NHS Test and Trace interim evaluation on acceptability and useability of Lateral Flow Viral Antigen detection devices for self-testing: *Initial report from the UK Lateral Flow Oversight Group* [CONFIDENTIAL]

Executive summary

- LFDs have high acceptability and useability

- Few adverse effects were reported in the first 1645 tests performed.

- There was no evidence of drop in self-reported performance following serial testing.

- There good feedback on the pilot implementation and significant support for serial testing using LFDs.

1. Background

The identification of individuals with SARS-CoV-2 infection is important to prevent the chain of transmission and prevent ongoing morbidity and mortality. The current 'standard' COVID-19 test involves reverse-transcription polymerase chain reaction testing of nasopharyngeal swab samples in specialised laboratories. However, there is data that suggests point of care diagnostic devices have acceptable performance characteristics. Lateral flow devices (LFD) are point of care diagnostic devices which measure viral antigen and have the addition benefits of delivering results rapidly in 15-30 minutes, have minimal infrastructure requirements and provide cost benefits.

A large body of work has been completed about LFD sensitivity, specificity and kit performance rates. However, to date, there have been no evaluations on acceptability and useability of users performing these devices. Furthermore, there have been no information derived from individuals who have performed testing over an extended period of time.

2. Aims & Objectives

The aims of this NHS Test and Trace evaluation were to assess the acceptability and useability of the *Innova SARS-CoV-2 Antigen rapid qualitative test* by means of a self-reported cross-sectional questionnaire.

Specifically, the objectives of this evaluation were to

- Identify acceptability of different aspects of the test including training, self-swabbing, performing the test and results interpretation
- Gain feedback on useability of these tests
- Understand how the acceptability and useability of these tests change with time
- To identify any adverse effects from long term use.
- To gain areas where improvements in use of these LFD tests could be improved.

3. Methodology

An anonymous survey was sent to individuals who had participated in an Innova LFD self-test. Specifically, the inclusion criteria included any individuals who had performed at least one self-test using the *Innova SARS-CoV-2 Antigen rapid qualitative test.* This survey was a web survey and consisted of 16 questions. Likert scales were utilised with a five-level scale. The survey was targeted at members of the armed forces and student pilot evaluations.

4. Results

Study population characteristics

A total of 163 individuals responded to the survey and in total, they had performed a total 1645 tests. 74.8% (122/163) of the respondents were male with a median age of 21 years (s.d 5.8 years). These individuals had performed their tests from the 6th of October onwards. 6.1% of individuals had performed the test just once and median number of tests performed by individuals was 8 tests.

Acceptability

Survey respondents noted that a high level of acceptability was noted for training. Overall, 88.9% (144/162) of individual reported their training was good/very good. 73.6% (120/163) of individuals received a physical demonstration, 8.6% (14/163) received a virtual demonstration, 14.7% (24/163) had video training and 3.0% (5/163) of individuals were trained with written information. There was/was not evidence of differences in acceptability based on training modality.

A moderate level of acceptability was noted in terms of performing a self-swab. 74.2% (118/159) of individuals noted that self-swabbing was easy/very easy. Only 8/159 (5.0%) noted that the self-swabbing was difficult and no respondents thought that self-swabbing was very difficult.

Performing the test was rated as easy/very easy by 92.9% of respondents (146/157). Only 1 individual noted that performing the test was difficult or very difficult (0.6%). Similarly, results interpretation was reported as being easy/very easy by 96.2% respondents (152/158). Only 1 respondent reported interpretation as being difficult or very difficult (0.6%, 1/158).

Useability

In terms of incorporating LFD use into the respondent's daily regimes, 157 individuals provided a response. In total 88.5% (139/157) noted that it was very easy/easy to incorporate testing into their daily activities. Overall, 95.4% (146/153) agreed or strongly agreed with the statement "I find the tests are acceptable to use". 87.0% (134/154) agreed or strongly agreed with the statement "I am willing to perform the test for two or three times a week for the next 3 months" and 80.5% (124/154) agreed or strongly agreed with the statement "I am willing to perform the test for two or three times a week for the next 6 months" (Figure 1)

Specifically, with regards to serial testing, 90.0% (140/154) agreed or strongly agreed with the statement, "I am willing to perform the test every day for a week if it avoids self-isolation" (Figures 1).

