Implementation of Rapid Point-of-Care SARS-CoV-2 Antigen Test in Emergency Pathway

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Introduction

During the early Covid-19 pandemic, the issue of patient-to-patient transmission within hospitals arose. A need was brought up for rapid Point-Of-Care tests for diagnosis of severe acute respiratory syndrome SARS-CoV-2 in the Emergency Department setting. The laboratory turnaround time for RT-PCR results did not allow for rapid and accurate patient allocation. Without rapid and accurate tests, there was a risk of nasopharynx transmission between patients, further contributing to infection through hospitals caring for already vulnerable people. Rapid tests would allow for patients to be allocated, supporting patient flow and reduction of Covid-19 transmission.

Aims

- Support evaluation of the national rollout of the programme for rapid covid testing in the hospital setting, especially emergency settings
- Impact on patient flow and pathway decision based on the rapid test results.

Implementation

- The University Hospitals of Leicester (UHL) NHS Trust adopted the use of LumiraDx™, to the implementation of a rapid LumiraDx™ SARS-Cov-2 Antigen immunoassay[1] in Emergency setting in two different hospital sites; Emergency Department (ED) and Clinical Decisions Unit (CDU)
- POCT Lab service hours Go-live date – 14 hours over seven day period two weeks post implementation 24 h 7 days a week
- Speedy delivery of this project was supported by a Trust wide response including recruitment, infection prevention, IT, clinical teams, microbiology, medical records and primarily POCT team.

