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-OCT-2022	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	1
QOP-25	Post- Market Surveillance (PMS) Procedure	3
PMS-0001	PMS Plan for the DHSC COVID-19 LFD device (3 and 7 kit)	2
RMF-001	Risk Management File	5
QP08-F02	LFD Hazard Traceability Matrix	1

Table 1: Reference to internal documentation

4. Standards and guidelines

- ISO 9001:2000 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 validation activities are planned as all lots received into the UK have now been validated.

(Refer to Attachment 8)

6.3 Product complaints & Qualtrics Survey Reports

- The number of kits distributed in this reporting period is **~21.12 Mil**

- Six complaints were received from Qualtrics, MHRA Yellow card and 119 Call in this reporting period and were discussed at the weekly incident review meetings and weekly Patient safety panel meetings.

- All 6 complaints were defined as non-reportable as per Med Dev 12.1 Rev 8.

- A total of 506 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	174	Not reportable	No batch specific trend observed. SCAR was raised in past with the supplier for this issue and corrective action was taken by supplier. However, as we are not procuring any more kits from the supplier no further action is required.	No further action. Complaints will be monitored for trending purposes. The supplier will be informed in case of a trend or an increased number of complaints.
Damaged Item	26	Not reportable	No action required no trend observed	Complaints will be monitored for trending purposes
Faulty test results	11	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Faulty items	64	Only 1 reportable	There was no trend observed for any batch.	CAPA was raised for 1 reportable complaint. For rest 63 complaints, no further action required. Complaints will be monitored for trending purposes
Empty extraction buffer	23	Not reportable	No batch specific trend observed. SCAR was raised in past with the supplier for this issue and corrective action was taken by supplier. However, as we are not procuring any more kits from the supplier no further action is required.	No further action. Complaints will be monitored for trending purposes. The supplier will be informed in case of a trend or an increased number of complaints
Insufficient buffer solution	102	Not reportable	No batch specific trend observed. SCAR was raised in past with the supplier for this issue and corrective action was taken by supplier. However, as we are not procuring any more kits from the supplier no further action is required.	No further action. Complaints will be monitored for trending purposes. The supplier will be informed in case of a trend or an increased number of complaints
Allergic reaction	04	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Patient injury	01	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Bar code/QR code issues	21	Not reportable	There was no batch specific trend observed for similar type of complaint.	No further action. Complaints will be monitored for trending purposes
Usability	44	Not reportable	Not enough provided by the reporters to confirm the type of usability issue	Updating Qualtrics survey to get more specific information about what was the exact usability issue faced by the reporter.
User error	04	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	110	Not reportable	Forwarded to NHS digital for further action	No further action required
Contaminated item	4	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.

Digital reader issues	24	Not reportable	Forwarded to NHS digital for further action	No further action required
Expired kit	04	Not reportable	Limited information available to confirm if the kit was expired at delivery or expired at use	Updating Qualtrics survey to get more specific information if the kit was expired at delivery or expired at use

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

*Not reportable: these complaints did not meet the reportability criteria set out in MED DEV 2.12 rev 8 vigilance standard and hence were decided to be non-reportable.

MED DEV 2.12 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 the reduced volume of overall complaints, the alert levels set for each category has been re-calculated to provide an accurate reflection of performance of the device. Figures below will show two separate lines representing the old alert level vs the new alert level.

This methodology is following QMS procedure "QOP-20 Complaints Procedure (Rev 04)" 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."

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 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 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 blue line (Refer to Figure 3).

