DOCUMENT VERIFICATION

Prior to using this document, the user is responsible for verifying that the revision and effective date are current.

REVISION HISTORY

Rev.	Effective Date	Changes Made to Document
1	14-07-2023	First Issue

1. Content

2. Introduction

The LFD kit is an IVD medical device intended by DHSC to be used *in vitro* for the examination of combined throat and nasal specimens derived from the human body solely for the purpose of providing information concerning Covid-19 infection. The device is classified as a **IVD Device for self-testing.**

The PSR report outlines, analyses and reports on the activities that were undertaken by DHSC to ensure the performance and safety of the DHSC LFD during its life cycle in line with the PMS Procedure and PMS Plan.

This was performed thorough the continuous data generation and assessment of the DHSC LFD performance post market and aims to discuss (through presentation of data) the questions below:

a) Were there any new hazard or hazardous situation(s) identified for the DHSC LFD's or has the risk acceptability changed?
b) Has any misuse of the DHSC LFDs occurred?
c) Do the DHSC LFD's still meet the user's needs after medium/long term clinical use?
d) Do users experience any usability issues?
e) Are there any recurring quality issues DHSC LFD's and can significant increasing/decreasing trends be identified for DHSC LFD' inadequate performance?

Refer to Table 5 for conclusions.

3. Reference documents

Doc ID	Doc name	Revision
QM-01	Quality manual	2
QOP-25	Post- Market Surveillance (PMS) Procedure	4
PMS0001	PMS Plan for the DHSC COVID-19 LFD device (3 and 7 kit)	2
RMF-0001	LFD Risk Management File	5
QP08-F02	LFD Hazard Traceability Matrix	3

Table 1: Reference to internal documentation

4. Standards and guidelines

- ISO 9001:2015 Quality management systems – Requirements.
- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.
- ISO 14971:2019 Medical devices -- Application of risk management to medical devices.

5. Methodology

- Data is gathered as per the PMS Plan referenced in Table 1.
- All inputs are stored in a centralised LFD PSR location on SharePoint
- All inputs are submitted via the relevant departments as per the PMS plan.

6. Findings /Results

6.1 In-House manufacturing inspection at Biotime

No further Innova product has been procured during this reporting window.

6.2 Receiving inspection - Intertek Testing in the UK

No further receiving inspections have been carried out for this reporting period as no further product has been procured and all lots received into the UK have been validated.

6.3 Product complaints & Qualtrics Survey Reports

- The number of kits distributed in this reporting period is **~1.3 mil which is a decrease of ~10.2 mil since the last reporting period.**

- No harm complaints were received from Qualtrics, MHRA Yellow card and 119 Call in this reporting period

- A total of 98 user reports were received from the Qualtrics survey in relation to the DHSC LFD during this reporting window.

- No Lot specific trend was identified in this reporting window.

- Further information on the trending categories, number of complaints, reportability/non-reportability, investigations and further actions is documented in Table 2.

(Refer to attachment 02.1)

Qualtrics and Yellow card complaints investigation				
Trending category	Number of complaints	Reportability	Investigation	Further actions
Missing components	18	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Damaged Item	6	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Faulty test results	1	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Faulty items	12	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Empty extraction buffer	7	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Insufficient buffer solution	29	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Allergic reaction	00	N/A	N/A	N/A
Patient injury	00	N/A	N/A	N/A
Barcode/QR code issues	03	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes
Usability	00	Not reportable	N/A	The Usability Category on the Qualtrics survey is no longer in use. It has been replaced by the more relevant category for Individual complaints. This category will be removed from future reports. User Experience (UX) is reported in section 6.5
User error	09	Not reportable	There was no trend observed for same type of user error	No further action. Complaints will be monitored for trending purposes
Reporting issue	09	Not reportable	Forwarded to NHS digital for further action	No further action required
Contaminated item	00	N/A	N/A	N/A
Expired kit	01	N/A	N/A	N/A
Service/Delivery	02	Not reportable	Forwarded to Complaints Team for further action	N/A
Digital Reader	01	Not reportable	Forwarded to Digital Reader Team for further action	N/A

Table 2: Summary of reportability/non-reportability for all complaints

*Not reportable: these complaints did not meet the reportability criteria set out in MEDDEV 2.12-1 rev 8 vigilance standard and hence were decided to be non-reportable.
MED DEV 2.12-1 rev 8 vigilance Guidance to support discussions at Incident Review Meetings & Patient Safety Panel:

- *Question A "Has an event occurred etc."*
- *Question B "Is DHSC device cause of incident"*
- *Question C "Has the event led to death or serious deterioration in health"*

6.4 Complaints Trending

Due to the reduced volume of overall complaints, the alert levels for each category are re-calculated each quarter to provide an accurate reflection of performance of the device. The figures below show the re-calculated alert levels for this period.

