# Incident and corrective and preventative action report
# MHRA incident reference: 2021/006/011/601/004
# Jacques du Preez
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## 1 Background

On Thursday, June 10, the FDA released a safety notice which warned US citizens to stop using the Innova SARS-CoV-2 Antigen Rapid Qualitative Test (hereafter referred to as the "Innova LFD Antigen Test" for diagnostic use due to a range of "significant concerns" around the product. They also sent a warning letter to Innova which set out the findings the FDA obtained from an inspection of Innova's medical device operations hub in Pasadena, California. Between the date of the inspection (across the end of March and early April) and now, the FDA has not received an adequate response to the non-conformities raised. The non-conformities raised can be summarised as follows.

1. Firstly, the inspection revealed that Innova had been distributing the product in the US without approval from the FDA (thereby breaching US law).

2. Secondly, the labelling of the product for the Innova 25s included a clinical performance section which claimed a level of sensitivity and specificity that was not matched by the evidence that the FDA had seen at the time of the inspection.

3. Thirdly that there were significant failures in the quality management system in the US company.

A fourth item, outside of the FDA letter, has been added by DHSC as Innova did not make DHSC aware of the audit and findings

Innova in the US did not provide an adequate response to the FDA audit findings which led to the FDA issuing a safety notice and Innova in the US issuing a recall of the:

- Innova COVID-19 Self-Test Kit (3T Configuration)

- Innova SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration)

- Innova SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration)

DHSC are both the legal manufacturer of Innova 3's and 7's which is made available in the UK under the NHS test and Trace brand name and is also distributor of Innova 25s. DHSC is a service provider/ commissioner with a clinical governance structure and operates clinical testing services via NHS Test and Trace, which use both the DHSC-manufactured Self-Test and the Innova 25s.

Upon becoming aware of the FDA enforcement action, DHSC initiated a formal review (both in its role as manufacturer of the DHSC Self-Test, distributor of Innova 25s and its role as clinical service provider) to determine if the FDA's claims represent a risk to patient safety and public health in the UK market. DHSC notified the MHRA through the Manufacturer's On-line Reporting Environment (MORE) of a potential safety incident (reporting reference 2021/006/011/601/004)

# 2 DHSC Investigations

This report examines the FDA findings to determine whether they impacted on the use of the Innova tests in the UK and sets out our response against each of these claims

## 2.1 FDA Claim 1: Not authorised to be made available in the US

The FDA inspection revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test had been distributed in the United States without marketing approval, clearance, or authorization from FDA

**DHSC Response:** Innova was initially lawfully introduced into the UK marketed as a general class CE marked IVD test for use by professionals. Subsequently the Department for Health and Social Care (DHSC) obtained an Exceptional Use Authorisation in December 2020 from the Medicines and Healthcare products Regulatory Agency (MHRA) for the use of Innova SARS-CoV-2-Antigen Tests in a self-test capacity for asymptomatic users.

DHSC became the legal manufacturer for packs of 3s and 7s and went through the correct regulatory procedures including usability testing, analytical performance testing at Porton Down and service evaluations to ensure the device performed as expected. No CAPA was raised for this claim as the CE marking of the professional use device and EUA for the self test devices is a statement of fact.

**Conclusion:** The Innova product met and obtained the regulatory approvals to be made available on the United Kingdom (UK)

## 2.2 FDA Claim 2: Performance claims not supported

The performance of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test device (25T) as detailed in the IFU has not been adequately established, presenting a risk of false results. The FDA noted that to date that they have not received reports of injuries or death associated with use of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test. The FDA where specifically concerned by;

- **False-negative results** which may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2
- **False-positive results** could lead to a delay in both the correct diagnosis and the initiation of an appropriate treatment for the actual cause of patient illness

**DHSC Response:** The DHSC use case for LFD focuses on the asymptomatic population and is different to how it has been indicated for use in the US. Thus, the risks identified to users are not strictly as presented by the recall letter and substantial mitigations are in place in the UK context. These are outlined formally in a risk assessment as part of the supporting information for CAPA 21-06-0031.