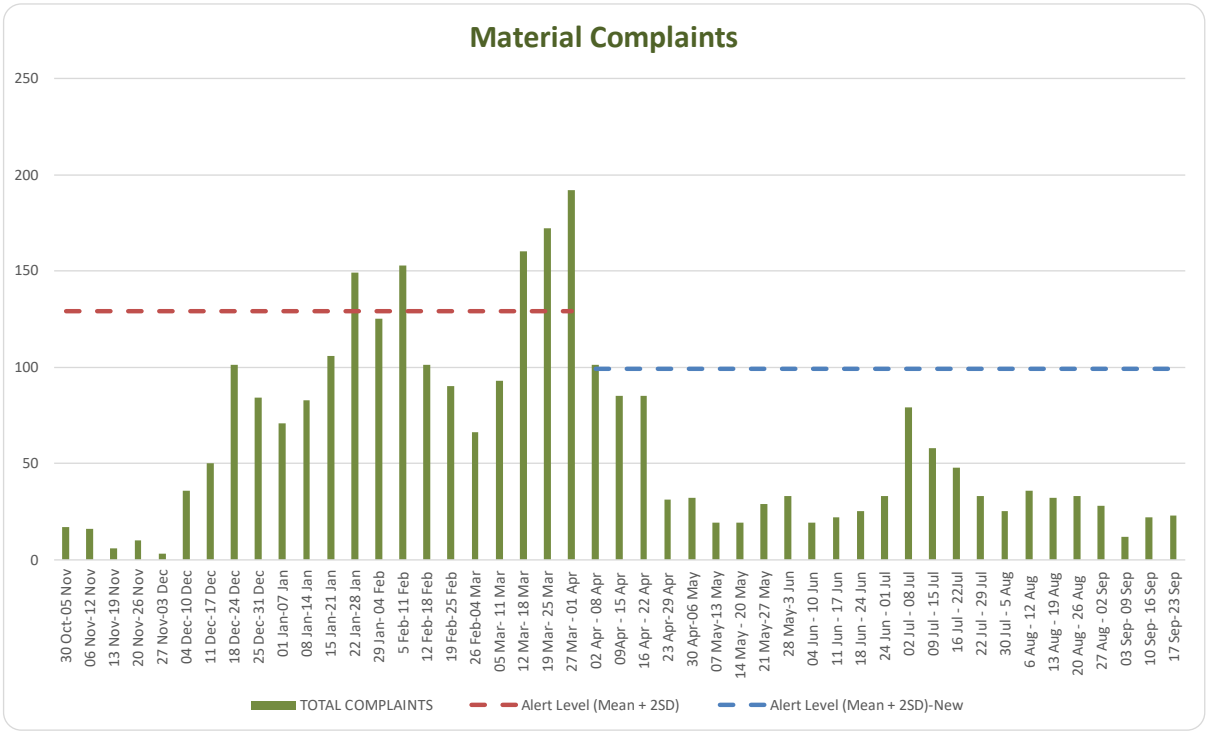

Figure 1: Material complaints weekly trending

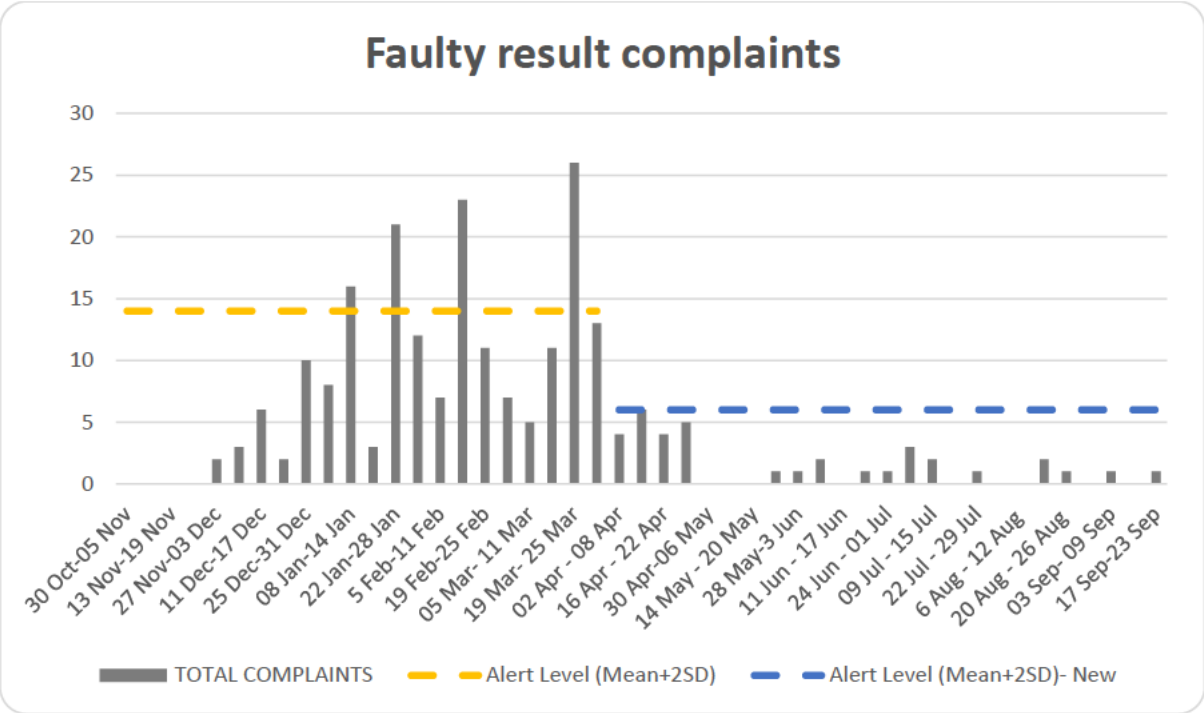