This methodology is following QMS procedure "QOP-20 Complaints Procedure (Rev 05)" and is defined as "Mean and standard deviation should be recalculated every quarter to ensure that they are still appropriate considering the changes in the number of complaints and distribution volume."

At the end of May 2023, the fortnightly monitoring periods were changed from a Saturday – Friday cadence to a Monday – Sunday cadence. This has resulted in one 9 day period from 20th May 2023 to 29th May 2023.

Current trending categories analysed through the Qualtrics data are grouped into three main categories:

1) **Material:** this includes trending categories: Missing item, Damaged Item, Faulty item, Contaminated Item, QR code issues, Empty Buffer Solution Sachet, Insufficient Buffer Solution. The number of complaints received in this category are below the updated alert threshold which is represented by the dark blue line (Refer to Figure 1).

2) **Faulty Test Results:** No sub-categories exist within this category of complaints. Number of complaints for this category is below the new alert threshold which is represented by the dark blue line (Refer to Figure 2).

3) **Harm & Allergy:** this includes complaints from Patient Injury and Allergic reactions as sub-categories. Harm-allergy complaints for this reporting period is below the new alert threshold which is represented by the dark blue line (Refer to Figure 3).

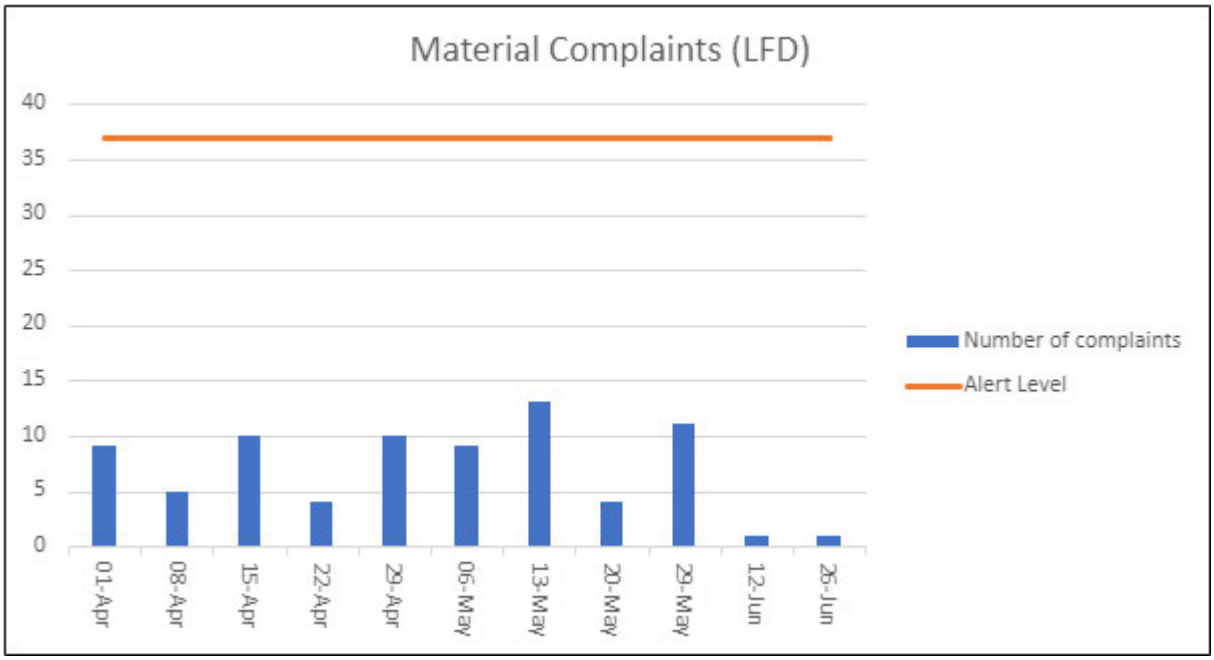

Figure 1: Material complaints weekly trending

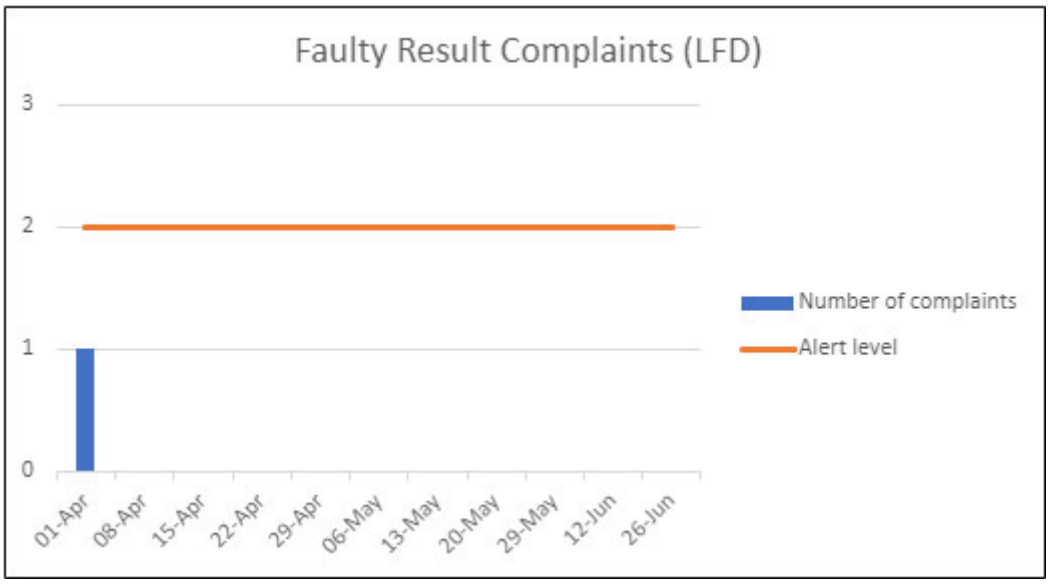

Figure 2: Faulty results complaint weekly trending

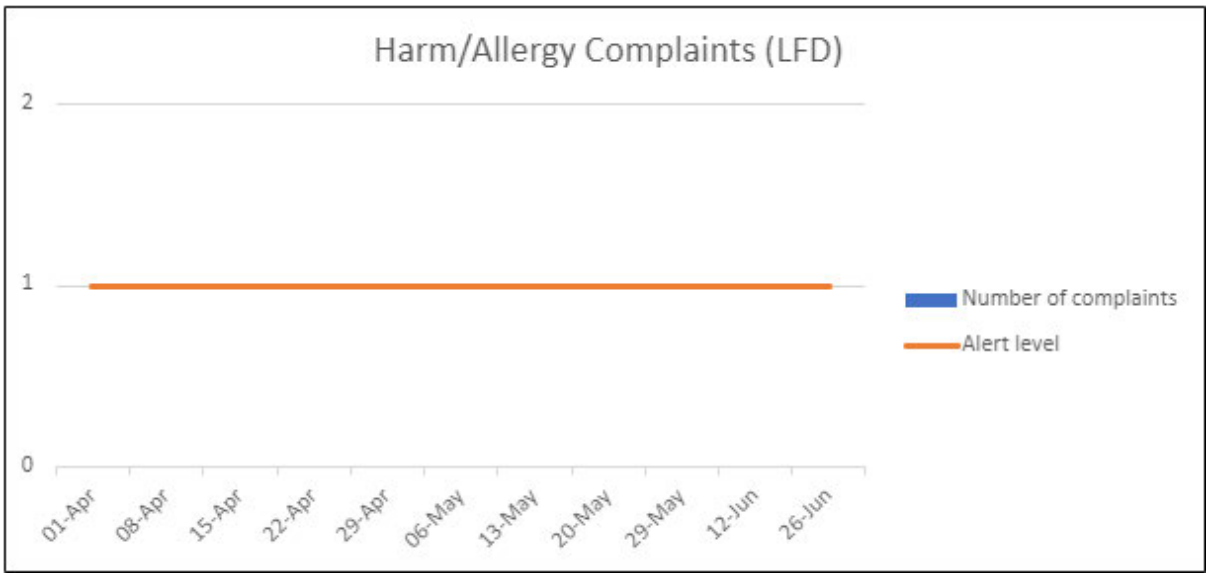

Figure 3: Harm-Allergy complaints weekly trending

(Refer to Attachment 02.2)

6.5 Qualtrics Survey (User Experience)

A total of 240 user responses were received during this reporting window of 01 April to 30th June 2023 for all LFD products for which the DHSC is either the legal manufacturer or importer/distributor (for Acon Flowflex, Orient Gene and Surescreen LFDs). 117 (48.5%) users completed 100% of the survey in an average time of 8.8 minutes

32.5% of these responses were related to the DHSC LFD Products (**highlighted in green in Attachment 02.3**)..

