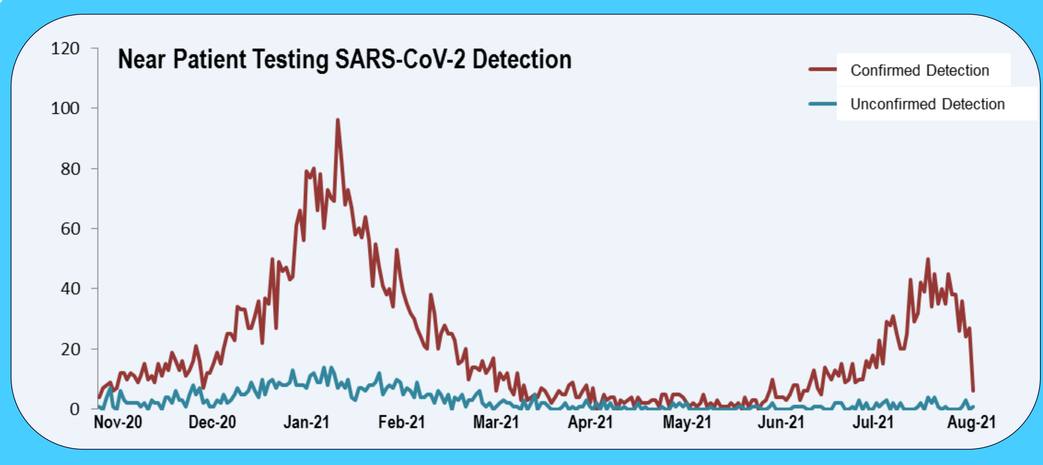

Figure 1: Combined data from NPT testing displaying detection of SARS-CoV-2 either confirmed by laboratory testing (dark red) or unconfirmed and considered "false positive" (teal).

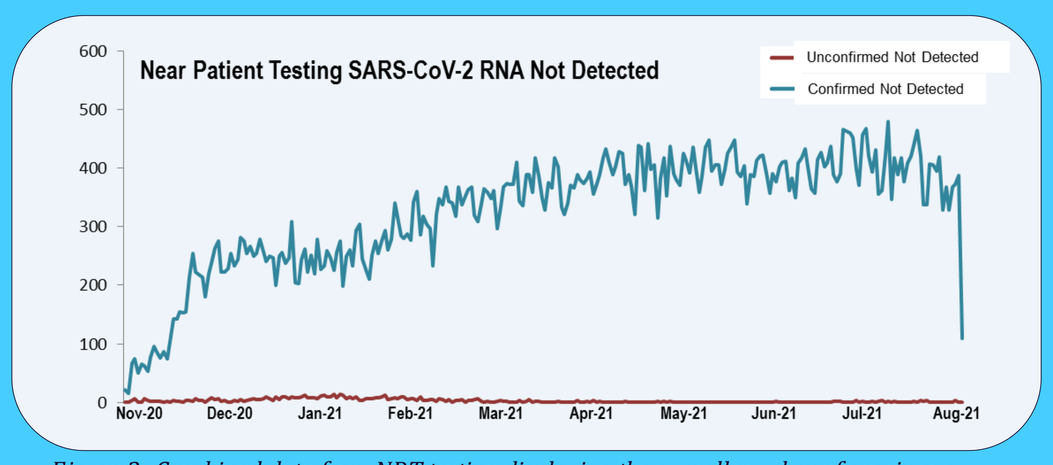

Figure 2: Combined data from NPT testing displaying the overall number of specimens reported as SARS-CoV-2 RNA Not Detected by NPT testing (teal), and the relative number of those which were reported as unconfirmed and considered "false negative" (dark red).

A.

POCT Results	Results of Laboratory Testing			
	Detected	Invalid/Indeterminate	Not Detected	Grand Total
LIAT	**944**	**273**	**15297**	**16514**
I	6	191	250	447
N	49	81	14946	15076
P	889	1	101	991
SAMBA	**1996**	**1494**	**55613**	**59103**
I	39	1204	852	2095
N	227	282	54549	55058
P	1730	8	212	1950

B.

SAMBA II		
Sensitivity	88.40%	86.90% to 89.79% (95% CI)
Specificity	99.61%	99.56% to 99.66% (95% CI)

LIAT		
Sensitivity	94.78%	93.15% to 96.11% (95% CI)
Specificity	99.33%	99.18% to 99.45% (95% CI)

Table 1: (A) table displaying information on the number of detected, invalid, not detected and indeterminate specimens reported during duplicate/confirmatory testing of the LIAT and the SAMBA II (B) Calculated clinical/diagnostic sensitivity and specificity for the LIAT and the SAMBA II

2942 were reported as Invalid/Indeterminate by the NPT tests, primarily by SAMBA II testing. 86487 samples (90.6%) were reported as SARS-CoV-2 RNA Not Detected by NPT laboratory testing, 54 were rejected due to inappropriate specimen type, or other analytical reasons (0.056%), and 5920 samples were reported as SARS-CoV-2 RNA Detected (6.8%).The change in these figures over time is shown in Figure 1 and Figure 2 and summarised in Table 1A.

The Roche LIAT has a diagnostic sensitivity of 94.78% (93.15-96.11%: CI 95%) and a diagnostic specificity of 99.33% (99.18-99.45%: CI 95%). The SAMBA II demonstrated at diagnostic sensitivity of 88.4% (86.9-89.79%: CI 95%) and a diagnostic specificity of 99.61% (99.56-99.66%: CI 95%). Displayed in Table 1B.

Performance and Impact of Near Patient Testing

Discussion

Positive predictive value based on local prevalence data for both LIAT and SAMBA at the time of writing (August 2021) is ~69% despite reasonable sensitivity. Currently community prevalence based on REACT study is 0.94%. (Birmingham is currently 303 cases per 100,000 population, we are currently seeing a pretest probability on NPT of 10% at time of writing). Conversely the negative predictive value is calculated for both assays at >99.9%.

Upon service implementation, immediate impact seen on turn-around times of patient's first test on arrival into hospital; an average 3 hours, reduced from ~16-33 hours.

Improved patient flow (patient time in A&E reduced) was observed.

Though initially there was a drop in the number of ward and bay closures by an estimated ~50% following implementation, this has remained stable despite reducing positive case load.

WMAS reported reduction in ambulance waiting to off-load on the hospital forecourt.

Conclusion

The diagnostic/clinical sensitivity and specificity of the LIAT and SAMBA II tests is in line with the initial verification, and has been shown to be able to provide a reliable, rapid service with the experience of testing over 95,000 specimens in a live testing environment. Post-implementation monitoring has been invaluable in understanding the limitations and effectiveness of these assays, and has time as gone on the need for confirmatory testing has been reduced as confidence in the test results of NPT has increased.

References

[1] Public Health England 2020, COVID-19: summary guidance for service providers on point of care or near-person tests for diagnosis and management - GOV.UK (www.gov.uk) Accessed 23/09/21

Acknowledgements

We acknowledge the essential support of he Microbiology Department of Queen Elizabeth Hospital and the Regional Public Health Laboratory at Heartlands Hospital for helping with ongoing performance monitoring and confirmatory testing