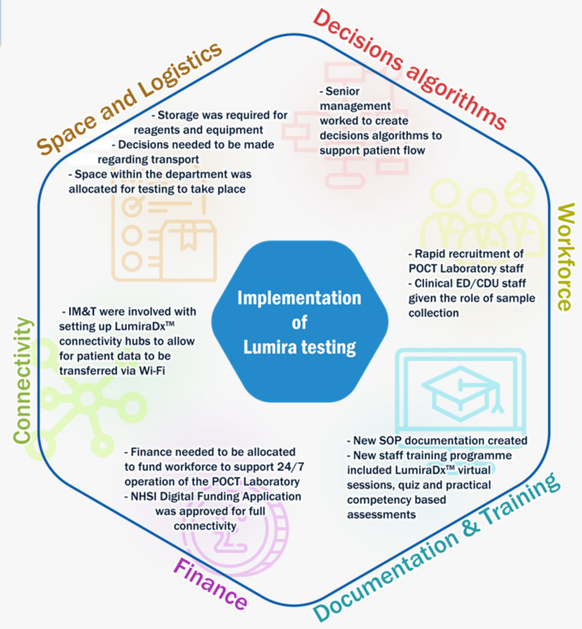

Figure 1. Implementation of LumiraDx™

Methods

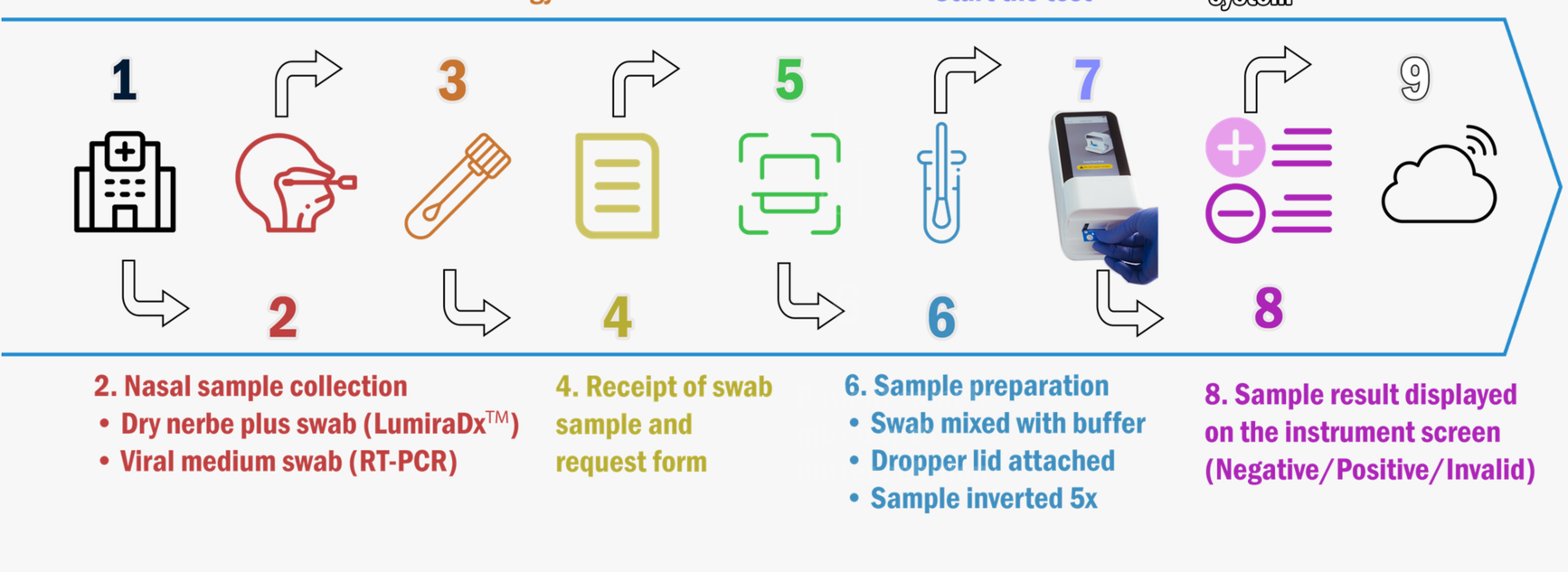

Figure 2. Arrow - Process Flow Chart For Rapid LumiraDx™ Testing in Emergency Department

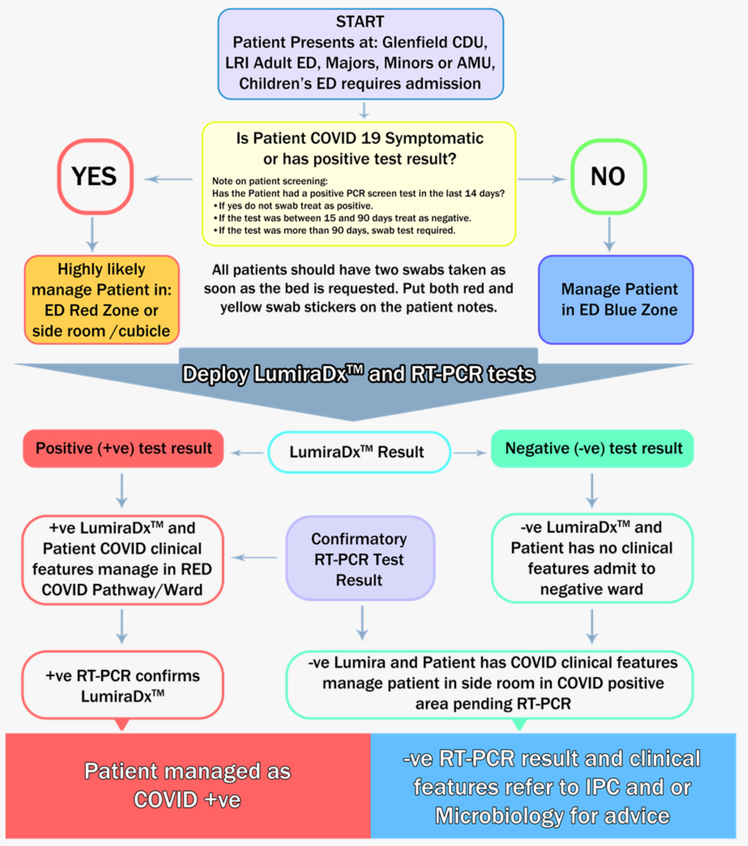

Figure 3. Clinical Algorithm Decision Making Guide

Results

Sample data from LumiraDx™ testing was collected for the period of 5th Jan 2021 to 13th June 2021 in comparison to the laboratory RT-PCR (range of different Nucleic Acid Amplification Test (NAAT) assays). The total number of tests performed n = 27547, of which 3434 tests had no comparator RT- PCR result so were excluded.