A series of questions relating to the user's overall experience can be seen in **Attachment 02.3**. Satisfaction rates were predominantly above 70% for most queries relating to the usability of the LFD products, except for:

1) ***Reporting of results (Understanding of IFU):*** 67.21% satisfaction rate which is an improvement since the last reporting period of 1.15%.
2) ***Processing the swab (Understanding of IFU):*** 65.28% satisfaction rate which is reduction on improvement of 7.99% since the last reporting period.
3) ***Taking the swab sample (Difficulty of process):*** 60.64% satisfaction rate, which is a reduction on improvement of 13.68% since the last reporting period
4) ***Taking the swab sample from a child (Difficulty of process):*** 66.67% satisfaction rate, which is a reduction on improvement of 8.33% since the last reporting period
5) ***Processing the swab sample (Difficulty of process):*** 49.41% satisfaction rate, which is a reduction on improvement of 5.92% since the last reporting period
6) ***Reading the result (Difficulty of process):*** 66.23% satisfaction rate, which is a reduction on improvement of 8.42% since the last reporting period
7) ***Interpreting the result (Difficulty of process):*** 64.47% satisfaction rate, which is a reduction on improvement of 6.96% since the last reporting period
8) ***Reporting of results (Difficulty of process):*** 52.94% satisfaction rate which is an improvement of 10.04% since the last reporting period.

On-going product improvements are supported at the procurement stage by the LFD Product Management team and information on user experience from the Qualtrics survey is shared with the team for continual improvement. As discussed in previous reporting periods, actions have already been instigated at the next round of invitation to tender (ITT). There have been no new purchases of LFDs since the beginning of 2022, and all feedback is based on the same version of LFD. There is currently no opportunity to improve feedback by introducing improvements. Further information has been retained in this PSR from the previous reporting period and referenced in **Section 6.6.**

(Refer to Attachment 02.3)

6.6 Product Management (Usability Studies)

The LFD Product Team are involved in a Three-Stage process aimed at continuously improving the usability of LFD products sourced by DHSC and supplied to the end users (see Figure 4).

The team have carried out usability research activities with 2000 users through a mixture of surveys and one to one interview. The purpose of this research is to understand (from the user's perspective) what improvements can be made to the LFD product supplied.

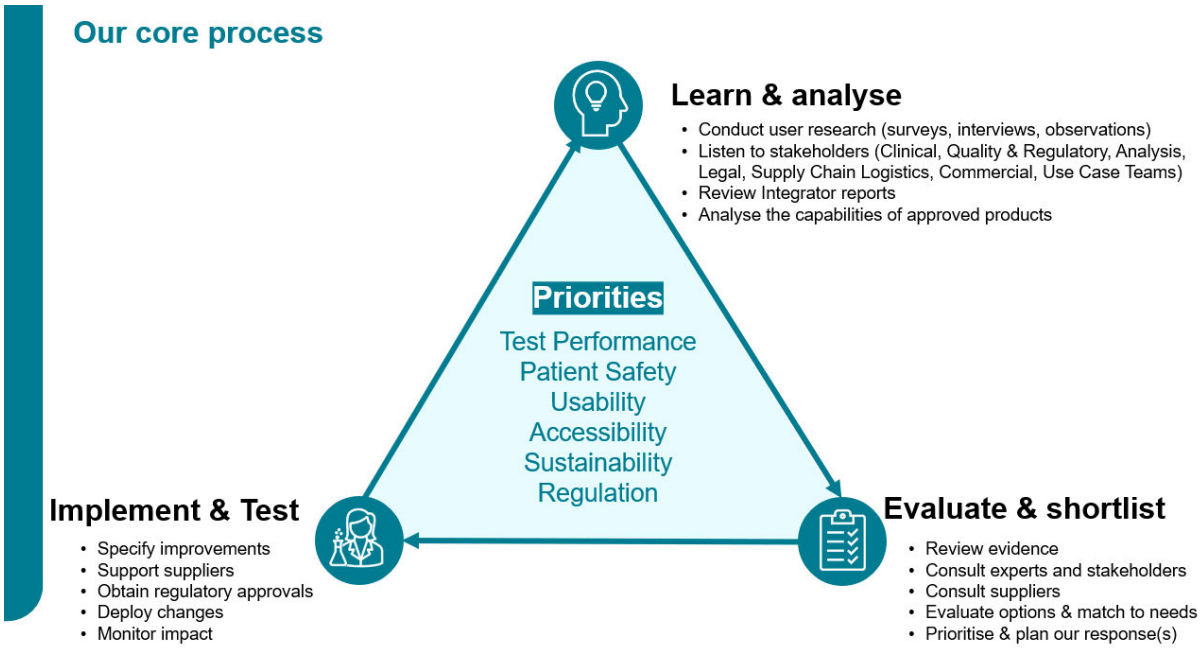

Figure 4: LFD Product Management Teams Core Process

Findings from these usability studies feed into improvements in the procurement exercises (Invitation to Tender ITT).