Figure 2: Faulty results complaint weekly trending

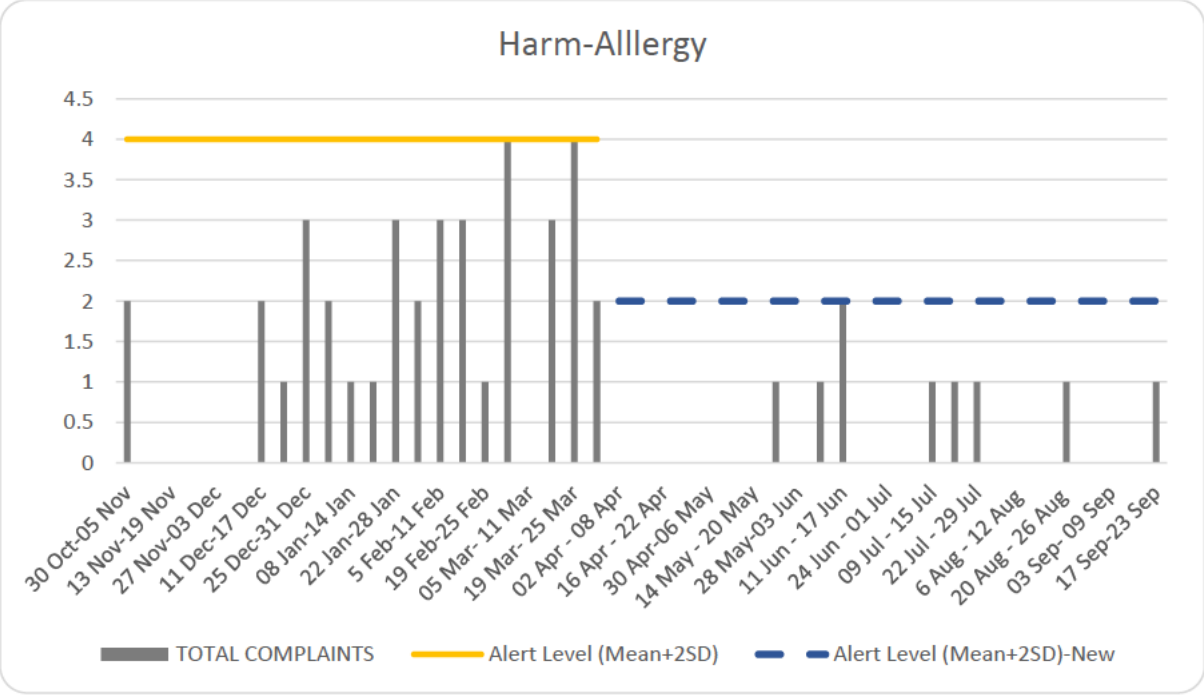

Figure 3: Harm-Allergy complaints weekly trending

(Refer to Attachment 2.2)