			PCR		
			Positive +	Negative -	Grand Total
LumiraDx	Positive +	Asymptomatic	249	82	331
		Symptomatic	475	56	531
		Total:	724	138	862
	Negative -	Asymptomatic	186	20192	20378
		Symptomatic	129	2743	2872
		Total:	315	22936	23251
		Grand Total:	1039	23074	24113

Figure 4. Overview of the number of test done in first 6 months of implementation

The specificity of the LumiraDx™ SARS-CoV-2-Ag 69.9% (66.7%/72.4)% and the negative predictive value (NPV) 98.6 (98.5/98.7)% were found to be good and give confidence in the result in symptomatic patients. The sensitivity 99.4% (99.2/99.5)% and the positive predictive value (PPV) was 83.9% (81.5/86.1)% varied when the prevalence (as measured by the positive PCR tests [Fig. 5]) decreased. The lower prevalence in the asymptomatic group required the need for confirmatory PCR test prior to transfer.

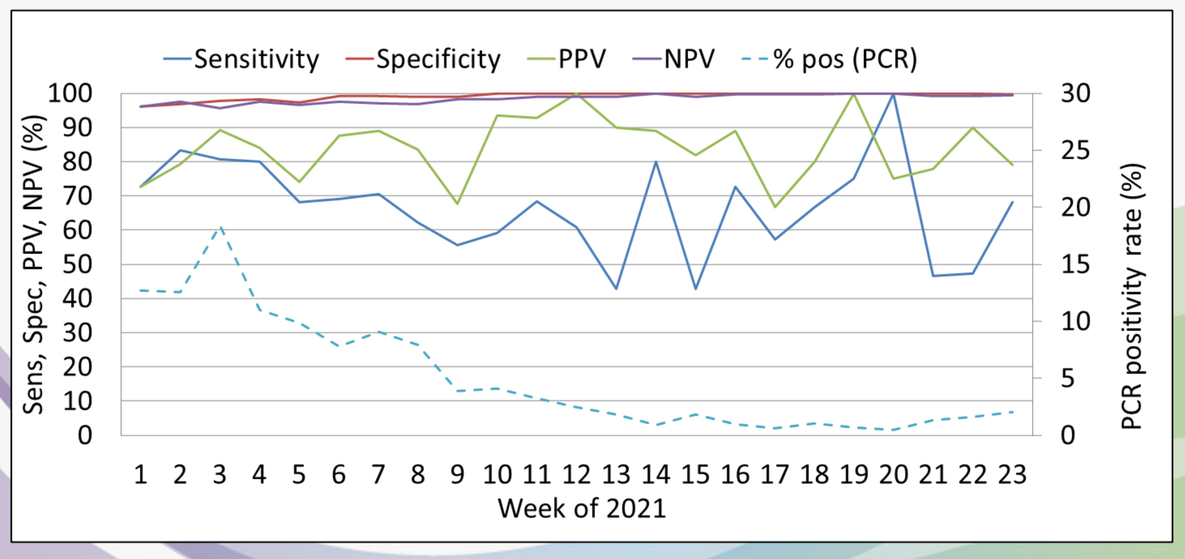

Figure 5. Line chart presenting sensitivity, specificity and predictive positive and negative prevalence commencing 05/01/2021 for Rapid Sars-CoV-2 Test (LumiraDx™) and RT-PCR

Conclusions

The introduction of the rapid LumiraDx™ SARS-Cov-2 Antigen Test immunoassay perceived many benefits such as assisting with rapid isolation and treatment plan for symptomatic positive patients. Although the use of this technology can assist with patient movement decisions the RT-PCR test is still deemed the gold standard for diagnostic purposes.

With continued monitoring of the specificity and sensitivity, changes may be made to the decision matrix algorithm for patient flow in the future. For instance if a patient is showing no Covid-19 symptoms and receives negative LumiraDX™ result, then there may be no need for RT-PCR test thereby speeding up the patient flow pathway (See Figure. 6)

Strengths	Weaknesses	Opportunities	Threats
• LumiraDx™ is currently in use in ED and CDU incorporated into patient management algorithms • Staff are familiar with operation • Rapid results in as little as 15 minutes allows faster patient triage decisions	• Requires double-swabbing of patients: not well-tolerated • Additional PCR test required (conflicting results) • Wasteful of resources • No RSV assay on LumiraDx™ - alternative required for paediatrics	• Ongoing use will provide robust evidence on the suitability for the LumiraDx™ system for detection of respiratory virus infections	• LumiraDx™ influenza assay CE marked end of 2021 - performance has not been evaluated. What if performance is not acceptable? • Supply is dependent on centralised government purchase – additional cost could be passed

Figure 6. SWOT analysis of the LumiraDx™ implementation

Acknowledgments

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References

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