Further information on some of the findings and actions were shared in the previous report and have therefore been omitted from this submission.

No further updates or planned studies are planned from the LFD Product Management team as sufficient data has been collected for the current range of LFD's. Any future studies planned will be discussed in the PSR report.

6.7 Real World Performance Monitoring

UKHSA has announced the conclusion of the Real-World Performance Monitoring service. This monitoring service was reliant on widespread testing using both LFD and PCRs. Changes to the National Testing Strategy, including the removal of the requirement to undertake a confirmatory PCR test after a positive LFD test result, has meant that this monitoring service was no longer fit for purpose.

A risk assessment was drafted to assess and reduce the residual risk of conclusion of this service as per QOP-45 Risk Assessment Procedure ISO 13485 Rev 2. The risk assessment procedure is a four-step process as follows:

1) **Step 1:** Assessing the inherent risk determined by severity (s) and probability (p) against criteria defined in the QOP.
2) **Step 2:** Assessing the strength of the controls (c) as per criteria defined in the QOP.
3) **Step 3:** calculating the Risk Value where Risk = [S x P x C] and correlating to a High, Medium or Low Risk rating as defined in QOP-45.
4) **Step 4:** Taking further action to mitigate and reduce the residual risk as far as possible depending on the outcome of the risk rating above. i.e. a High Risk/Medium Risk Rating may require additional actions to reduce the residual risk as far as possible.

Following the above risk assessment procedure, the conclusion of the RWPM service was assigned a risk value of 10 which is an overall “Low Risk”. This was due to having the following controls in place:

1) Continued oversight of Post Market Surveillance activities including vigilance reporting and clinical assessment of complaints.

2) Continued literature reviews as part of Post Market Surveillance activities to ensure any publications highlighting issues with similar devices are reviewed and assessed by DHSC (UKHSA) and any triggers actioned.

3) Continued Variant Of Concerns monitoring activities to be carried out by the VOC team to ensure that new strains of SARS-CoV-2 are assessed against the performance of the device.

4) Further service evaluations to be carried out if a "trigger" is identified from any of the activities listed above.

(Refer to attachment 03.0)

6.8 Post Market Performance Follow Up

DHSC implemented a series of ongoing evaluations. The objective of these evaluations was to determine whether lateral flow device (LFD) performance seen in pre-deployment evaluations were achieved when deployed by the testing service.

Biotime's Ongoing evaluation and DHSC 3&7 self-test post-market clinical performance follow-up report 3 was submitted to the MHRA on Tuesday 20th September 2022.

The reporting period for report three was 22nd Sep 2021 – 21st Mar 2022. The overall objective of the report is as follows:

a. To confirm the safety and performance of Biotime LFD throughout its expected lifetime
b. To identify previously unknown risks or limitations to performance and contra-indications to changing epidemiological factors e.g., variant, vaccination status, prevalence
c. To identify and analyse emergent risks based on factual evidence
d. To ensure the continued acceptability of the clinical evidence and of the benefit-risk ratio
e. To identify possible systematic misuse.

A summary of the report is as follows:

- Sensitivity was higher in post-deployment than at baseline in self-test settings and not different to baseline in assisted test settings
- Sensitivity in all analysis sets was non-inferior to baseline
- Specificity was higher in post-deployment than at baseline in all analysis sets
- Symptomatic disease independently increased the sensitivity of LFDs
- The sensitivity of LFDs did not appear to be significantly affected by variant, vaccination status, time period, or the time delay between symptom onset and taking the LFD test.
- All other outcomes showed similar or improved results in post-deployment than at baseline

The evidence generated as part of this evaluation demonstrated that the LFD kits utilised as part of the National Testing Programme provided sufficient diagnostic performance relative to baseline for use as part of a public health intervention.

6.9 Variants of Concern (VOC)

The Variant of Concern Assurance Group (VOC) within the UKHSA are responsible for continuous monitoring of SARS-COV-2 variants. A cross-functional VOC meeting is in place, and the MHRA and the Regulatory & Quality team attend to provide updates on the status of variants and discuss on-going activities. Weekly meetings continue to take place with key stakeholders for continuous monitoring.