6.5 Qualtrics Survey (User Experience)

A total of 1318 user responses were received during this reporting window of 1st July – 23rd Sep for all LFD products for which the UKHSA is either the legal manufacturer or distributor.

43.78% of these responses were related to the DHSC LFD Products (**highlighted in green in Attachment 2.3**). 805 users completed 100% of the survey in an average time of 8.25 minutes.

A series of questions relating to the user's overall experience can be seen in **Attachment 2.3**. 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):*** 51.16% satisfaction rate which is a reduction on improvement since the last reporting period of 4.21%.
2) ***Reporting of results (Difficulty of process):*** 37.33% satisfaction rate which is an improvement of 8.20% 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 to be 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). Further information has been retained in this PSR from the previous reporting period and referenced in **Section 6.6.**

(Refer to Attachment 2.3)

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.

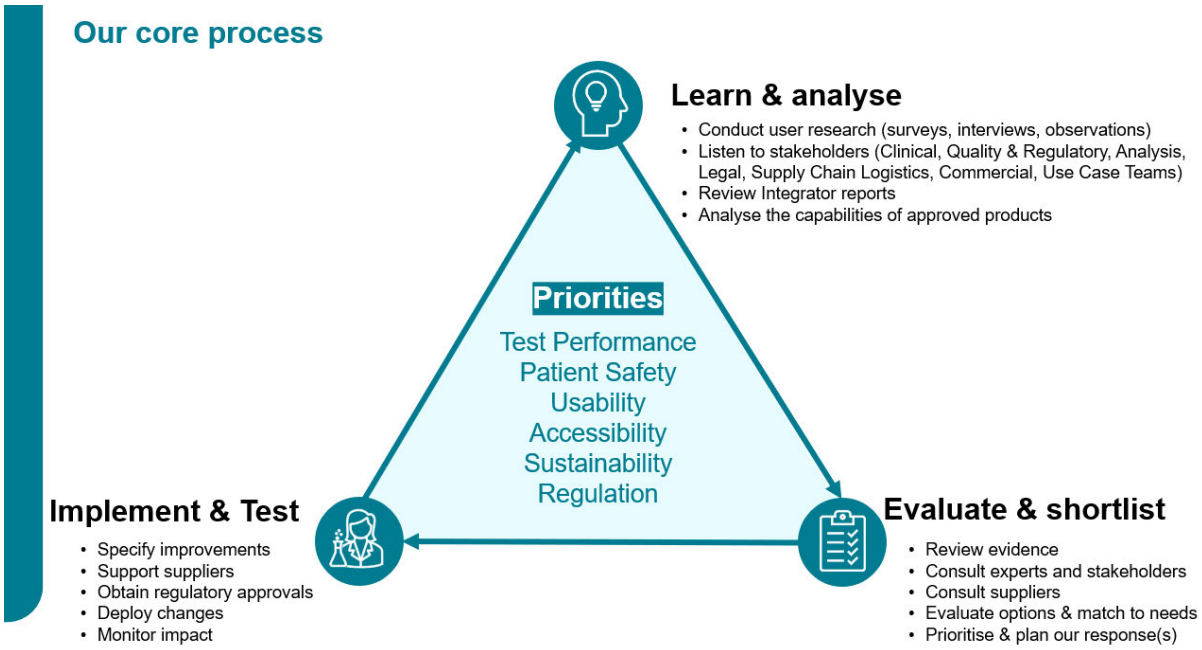

Figure 4: LFD Product Management Teams Core Process

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

The Real-World Performance Monitoring Team carry out routine performance of device and service performance using real-world data generated within NHS Test & Trace covering all services and devices.