Public Health Risk Assessment for use of the Innova LFD Antigen Test in the UK

The DHSC public health risk assessment has identified six key public health risks associated with use (or lack of use) of the device in the UK and each is described in more detail:

1. Risk of a false positive result;
2. Risk of a false negative result in the context of one-off asymptomatic testing;
3. Risk of a false negative result in the context of regular asymptomatic testing;
4. Risk of a false negative result in the context of outbreak or high-risk setting testing;
5. Risk of a false negative result in the context of daily contact testing;
6. Risk of interruption or cessation of testing

**1 False Positive Results**

A false positive result is defined as the LFD antigen test returning a "positive" result when the individual is in reality not infected. The rate of false positives among those tested is determined by the device specificity and the disease prevalence, with the rate of false positives increasing for lower prevalence. The impact of a false positive result is an avoidable period of self-isolation, and the individual-level downstream economic, social and psychological consequence of this. If the rate of avoidable self-isolation becomes very high there is the potential for public health harm through a reduction in public belief in a positive test result and so individuals who have a true positive result not abiding by self-isolation requirements. When prevalence is low, the risks associated with false positives are mitigated by using a different test to confirm an initial positive result – within NHS T&T this second test is a reflex confirmatory qRT-PCR test.

Results from initial evaluations of the Innova LFD carried out by Public Health England and University of Oxford estimated a high specificity of 99.7%. However, DHSC analysis of real-world positivity rates from approximately 25,000 Innova LFD Antigen tests delivered in the community as part of NHS Test and Trace testing, combined with mathematical modelling suggests that the Innova LFD devices are outperforming these initial estimates in mass testing use. This larger analysis estimates the real-world specificity of the Innova LFD device to be greater than 99.97%[1].

**2 and 3 False Negative Results in the context of one-off or regular asymptomatic testing**

A false negative result is defined as the LFD antigen test returning a "negative" result when the individual is in reality infected. The rate of false negatives among those tested is determined by the device sensitivity and the disease prevalence, with the number of false negatives increasing in higher prevalence. The impact of a false negative result is a potential misplaced sense of reassurance on the part of the person who has received the result, and who may therefore take inappropriately risky actions such as not adhering to social distancing or good hygiene guidelines. The public health harm that could arise from this varies according to the viral load (and likely infectiousness) of the individual. The majority of people with low or

[1] DHSC, National Testing Programme: Evidence Summary for Strategy and Policy, May 2021

moderate viral loads (<1 million genome copies/ml) will have little actively infectious virus, so the public health harm arising from a false negative in these individuals will be relatively minimal. People with a viral load over 1 million genome copies/ml are highly likely to be infectious, meaning the public health harm arising from a false negative will be onward transmission.

The main mitigation to reduce the impact of this risk is information within the LFD antigen test IFU that states, "*Negative Result If you get a negative result, you were likely not infectious at the time you took the test. A negative test result, however, is not a guarantee that you do not have COVID-19. If you test negative, you must continue to follow national and local rules and guidelines, including regular handwashing, social distancing and wearing face coverings, where required. If you develop symptoms of a high temperature, a new, continuous cough or a loss or change to your sense of taste or smell, you and your household must self-isolate and get another test at www.gov.uk/get-coronavirus-test or by calling the customer contact centre. Lines open every day, 7am to 11pm*." Behavioural responses to an LFD antigen test result is a key area of evaluation as part of real-world data monitoring. Initial behavioural data collected during March 2021 from the general public has provided useful insight for when an individual receives a negative test result. Research has found 8 in 10 people would continue to follow hands/face/space after getting a negative LFD test result and 87% were aware there is at least some risk of passing on coronavirus even after a negative result. Of note, the research showed only 1 in 3 would not socialise indoors in the event of a negative result. Although this does not contextualise the individual actions in the event that no test result been received, this highlights the importance of the work DHSC is doing on messaging to ensure individuals are aware they may still be infectious or have the virus even after a negative test[2]. In the context of regular asymptomatic testing regimes (e.g., schools) an additional mitigation to the PH impact of a false negative is the regular nature of testing, which provides more 'opportunities' to detect an infection if the first test does not identify it.

Overall, as discussed above, the latest performance management evidence from live use of the Innova LFD antigen test within NHS T&T suggests the rate of false negatives is currently low[3]: 95% true positive detection rate for individuals with viral load over 1 million copies/ml.

