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

Jasminder K Dhillon, Lukasz S Ceglarski, Emile Coady and Lukasz Stolarczyk

Department of Point-of-Care, Pathology, University Hospitals of Leicester (UHL) NHS Trust, Leicester, United Kingdom.

Keywords: SARS-CoV-2, RT-PCR, Rapid Antigen Lumira™ testing

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 nosocomial 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 design based on the rapid test results.

Implementation

- The University Hospitals of Leicester (UHL) NHS Trust adopted the use of Lumira™, to the implementation of a rapid Lumira™ SARS-CoV-2 Antigen Immunoassay 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.

Methods

1. Patient presents at UHL ED or CDU
2. Nasal nasopharyngeal swab (Lumira™)
3. Sample transport
   - Lumira™ > POCT Lab
   - RT-PCR > Virology Lab
4. receipt of swab
   - sample and request form
5. Test initiation
   - barcode scanned
6. Sample preparation
   - Swab mixed with buffer
   - Dropper lid attached
   - Sample inverted 5x
7. Sample testing
   - Insert test strip
   - Add patient sample
   - Start the test
8. Electronic patient result stored in the clinical test and trust integration system
9. Sample test displayed on the instrument screen (Negative/Positive/Invalid)


Results

Sample data from Lumira™ 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.

The specificity of the Lumira™ 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 99.9% (99.2%-99.5%) and the positive predictive value (PPV) was 83.9% (83.5%-83.1%) varied when the implementation (as measured by the positive PCR tests [Fig. 5]) decreased. The lower variation in the asymmetric group required the need for confirmatory PCR test prior to transfer.

Conclusions

The introduction of the rapid Lumira™ 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 Lumira™ result, then there may be no need for RT-PCR test thereby speeding up the patient flow pathway (See Figure 6).

Acknowledgments

Many thanks to Dr Christopher W Holmes (Consultant Clinical Scientist), Lumira™ for the copyright image permission, POCT Team

References

3. UH Standard Operating Procedure for: Leicester Royal Infirmary (LR) Emergency Department (ED) and Clinical Decisions Unit (CDU) at Glenfield Hospital Feb 2021 v2.