Below are summaries for the Void rates, confirmatory PCR rates, variant analysis, and the number of positives (i.e., positivity rates), for the reporting period 1st July – 23rd Sep 2022.

Official Sensitive

DHSC 7s: Summary

Exec summary | Positivity rates | Void rates | LFD / PCR concordance | Variants | Appendix

Key metrics	What this metric tells us	Performance expectation given current population prevalence level of disease
Void rate	Measuring void rates provides insights into how users interpret results. Measuring void rates at a site level can be used as an indicator of batch performance.	Based on previous service evaluations analysis, it was established that the expected performance level for the site-level void rate should not be significantly different from the 1.2% void rate Lower CI (as outlined in the technical document for Innova 3&7 self-test).
LFD / PCR concordance rate	Measuring the LFD / PCR concordance rate provides an assessment of false positive rates. By reviewing this at a service team and site level, it provides assurance as to the reliance which can be placed on a positive LFD result and allows the source of high false positive rates to be investigated.	Services / sites are flagged if the rate is below 70% and lower than the Expected Concordance Rate Lower Est. Expected performance is based on prevalence as LFD / PCR Conc rates are expected to decrease in line with decreasing prevalence, and vice versa.
Variant analysis	Measuring the number of, and relative proportion of SARS-CoV-2 strains detected via LFD and concurrent PCR plus sequencing / genotyping. This is compared with proportion of strain cases detected in the general population.	Comparing the relative proportion of strain detections measures whether LFDs are adequately detecting the spread of strains. It also allows to mitigate changes in sequencing coverage.
Number of positives (incl. positivity rate)	Measuring positivity provides an understanding into the number of cases that are being detected. It also allows to quantify the number of positive cases identified via LFD testing.	Given prevalence at a certain time-period, a site is expected to have stable and consistent positivity rates The positivity rate changes in line with prevalence.

Trend data

Reporting Period end	Void rate	Positivity rate	Conc PCR count	LFD/PCR conc rate
18/06/2021	0.12%	0.40%	19,851	88.10%
02/07/2021	0.12%	0.84%	45,403	89.70%
16/07/2021	0.12%	1.61%	89,939	91.60%
30/07/2021	0.13%	1.62%	70,509	91.20%
11/08/2021	0.13%	1.64%	38,788	91.89%
27/08/2021	0.12%	1.71%	43,214	93.27%
10/09/2021	0.11%	1.37%	43,901	91.81%
24/09/2021	0.11%	1.36%	40,670	89.82%
08/10/2021	0.11%	1.56%	59,567	83.96%
22/10/2021	0.11%	1.94%	51,841	90.75%
05/11/2021	0.12%	1.63%	45,114	93.39%
19/11/2021	0.12%	1.48%	38,907	92.26%
03/12/2021	0.13%	1.49%	37,425	91.53%
17/12/2021	0.14%	1.76%	46,176	91.39%
31/12/2021	0.15%	4.10%	94,924	95.27%
14/01/2022	0.11%	4.74%	103,201	92.56%
28/01/22	0.12%	7.38%	47,967	91.35%
11/02/2022	0.11%	6.85%	35,658	91.01%
25/02/2022	0.10%	4.92%	18,597	91.70%
11/03/2022	0.10%	7.67%	24,746	95.90%
25/03/2022	0.11%	13.44%	40,572	96.20%
08/04/2022	0.10%	13.36%	17,099	95.50%
22/04/2022	0.10%	11.02%	1,640	93.50%
06/05/2022	0.09%	6.29%	638	89.30%
20/05/2022	0.09%	5.03%	375	88.95%
03/06/2022	0.07%	4.71%	262	85.9%
17/06/2022	0.11%	8.58%	558	91.6%
01/07/2022	0.14%	13.31%	1,583	91.0%
15/07/2022	0.17%	15.83%	1,788	91.5%
29/07/2022	0.17%	9.98%	864	88.9%
12/08/2012	0.19%	5.31%	206	88.6%
26/08/2022	0.16%	4.46%	314	83.6%
09/09/2022	0.18%	6.28%	277	91.1%
23/09/2022	0.19%	11.88%	423	89.6%

