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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	17-Jun-2022	First Issue

1. Content

1. Content
2. Introduction
3. Reference documents
4. Standards and guidelines
5. Methodology
6. Findings /Results
 - 6.1 In-House manufacturing inspection at Biotime
 - 6.2 Receiving inspection - Intertek Testing in the UK
 - 6.3 Product complaints & Qualtrics Survey Reports
 - 6.4 Complaints Trending
 - 6.5 Qualtrics Survey (User Experience)
 - 6.6 Product Management (Usability Studies)
 - 6.7 Real World Performance Monitoring
 - 6.8 Post Market Performance Follow Up
 - 6.9 Variants of Concern (VOC)
 - 6.10 CAPA
 - 6.11 SCAR – Supplier Corrective Action Report
 - 6.12 Risk Management
 - 6.13 Literature Review & State of the Art (SOTA)
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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.

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6. Findings /Results

6.1 In-House manufacturing inspection at Biotime

There were no inspections carried out between the reporting period of 7th May and 3rd Jun 2022 following conclusion of QC of the previous contract on 30/01/2022. No further Innova product has been procured during this reporting window.

6.2 Receiving inspection - Intertek Testing in the UK


A total of 3,855 samples underwent validation from the 7th May – 3rd Jun 2022, from 41 lots. All lots passed and were accepted into the supply chain. 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 ~ **2.05 million** which is decrease of ~**6.11 million** over the previous reporting period.
- A total of 4 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 4 of those complaints were defined as non-reportable as per Med Dev 12.1 Rev 8.
- A total of 68 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)

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Qualtrics and Yellow card complaints investigation				
Trending category	Number of complaints	Reportability	Investigation	Further actions
Missing components	32	Not reportable	Corrective actions were taken as part of the previous SCAR raised with the supplier. The complaints received are for the batches which were delivered before the corrective action were implemented. There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Damaged Item	6	Not reportable	No action required	Complaints will be monitored for trending purposes
Faulty test results	2	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Faulty items	17	Not reportable	There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes
Empty extraction buffer	1	Not reportable	Corrective actions were taken as part of the previous SCAR raised with the supplier. The complaints received are for the batches which were delivered before the corrective action were implemented. There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Insufficient buffer solution	16	Not reportable	Corrective actions were taken as part of the previous SCAR raised with the supplier. The complaints received are for the batches which were delivered before the corrective action were implemented. There was no trend observed for any batch.	No further action. Complaints will be monitored for trending purposes.
Allergic reaction	1	Not reportable	There was no batch specific trend observed for similar type of complaint.	No further action. Complaints will be monitored for trending purposes
Bar code/QR code issues	22	Not reportable	Complaints forwarded to NHS digital team for investigation	No further action.
Usability	6	Not reportable	There was no trend observed for any specific type of usability issue	No further action. Complaints will be monitored for trending purposes

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”

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6.4 Complaints Trending

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. Number of complaints is well below the trigger threshold for this reporting period.
- 2) **Faulty Test Results:** No sub-categories exist within this category of complaints. Number of complaints for this category is well below the trigger threshold for this reporting period.
- 3) **Harm & Allergy:** this includes complaints from Patient Injury and Allergic reactions as sub-categories. Harm-allergy complaints for this reporting period is 0 and therefore the alert was not triggered.