**4 and 5 False Negative Results in the context of outbreak or high-risk setting testing, or in the context of daily contact testing**

The public health risks associated with false negative results in these settings are identical to those outlined for one-off or regular asymptomatic testing. However, the PH harm associated with a false negative is higher in these settings due to the higher level of vulnerability of the individuals involved. Beyond the mitigations discussed above, within these high-risk settings the public health harm is further mitigated through use of specialised testing regimes. For example, in care home outbreaks all staff must undertake seven days of LFD testing, even if they are not a contact of a positive case. Similarly, in schools-based outbreaks all families of children and staff can be asked to undertake PCR testing to identify any infections not detected by LFD testing.

[2] DHSC, National Testing Programme: Evidence Summary for Strategy and Policy, May 2021
[3] DHSC, In vitro and clinical post-market surveillance of Biotime SARS-CoV-2 Lateral Flow Antigen Device in detecting the SARS-CoV-2 Delta variant (B.1.617.2): Draft Summary Report, June 2021

Further, currently the Innova LFD antigen test is only used for daily contact testing in the context of a research trial. Within the protocol for this trial participants also are required to undergo regular PCR testing, mitigating the risk of LFD false negative results.

## 6 Interruption or cessation of LFD testing

Within the context of the NHS T&T programme LFD antigen tests are used only on asymptomatic individuals. Around one in three people with SARS-CoV-2 never develop symptoms[4], and asymptomatic individuals may represent a large proportion of the infected population who are unwittingly contributing to large-scale transmission. Asymptomatic testing at scale allows identification of people with transmissible virus. As of 19th May 2021, LFD antigen testing had identified 222k positive asymptomatic cases that might not otherwise have been identified. It is estimated that this has reduced community transmission of SARS-CoV-2 by 2-13%[5].

In order to identify asymptomatic infectious people so they can self-isolate and interrupt viral transmission, testing needs to be delivered at a much greater scale than exists for symptomatic diagnosis. Additionally, people who are tested need to be told their COVID-19 status as fast as possible to minimise unnecessary isolation and improve overall compliance. While tests undertaken in centralised laboratories can theoretically achieve this scale, the transport of samples from person to lab for processing increases the turnaround time for an individual's results. In general, this turnaround time and the logistics of sourcing, electronically tracking, couriering, receipting, and robotically processing the large number of samples makes laboratory-based tests impractical for asymptomatic testing at the scale required. This makes tests that do not require a laboratory attractive for mass testing: at present only LFD antigen tests are available at the required scale.

In the event that a supply of LFD antigen tests were not available, asymptomatic mass testing would need to be reduced or ceased entirely. The public health harm from this would be a reduction in COVID-19 infections identified, increased onward transmission and a likely increase in subsequent morbidity and mortality (albeit the trend of increasing vaccination will act to limit this). To mitigate this risk, additional non-pharmaceutical public health interventions may need to be considered

Performance of the Innova LFD Antigen Test in the UK

As discussed above, the Innova antigen test has been used to detect Covid-19 amongst the asymptomatic population. Asymptomatic people do not have signs of Covid-19 and would not normally be looking for a diagnosis. The public health and clinical strategy of their use is about risk reduction and case finding. DHSC has not relied on Innova Medical Group Inc to determine the performance of the testing, rather has developed robust validation and performance monitoring processes independent of Innova that determine performance prior to and/or at the point of implementing testing. There is a substantial post market surveillance activity to ensure performance continues at expected levels. This independent evidence base has been used to inform approaches to false negative and false positive results within the DHSC led programmes

[4] DHSC, National Testing Programme: Evidence Summary for Strategy and Policy, May 2021
[5] DHSC, Asymptomatic Testing Review, May 2021

The detail of the review has been written up in the following CAPA

- CAPA 21-06-0031 - Clinical Performance and Risk Assessment

DHSC has an established validation process commissioned from PHE Porton Down and overseen by the LFD Oversight Group for all LFD antigen tests proposed for use within the national testing programme. The protocol is delivered in 3 phases. Phase 1 is a desk-top assessment of product viability carried out by DHSC. Phase 2 is a futility test at PHE Porton Down to prioritise products for further assessment by identifying kit failure rate, whether known negative samples give a negative result (indicator of specificity), whether known positive samples give a positive result (indicator of sensitivity), and an initial view on usability of each test. Spiked samples are serially diluted and assessed for each test. Phase 3 involves evaluation of each LFD antigen test against a larger clinical reference panel (1,000 true negatives and 200 true positives).