Table 1: Trend data of key metrics in all reporting periods

4 RWPM Report DHSC 7s 01/07/2022 - 23/09/2022

Figure 5: DHSC 3/7 self-test summary Period 1st Jul to 23rd Sep 2022

(Refer to Attachments 3.1 & 3.2)

6.8 Post Market Performance Follow Up

DHSC has implemented a series of ongoing evaluations. The objective of these evaluations is to determine whether lateral flow device (LFD) performance seen in pre-deployment evaluations are achieved when deployed by the testing service and to ensure that these continue to be suitable for use in services offered by NHS Test and Trace.

Biotime 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 is 22nd Sep 2022 – 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 demonstrates that the LFD kits utilised as part of the National Testing Programme continue to provide sufficient diagnostic performance relative to baseline for use as part of a public health intervention within NHS Test & Trace to curb the spread of the SARS-CoV-2 pandemic

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 has now been setup and the MHRA and the Regulatory & Quality team are in attendance to provide weekly updates on the status of variants and share an overview of on-going activities.

On the 21st September 2022, the MHRA raised a concern regarding some of the information shared on the VOC assurance group meetings and requested that the UKHSA investigate. On the 27th September 2022 a meeting took place between the MHRA and UKHSA to discuss the signal raised by the MHRA. On the 28th September 2022 a formal response to the MHRA was sent by the UKHSA Regulatory team. A copy of the response can be seen in Attachment 04.

(Refer to attachment 04)

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	01

Table 3: CAPA Status Overview

No	CAPA No	Start Date	Source	Problem statement	Status/ progress	Due date	Reason for extension if overdue
26	CAPA-21-06-0039	26-Nov-21	PMS Activities	CAPA raised due to a spike in LFD complaints taking them over the acceptable threshold	Closed	VOE due 1st July 2022	CAPA closed as effective.
27	CAPA-22-01-0041	05-Jan-2022	PMS Activities	CAPA raised due to batch of [redacted] kits failing Intertek validation.	Closed	30-June-2022	CAPA closed as effective.
28	CAPA-22-07-0049	01-Jul-22	PMS Activities	CAPA raised to address the issue of incorrect brand of LFD sent to Welsh Home channel without welsh IFU.	Open	30-October-2022	N/A

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 ***(Refer to Attachment 04)***. 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. Furthermore, the MedBoard platform is utilized to obtain current data on incidents, Field Safety Corrective Actions (FSCAa), etc. reported to or by regulatory agencies internationally.

The literature search & SOTA search is carried out monthly in line with the PSR reporting schedule and utilizes multiple electronic search databases (e.g., PubMed, Embase & Medboard) 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 will be continuously reviewed with the support of PHCO for on-going performance evaluation and separately, a high-level summary is provided in the monthly PSR report.

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. Due to the timing of this report and the move towards a quarterly reporting cadence, in this periodic summary report, a submission of two reports can be found. The first report is via the external consultancy and covers the period of July 2022. The second report is an internal UKHSA report which covers August through to September 2022.

External Consultancy Update: the August update was conducted on 01 August 2022. One new safety and performance article was found; no new SOTA articles were found. The article found was excluded during abstract review (stage 1) due to not being relevant to the target device.