Objectives of the VOC Assurance Group

- A robust system of assay performance monitoring against new VOC, and appropriate mitigations
- Appropriate governance structure
- Effective communication and escalation of issues and decisions to relevant partners

How is this achieved

a) Horizon scanning of variants and mutations

b) Evaluating real time test performance data (Real World Data, PLOD data, Quality incident reports)

c) Conducting regular *in silico* analysis of assay (molecular) and development of new requirements for MHRA IVD process

d) Putting in place an early warning system for laboratories to report and refer concerns in assay performance that may be related to new or unidentified variants. (Antigen/LFDs & Molecular Testing)

e) Establishing process for the ongoing assurance of assays through in vitro “wet-testing” of assays using virus materials for variants of concern.

f) Risk assessments of tests predicted to be impacted by novel variants or mutations

Impact of current circulating VOCs on the DHSC 3T/7T Covid-19 Self-Test LFD

There are currently no concerns about the mutations contained within any of the circulating VOCs having a negative impact on the DHSC 3T/7T COVID-19 Self-Test LFD.

6.10 CAPA

- Refer to Table 3 for a CAPA Status Overview
- Table 4 for List of open CAPA's and current progress and due dates.

CAPA Status	No
Open	00

Table 3: CAPA Status Overview

No	CAPA No	Start Date	Source	Problem statement	Status/ progress

Table 4: List of open CAPA's, Status & Due date

6.11 SCAR – Supplier Corrective Action Report

No new SCARs were raised by DHSC to Innova for this reporting period. It is important to note that no new EUA stock will be ordered from Innova. Any actions from existing SCARs will not be realised as all stock is already received by UKHSA. SCARs are being raised to support the supplier to continuously improve processes.

6.12 Risk Management

LFD Risk management File (RMF) was updated to RMF-0001 Revision 5 and HTM Hazard traceability Matrix Rev5. The RMF updated to new template for compliance with ISO 14971:2019.

No new Hazards were identified during this reporting period as part of the continual monitoring through post-market surveillance activities.

6.13 Literature Review & State of the Art (SOTA)

In collaboration with an external consultancy, DHSC has developed a Literature Search Protocol. The intention of the literature search is to review the continued clinical safety and effectiveness of the Lateral Flow Device kit when used for the intended purpose.

The literature search & SOTA search is carried out monthly, and utilizes multiple electronic search databases (e.g., PubMed, Embase) as highlighted in the protocol. It is worth highlighting that due to the frequency and timing of the LFD PSR reports, it is not practical nor feasible to provide a detailed analysis and conclusions of findings from the literature search report. However, the literature searches are continuously reviewed with the support of PHCO for on-going performance evaluation and separately, a high-level summary is provided in the PSR reports.

In August 2022, the contract with the external consultancy carrying out the Literature Review as a service to UKHSA ended. The UKHSA has subsequently worked cross-functionally to implement an internal literature review process utilizing the Knowledge & Libraries team services and appraisal through a UKHSA Scientific Advisor.

UKHSA Internal Literature Review Update:

From the three Scientific Papers that were identified for the May 2023 report (covering 27 March 2023 to 25 April 2023) report, **one** passed both the first and second appraisal to pass into the data extraction stage of this Literature Review.

From the one Scientific Paper that was identified for the June 2023 report (covering 24 April 2023 to 25 May 2023), **zero** passed both the first and second appraisal to pass into the data extraction stage of this Literature Review.

From the three Scientific Papers that were identified for the July 2023 report (24 May 2023 to 27 June 2023), **zero** passed both the first and second appraisal to pass into the data extraction stage of this Literature Review.

Summary of inclusions for this reporting period:

202305.1 *David W Eyre, Matthias Futschik, Sarah Tunkel, Jia Wei, Joanna Cole-Hamilton, Rida Saquib, Nick Germanacos, Andrew R Dodgson, Paul E Klapper, Malur Sudhanva, Chris Kenny, Peter Marks, Edward Blandford, Susan Hopkins, Tim E A Peto, Tom Fowler*

Performance of antigen lateral flow devices in the UK during the alpha, delta, and omicron waves of the SARS-CoV-2 pandemic: a diagnostic and observational study

Please note that this paper was produced by UK Health Security Agency, and summarizes the Performance Evaluation Reports that have already been submitted to the MHRA.

This study was funded by Funding UK Health Security Agency, the UK Government Department of Health and Social Care, National Institute for Health Research (NIHR) Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance, and the University of Oxford NIHR Biomedical Research Centre.

The aim of the study was to improve the understanding of LFD performance with changes in variant infections, vaccination, viral load and LFD use in the identification of infectious individuals.

Results were prospectively collected from paired LFD and RT-PCR test results in both asymptomatic and symptomatic participants in the UK between Nov 4, 2020, and March 21, 2022.