NHS Test and Trace has an ongoing programme of service evaluation and QA for LFD antigen tests that have successfully completed validation at PHE Porton Down. This comprises clinical evaluation via routine monitoring of performance using real-world data, and ongoing evaluation of device performance.

All LFD antigen tests that pass Phase 3 of the validation process are also subjected to repeated assessment for performance against emerging SARS-CoV-2 variants, both *in vitro* at PHE Porton Down and via clinical performance assessment using real-world data from NHS T&T services.

To date we have identified no issues that lead us to question clinical performance of the produce. In June 2021 *in vitro* and clinical assessment was made of the performance of the Innova LFD antigen test against the Delta variant. This demonstrated that no discernible difference exists between the Innova LFD antigen test's ability to detect the Delta variant compared to the Alpha variant across the range of viral concentrations. This analysis also estimated that the real-world performance of the LFD test is above that estimated from field trials at the time of introduction into service.

**Conclusion**

Substantial work has been undertaken to understand performance of the Innova LFD within the Programme. Major safety and public health risks to people in undertaking testing has been assessed by the programme based on a clear understanding of these risks, and mitigation are in place.

In the event that a supply of LFD antigen tests was not available, asymptomatic mass testing would need to be reduced or ceased entirely. The public health harm from this would be a reduction in COVID-19 infections identified, increased onward transmission and a likely increase in subsequent morbidity and mortality (albeit the trend of increasing vaccination will act to limit this). To mitigate this risk, additional non-pharmaceutical public health interventions may need to be considered.

## 2.3 FDA Claim 3: Significant deficiencies in the Quality Management System

The FDA warning letter identified significant failures in the quality management system of Innova in the US. These non-conformities included

2.3.1 **Failure to establish procedures for control and distribution of finished devices**

2.3.2 **Failure to establish procedures to control product that does not conform to specified requirements**

2.3.3 **Failure to establish procedures for corrective and preventative action**

2.3.4 **Failure to establish procedures for receiving, reviewing, and evaluating complaint**

2.3.5 **Failure to establish procedures to ensure that all purchased or otherwise received product and services conform to specified requirements**

2.3.6 **Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures**

**DHSC Response:** DHSC is the legal manufacturer for the self-test Innova devices and a distributor for assisted use tests and therefore has put in place a quality management system and quality assurance processes that applies to all Innova kits purchased. Product is shipped directly from the manufacturer in China to the UK and the DHSC quality system covers the product from the manufacturer in China through to the end user in the UK. We have examined each of the non-conformities identified at the US company to determine whether we had any of the US identified deficiencies in our quality management system or could derive further learnings from the US investigation. The detail of these reviews has been written up in the following CAPA's:

- CAPA 21-06-0031 - Clinical Performance and Risk Assessment
- CAPA 21-06-0032 - Quality Management System
- CAPA 21-06-0033 - Supplier Management

2.3.1 **Failure to establish procedures for control and distribution of finished devices.**
Innova products went through a rigorous sign off process before being taken onboard by the DHSC. Only devices approved through this process can be distributed.

Currently individual batches of Innova product are released based on an exception basis. We have identified that an explicit sign off for each and every batch would be better practice.

2.3.2 **Failure to establish procedures to control product that does not conform to specified requirements'**
Following production, lots are subject to an inspection carried out by an external company (ET2C) to meet acceptable quality limit (AQL) standards to general inspection level II which requires the inspection of 1,500 devices per million. This inspection is carried out on-site at the factory and only lots that pass this inspection process are released for shipment.

A total of 1000 inspections have been performed on Innova test kits since 21/09/20 and of 67 red flags have been raised. These were resolved at the Biotime factory and re-inspections performed before releasing the product.

In addition, 100 kits per million are expedited to the UK for batch validation by Intertek, a third-party testing house, who assure that that the tests perform accurately and that nasopharyngeal swabs provided in test kits are sterile as per ISO 11737-1. Over 1000 batch validation reports have been generated of these

- No failures of swab sterility
- Six tests out of the 100,000 (0.006%) tested failed the test function due to;
    - 3 cases where test strips had been installed into cassette incorrectly. 2 of these were placed in a manner that the control line was not visible, one was a case of the test strip having been inserted into the cassette upside down.
    - 2 instances of staining on the test strip which prevented identification of a positive test.
    - 1 instance where sample tracked to one side missing the test line.