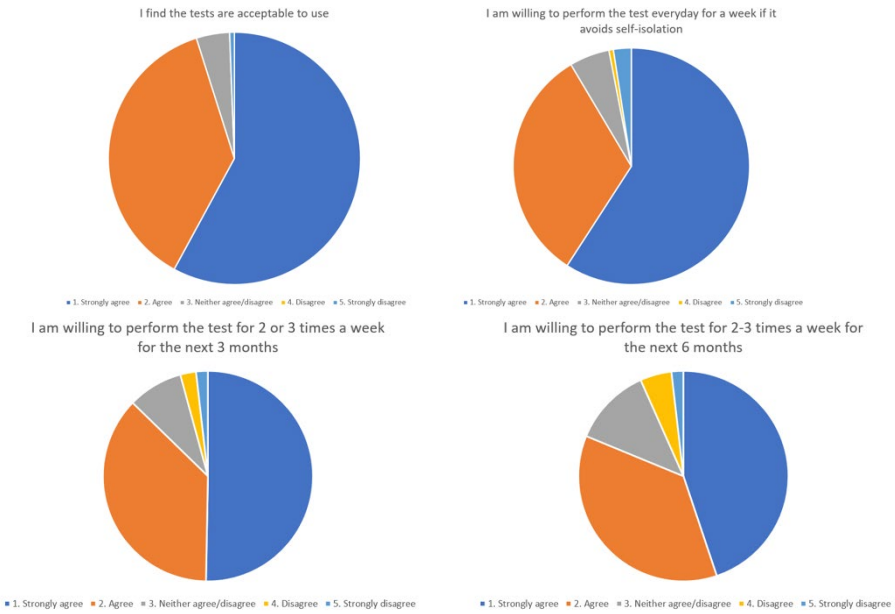
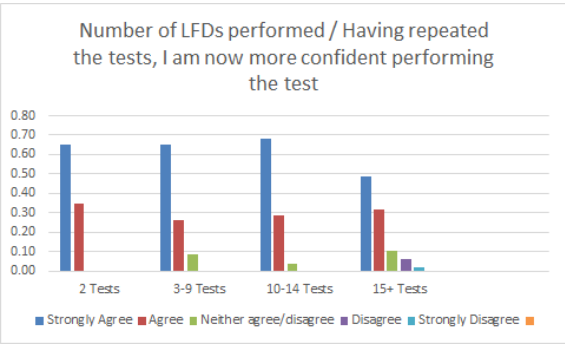
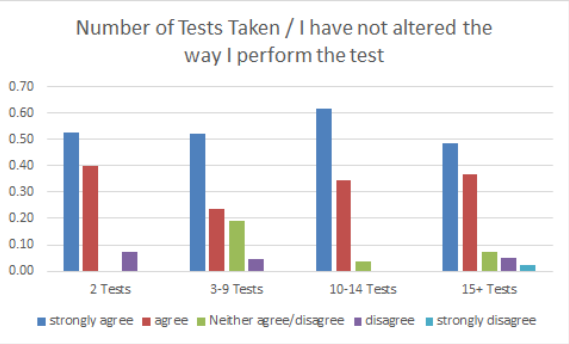


Figure 1. Piecharts showing useability of LFD tests

Temporal correlation

Comparing individuals who had done a <10 tests to those who had performed =>10 tests, there were no differences in the proportion of individuals noting positive responses in useability. 88.1% (52/59) of individuals who did 9 or less tests recorded positive responses to the statement "I find these tests acceptable to use" compared to 87.5% (56/64) of individuals who did 10 or more tests. We also show no self-reported evidence that individuals alter the way they perform the test over time.





Adverse side effects

2 individuals reported an adverse effect (1.2%, 2/163). One individual reporting vomiting following performing the tests. Another individual having itchy eyes having performed the test.

Areas for improvement

Only 13 respondents suggested improvements to the service. 5 individuals questioned the accuracy of these tests and requested clarity on why testing was being performed. 3 individuals provided positive feedback. The remaining comments were recommendations on how and when testing should be performed.

5. Conclusions

In this survey of the acceptability and useability into the use of the *Innova SARS-CoV-2 Antigen rapid qualitative test,* feedback was generally positive. There is evidence that individuals do not have any issues with training, self-swabbing, performing the test or interpreting the results. Of these areas, results interpretation was felt to be easy/very easy, with the greatest difficulty in performing self-swabbing. Adverse events were very rare. There was no evidence that acceptability or useability deteriorated over time. >80% of individuals felt that they would support serial testing. Potential areas for improvement are to improve explanation on why testing should be performed. Further surveys and evaluations will be necessary to assess self-reported useability and accessibility in other groups performing the tests.