The LFDs evaluated were the Innova SARS-CoV-2 Antigen Rapid Qualitative Test, the Orient Gene Rapid Covid-19 (Antigen) Self-Test, and the Acon Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing).

Test results were collected across various community testing settings, including pre-deployment testing sites, routine testing centres, homes, schools, universities, workplaces, targeted community testing, and from health-care workers.

Multivariable logistic regression was used to analyse LFD sensitivity and specificity using RT-PCR as a reference standard. Analysis were adjusted for viral load, LFD manufacturer, test setting, age, sex, test assistance, symptom status, vaccination status, and SARS-CoV-2 variant.

The national contact tracing data from NHS Test and Trace (Jan 1, 2021, to Jan 11, 2022) were used to estimate the proportion of transmitting index patients (with ≥1 RT-PCR-positive or LFD-positive contact) potentially detectable by LFDs (specifically Innova, as the most widely used LFD) with time, accounting for index viral load, variant, and symptom status.

A total of 75,382 pairs of LFD and RT-PCR paired tests were analysed. Of these, 4131 (5·5%) were RT-PCR-positive. LFD sensitivity versus RT-PCR was 63·2% (95% CI 61·7–64·6) and specificity was 99·71% (95% CI 99·66–99·74). Increased viral load was independently associated with being LFD positive (adjusted odds ratio [aOR] 2·85 [95% CI 2·66–3·06] per 1 log10 copies per mL increase; p<0·0001).

There was no evidence that LFD sensitivity differed for delta (B.1.617.2) infections versus alpha (B.1.1.7) or pre-alpha (B.1.177) infections (aOR 1·00 [0·69–1·45]; p=0·99), whereas omicron (BA.1 or BA.2) infections appeared more likely to be LFD positive (aOR 1·63 [1·02–2·59]; p=0·042).

Sensitivity was higher in symptomatic participants (68·7% [95% CI 66·9–70·4]) than in asymptomatic participants (52·8% [50·1–55·4]). Among the 347,374 unique index patients with probable onward transmission, 78·3% (95% CI 75·3–81·2) were estimated to have been detectable with LFDs (Innova), and this proportion was mostly stable with time and for successive variants.

Overall, the estimated proportion of infectious index patients detectable by the Innova LFD was lower in asymptomatic patients (57·6% [53·6–61·9]) versus symptomatic patients (79·7% [76·7–82·5]).

LFDs remained able to detect most SARS-CoV-2 infections throughout vaccine roll-out and across different viral variants. LFDs can potentially detect most infections that transmit to others and reduce the risk of transmission. However, performance is lower in asymptomatic individuals than in symptomatic individuals.

(Refer to Attachment 04)

7. Conclusion & Risk-Benefit Determination

The DHSC LFD test is intended to detect the presence of coronavirus (Covid-19) antigen in humans to enable the spread of the virus to be reduced in the community. The overall purpose of post-market surveillance activities is to ensure that the device continues to meet its intended purpose.

Questions posed in the Post Market Surveillance plan (PMS-001) and at the beginning of this report have been addressed in Table 5 and summarised in this section.

The Real-World Performance Monitoring Service (RWPM) has concluded however a risk assessment has been drafted and the residual risk remains low.

PMPF Report 3 was submitted to the MHRA 20th September 2022, titled "Biotime Ongoing evaluation and DHSC 3&7 self-test post-market clinical performance follow-up report 3" and published on 25th August 2022 and covering the period 22nd Sep 2022– 21 Mar 2022. Findings from this report confirmed that the DHSC LFD performance is equivalent to or better than those in the baseline performance and following the ASC Staff Root Cause Analysis and Risk Assessment Report, the Biotime LFD remains appropriate for use as a public health intervention to reduce the impact of the SARS-CoV-2 pandemic in all archetypes assessed. If Post Market Surveillance activities signal a potential concern, then an adhoc service evaluation will be undertaken.

No new Hazards were identified during this reporting period as part of the continual monitoring through post-market surveillance activities.

UKHSA has not instigated a re-call nor issued any Field Safety Corrective Action Notices during this reporting period.

One new scientific publication was found for this reporting period. This paper paired LFDs and PCR test results to understand the sensitivity of the LFDs in the presence of vaccinations and different variants. The LFDs investigated were Innova, Orient Gene and Flowflex. Sensitivity (the ability of a test to correctly identify patients with a disease) across all LFDs versus RT-PCR was 63·2% (95% CI 61·7–64·6) and specificity (the ability of a test to correctly identify people without the disease) was 99·71% (95% CI 99·66–99·74). The was no evidence that the sensitivity of the LFDs were negatively impacted by the alpha, beta or delta variants, and the omicron BA.1 and BA.2 variants seem to slightly improve the sensitivity of the LFDs. The sensitivity of the LFDs appears to be better within symptomatic individuals compared to asymptomatic individuals.