No systemic or significant issues have been identified

For inspection at origin, should a lot fail inspection, this is quarantined at the factory and subject to a complete inspection by Biotime (factory of manufacture). Following complete inspection by Biotime, the external inspection service will re-inspect goods, again to the AQL standard. Only following successful re-inspection will goods be released. However, should such event occur, non-conformance procedure (QP-23) would be followed.

### 2.3.3 Failure to establish procedures for corrective and preventative action

DHSC has an established corrective and preventative action procedure (QP-24) which is actively used. Following a recent MHRA audit it was identified that regulatory clinical input and the consistency of the clinical decisions made needed to be strengthened. Improvement to this process has started and is associated with CAPA 21-06-0012.

We have previously raised corrective actions to Biotime and sub-suppliers. These CAPAs were raised in response to extraction tube buffer leakage, foreign objects in extraction tubes, and dirt marks found on some swabs. Corrective actions were issued down to sub-supplier level and follow ups were conducted concluding the appropriate corrective actions were implemented. To date, all Innova specific product actions have been resolved.

### 2.3.4 Failure to establish procedures for receiving, reviewing, and evaluating complaint

DHSC has an established process (QP-20 Rev 2) for receiving and reviewing complaints. This process is fragmented and relies on the MHRA yellow card process. Further development of a end user complaints process has been identified as a priority area for improvement and has its own CAPA 21-06-0011

We also have Post Market surveillance procedure (QP-25 Rev 1) designed to identify emerging risks and issues. Fortnightly Periodic Safety Reports (PSR) are sent to the MHRA. This is a detailed report on post market activities and includes information on;

- Manufacturing batch validation reports; due to a cease in production at Biotime (end of 400M contract), there have been no updates for this recently
- Product complaints
- Qualtrics customer survey
- Real world performance monitoring
- CAPA and supplier corrective action request (SCAR)

The most recent PSR was titled "LFD PSR fortnight Report for 22 May to 4 Jun 2021" and no new actions where identified in this report.

### 2.3.5 Failure to establish procedures to ensure that all purchased or otherwise received product and services conform to specified requirements

The DHSC has an established validation process commissioned from PHE Porton Down which is overseen by the LFD Oversight Group. Post-deployment of the Innova LFD's, DHSC operates a routine programme of post-market surveillance to monitor performance of the devices. This encompasses clinical evaluation via routine monitoring of performance using real-world data, and ongoing evaluation of device performance. These are key to enable the continuous monitoring of performance outcomes in a real-world setting compared to initial estimates on which decisions for deployment were made. This process also detects any early signals of a change in performance as new variants are detected. Innova is subjected to repeated assessment for performance against emerging SARS-CoV-2 variants, both *in vitro* at PHE Porton Down and via clinical performance assessment using real-world data from DHCS services.

All product received is validated per batch in China by ET2C and in the UK by Intertek see point 2.3.2 above. This is an ongoing control. A recent MHRA audit identified that NHSTT should be more detailed in setting out the product performance expectation in the contract with Innova and this will be addressed as part of our MHRA audit follow up.

### 2.3.6 Failure to develop, maintain, and implement written Medical Device Reporting (MDR) procedures

We have a medical device reporting procedure (QP-21 Rev 2) which is our vigilance procedure. We follow this procedure when raising incidents including the raising of this incident.

**Conclusion on Quality Management System findings**

The FDA identified a number of quality management and assurance non-conformities for Innova in the US. DHSC as the legal manufacture and distributor in the UK of the Innova antigen tests has set up our own quality management and assurance processes.

DHSC have identified that we do have quality processes in place for all of the issues raised and that these have been used and are working. However, we recognise that some of these processes require improvement, as was identified in the recent MHRA audit. In particular, a unified end user complaints process, strengthening the release process, detailed product performance specification in tenders and contracts, and consistency in our clinical decisions in the complaints process.