UKHSA Internal Literature Review Update:

In collaboration with an external consultancy, DHSC has developed a Literature Search Protocol. This is the first time that the Literature Review is completed internally by the UKHSA following this 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 in line with the PSR reporting schedule and utilizes multiple electronic search databases (e.g., PubMed, Embase & Medboard) 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 will be continuously reviewed with the support of PHCO for on-going performance evaluation and separately, a high-level summary is provided in the quarterly PSR report.

The October 2022 Literature Review report was conducted between the 5 and 11 October 2022 and includes the September 2022 literature search (conducted between 31 July to 23 August 2022) and the October 2022 literature search (conducted between 22 August to 21 September 2022).

From the 12 publications that were identified in the September literature search, and the two publications that were identified in the October Literature Review, one publication (*202209.1 J. Dinnes, P. Sharma, S. Berhane et al , Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection (Review) Jul 2022)* successfully passed both the first and second appraisal process.

This publication was a systematic review that looked at studies on both symptomatic and asymptomatic populations. The systematic review did not take into account the different variants that were present at the time of the studies, so acts as an overall estimate at the effectiveness of the antigen tests investigated regardless of variants in circulation and found that:

At 5% prevalence using summary data in symptomatic people during the first week after symptom onset, the positive predictive value (PPV) of 89% means that 1 in 10 positive results will be a false positive, and around 1 in 5 cases will be missed.

At 0.5% prevalence using summary data for asymptomatic people, where testing was widely available and where epidemiological exposure to COVID-19 was suspected, resulting PPVs would be 38% to 52%, meaning that between 2 in 5 and 1 in 2 positive results will be false positives, and between 1 in 2 and 1 in 3 cases will be missed.

UKHSA have considered this study, and note that the data used is not product specific, and does not consider different variants. UKHSA undertakes testing on all products that it distributes, and continues to monitor performance as part of routine surveillance activity. UKHSA have not identified any cause for concern as part of this routine surveillance.

(Refer to Attachment 07)

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.

It is noted that performance of the device demonstrated a Void Rate of **0.17%** for the period of the 1st July 2022 through to 23rd September 2022 and performs within the expected performance levels.

The average LFD / PCR concordance rate of 89.9% for the reporting period is above expectations and provides assurance of positive LFD results confirmed by matched, positive PCRs for the DHSC 7 kits.

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.

No new Hazards were identified during this reporting period as part of the continual monitoring through post-market surveillance activities. Hazards identified in the previous reporting period were assessed and there was no change in the risk acceptability policy.

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

One publication (*202209.1 J. Dinnes, P. Sharma, S. Berhane et al , Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection (Review) Jul 2022)* was reviewed as part of the literature review as per Section 6.13

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 plan, these include:

a) Early indication of possible infection with Covid-19 while still asymptomatic
b) Prevention of spread of Covid-19 virus
c) Prevention of 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	On-going real-world performance monitoring indicates void rates below expected threshold and confirmatory PCR tests in line with expectations.	**Section 6.7** **Section 6.8**
d) Do users experience any usability issues?	No	Satisfaction rates are above 70% with regards to usability of the devices. Any minor issues identified are feeding into continuous improvement activities at the procurement stage.	**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	Issues relating to missing items were observed. A SCAR has already been raised against Innova/Biotime. Immediate containment action not deemed necessary as the risk on patient safety is minimal. Any improvements by Innova will not be realised as all products are received by UKHSA.	**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 result of the PMS activities analysed/discussed in this report the PMS Team advice is to continue distributing the current EUA cleared product.

8. Recommended Actions

No	Added	Action	Responsible Name	Due Date	Status
1	N/A	N/A	N/A	N/A	N/A

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 2.1 – 2.3)
Attachment 03: RWPM Innova 3s and 7s
Attachment 04: RWPM Innova 25's
Attachment 05: QP08-F02 LFD Hazard Traceability Matrix v.01 Issued 22.12.2021
Attachment 06: Literature Search Report - Lateral Flow Device 202204 without papers

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