To further mitigate the risk of Variant mutation on device performance, the UKHSA maintains a Variant Of Concern working group who continuously monitor emerging variants, provide feedback and suggestions on additional studies required, and instigate additional studies if required.

Based on the information discussed in this periodic summary report, the DHSC maintain the position that the benefits of use of Lateral Flow Devices continue to outweigh the risks identified in the risk management report. The benefits include:

a) Early indication of possible infection with Covid-19 while still asymptomatic
b) Reducing spread of Covid-19 virus by alerting users to possible infection
c) Reducing the need for unnecessary self-isolation/travel restriction therefore improving patient/user quality of life.
d) Widespread PCR testing is operationally unfeasible

Question	Answer	Comments	Evidence
a) Were there any new hazard or hazardous situation(s) identified for the DHSC LFD's or has the risk acceptability changed?	No	No new hazards identified in this reporting period.	**Section 6.12**
b) Has any misuse of the DHSC LFDs occurred?	No	No formal complaints or reports in Qualtrics received to indicate the DHSC LFD was misused.	**Section 6.3**
c) Do the DHSC LFD's still meet the user's needs after medium/long term clinical use?	Yes	Findings from PMPFR report 3 confirmed that the DHSC LFD performance is equivalent to or better than those in the baseline performance and following the ASC Staff Root Cause Analysis and Risk Assessment Report, the Biotime LFD remains appropriate for use as a public health intervention to reduce the impact of the SARS-CoV-2 pandemic in all archetypes assessed.	**Section 7**
d) Do users experience any usability issues?	Yes	Satisfaction rates are generally above 70% with regards to usability of the devices. There has been a small reduction in satisfaction rates for some areas. Usability concerns are raised at the Patient Safety Panel to determine if any further action is required. Any minor issues identified feed into continuous improvement activities at the procurement stage. All devices have been distributed, and so there is currently no opportunity to implement improvements	**Section 6.5** **Section 6.6**
e) Are there any recurring quality issues DHSC LFD's and can significant increasing/decreasing trends be identified for DHSC LFD' inadequate performance?	No	No recurring quality issues, and no significant trends have been identified.	**Section 6.4** **Section 6.11**

Table 5: Questions posed by PMS-001 Plan for DHSC LFD Products

No emerging issues or safety signals identified. As a result of the PMS activities analysed/discussed in this report the PMS Team advice is that product that has already been distributed by UKHSA is safe for continued use up until the expiry data of the product. The EUA for this product expired on 30th June 2023, and UKHSA has not distributed any of this product after this date.

8. Recommended Actions

No	Added	Action	Responsible Name	Due Date	Status
1	20th January 2023	Flag study (Roderick P. Venekamp, Ewoud Schuit, Lotty Hooft, et al) found during the UKHSA literature search to PHCO [redacted]	[redacted]	Immediate	Closed
2	17th April 2023	There is conflicting information on the impact of the omicron variant on LFDs across the papers within the literature review for this and the previous reporting period. This was discussed with key UKHSA experts, including PHCO. A recent publication using paired LFD and RT-PCR test results that were prospectively collected from asymptomatic and symptomatic participants in the UK between Nov 4, 2020, and March 21, 2022, to support the National Health Service (NHS) England's Test and Trace programme (https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(23)00129-9/fulltext) confirmed that the LFDs for which the DHSC is either the legal manufacturer or importer/distributor are not negatively impacted by the omicron variant. In addition to this and to continue to monitor and mitigate this risk, UKHSA carries out its own LFD Service Evaluations and discusses the potential impact of the Variant of Concern (VOC) on the LFDs on a weekly basis.	[redacted]	Immediate	CLOSED Ongoing VOC meetings

9. Attachments

Attachment 01: PMS-0001, PMS Plan for the DHSC Covit-19 LFD Devices (3 and 7 kit) Rev2, 29-July-2021
Attachment 02: DHSC PSR – Complaints & Qualtrics data (Attachments 02.1 – 02.3)
Attachment 03: RA-22-15 - Conclusion of Real-World Performance Monitoring Service
Attachment 04: Literature Review on the safety and performance of the DHSC Innova Lateral Flow Device_v4.0

10. Author

	Job Title	Name	Email
Compiled by	Senior Quality Manager	[redacted]	[redacted]