We continue to actively strengthen and build out our existing quality systems and the issues raised in the FDA report about Innova in the US are not concerns we have with DHSC UK's quality management and assurance processes.

# 3 Failure of Innova to Notify DHSC of FDA audit and findings in the USA

Innova's current contract includes a clause requiring them to share concerns and information of this nature, as below:

"*If there are any quality, performance and/or safety related reports, notices, alerts or other communications issued by the Supplier or any regulatory or other body in relation to the Goods, the Supplier shall promptly provide the Authority with a copy of any such reports, notices, alerts or other communications"*

There is a comprehensive programme of both formal and informal engagement with Innova, including a daily call between Innova reps in the US, and DHSC colleagues in commercial, supply chain and logistics, and product management. There is further daily email and messages between various DHSC teams and Innova colleagues in the US, and less frequently with Biotime contacts in China. At no point has the voluntary recall or FDA investigation been highlighted.

This raises a question of trust and transparency. It is unclear if this was a deliberate decision on Innova's part to withhold this information or a naivety of the requirement to do so (despite the contractual clause). The lateral flow market is an immature one and Innova are not alone in lacking experience in the field of regulatory compliance.

DHSC have determined that it should

- Strengthen the contractual arrangement further and remind LFD suppliers of the requirement to provide DHSC this information on a timely basis.
- Put in place a process to request to this information on a monthly basis from suppliers who will be required to confirm that they have not had any such events or regulatory contact and if they have the detail and outcome of those discussions.
- Request an update on the US regulatory position and Innova's strategy for that market.

# 4 Outcome from Incident Investigation

DHSC immediately pulled together a cross functional team and reviewed each of the concerns raised by the FDA regarding the US operations of Innova Group and the use of their SARS-CoV-2 Antigen Rapid Qualitative Test in US market to determine whether they apply to the UK programme of testing.

When making the Innova LFD antigen tests available on the UK market we complied with the UK requirements and obtained an Exceptional Use Authorisation from the MHRA for the self test devices. We are satisfied that the Innova tests used in the UK are legally on the market .

We conducted a full review of our quality processes at short notice and are satisfied that the Quality Management System put in place by DHSC as the legal manufacture, distributor and clinical service provider is operating effectively. The points raised by the FDA regarding Innova in the US do not apply to DHSC. We are aware of a few areas for improvement that have previously been identified and we have a programme in place to address these. They include;

- A complaints process to enable user to directly raise and register complaints with DHSC that does not rely on the MHRA yellow card system, records contact details and can differentiate between manufacturers.
- Strengthening the batch release process to move away from by exception to explicit signoff
- Providing detailed product performance specification in tenders and contracts
- Consistency in the process of referral to the patient safety team and strengthening the regulatory clinical evaluation resources as part of complaints management process
- Implementing a control requiring suppliers to confirm regulatory contact and feedback from regulators they have been involved with around the world.

We are satisfied that the Innova tests used as part of the NHS T&T asymptomatic testing programme performs at the level required, including against known variants of concern such as Alpha and Delta, and that our ongoing monitoring of real world, performance and post market surveillance have not raised concerns that indicated they are not performing as intended.

In considering the balance of risk and mitigations it is also important to consider the impact of withdrawing testing. While we are in a procurement process which includes alternative providers, in the short term there are no alternative sources of similar tests. The impact of asymptomatic testing has recently been assessed by an internal DHSC review and accounts for the identification of 222,000 positive asymptomatic cases that might not otherwise have been identified. It is estimated that this has reduced community transmission of SARS-CoV-2 by 2-13%

We are not satisfied that the DHSC were not made aware of the FDA audit and findings even though Innova had ample opportunity to do so, and contractual provision indicates they should have. We are implementing a more robust process to require disclosure from Innova and other LFD manufacturers as and when they contract with DHSC.

In summary our review of DHSC quality and assurance processes and supporting evidence show that the situation Innova finds themselves in the US has not put the Public in the United

Kingdom at any increased risk or introduced any new risks. We are confident that DHSC Innova LFD antigen tests are performing as expected and play a key role in the national testing strategy. The DHSC quality management system, quality assurance processes and the public health clinical processes wrapped around the delivery of the Innova LFD antigen tests are operating effectively. Based on the positive outcome of this investigation we will continue to use the Innova products as part of our national testing strategy.