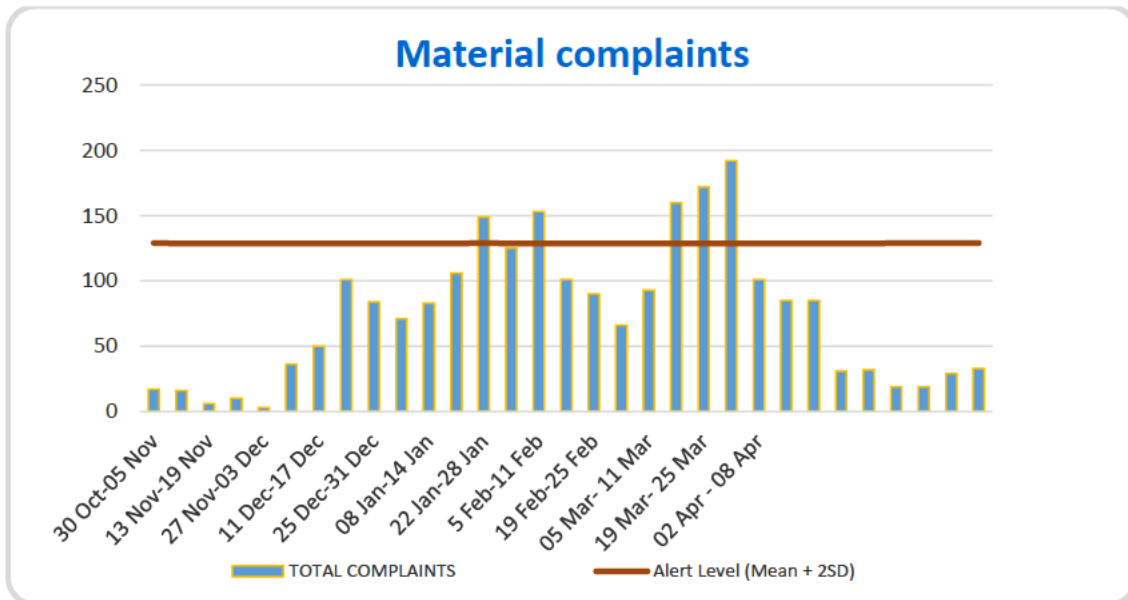



Figure 1: Material complaints weekly trending

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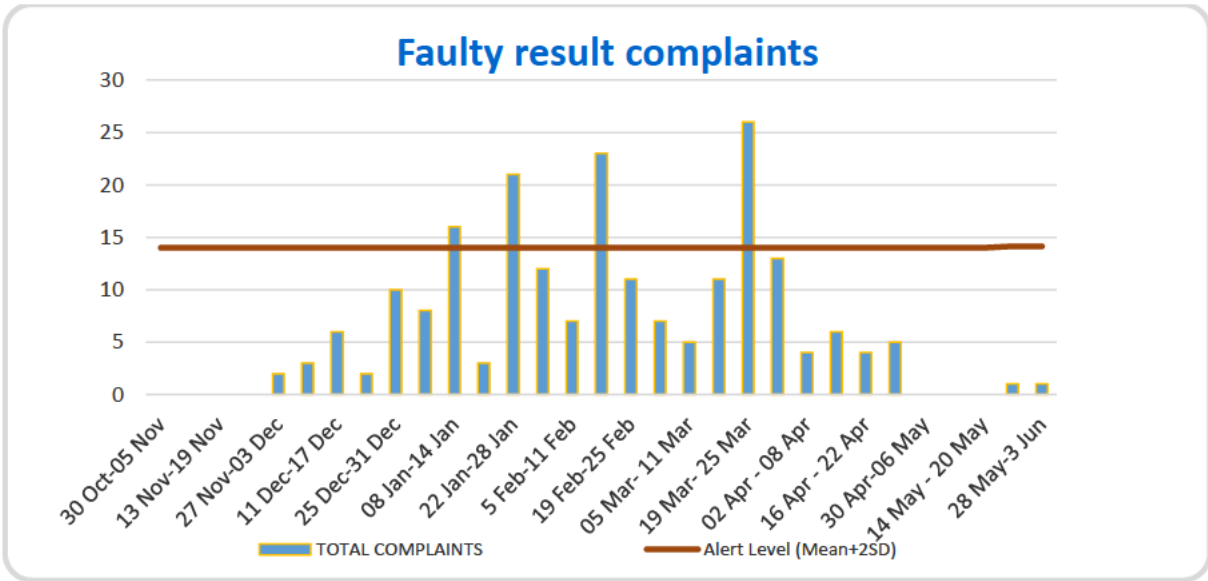


Figure 2: Faulty results complaint weekly trending

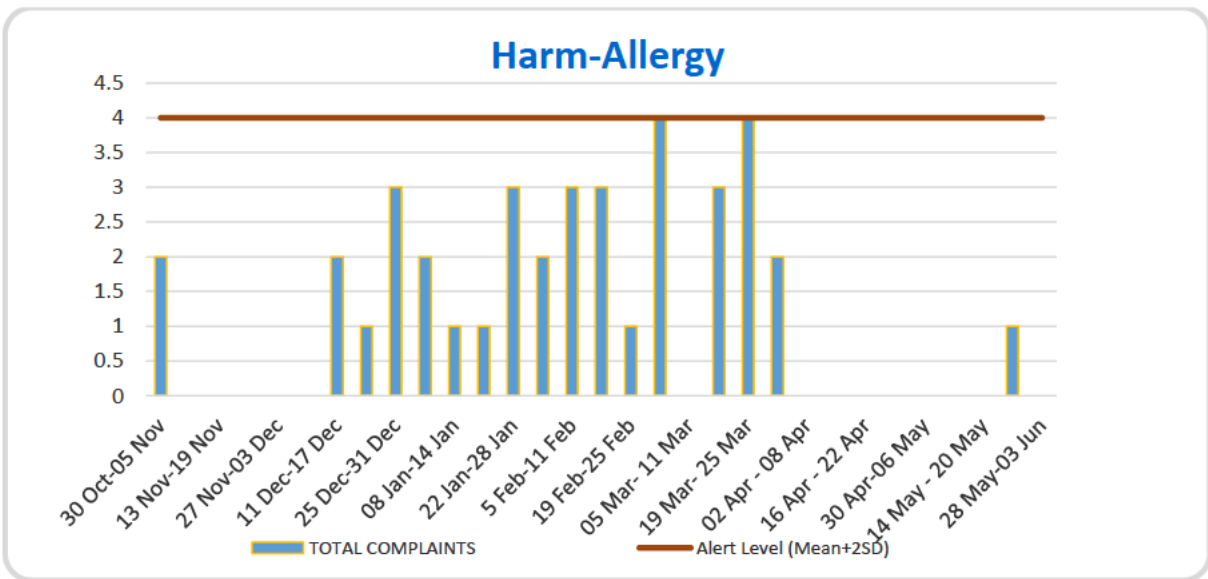



Figure 3: Harm-Allergy complaints weekly trending

(Refer to Attachment 2.2)

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6.5 Qualtrics Survey (User Experience)

A total of 424 user responses were received during this reporting window of 7th May – 3rd Jun for all LFD products for which the UKHSA is either the legal manufacturer or distributor.


37.26 % of these responses were related to the DHSC LFD Products (**highlighted in green in Attachment 2.3**). 352 users completed 100% of the survey in an average time of 7.25 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):** 52.94% satisfaction rate which is a reduction on the last reporting period by 4.88%.
- 2) **Reporting of results (Difficulty of process):** 46.50% satisfaction rate which is a reduction of 3.94% 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)

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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.

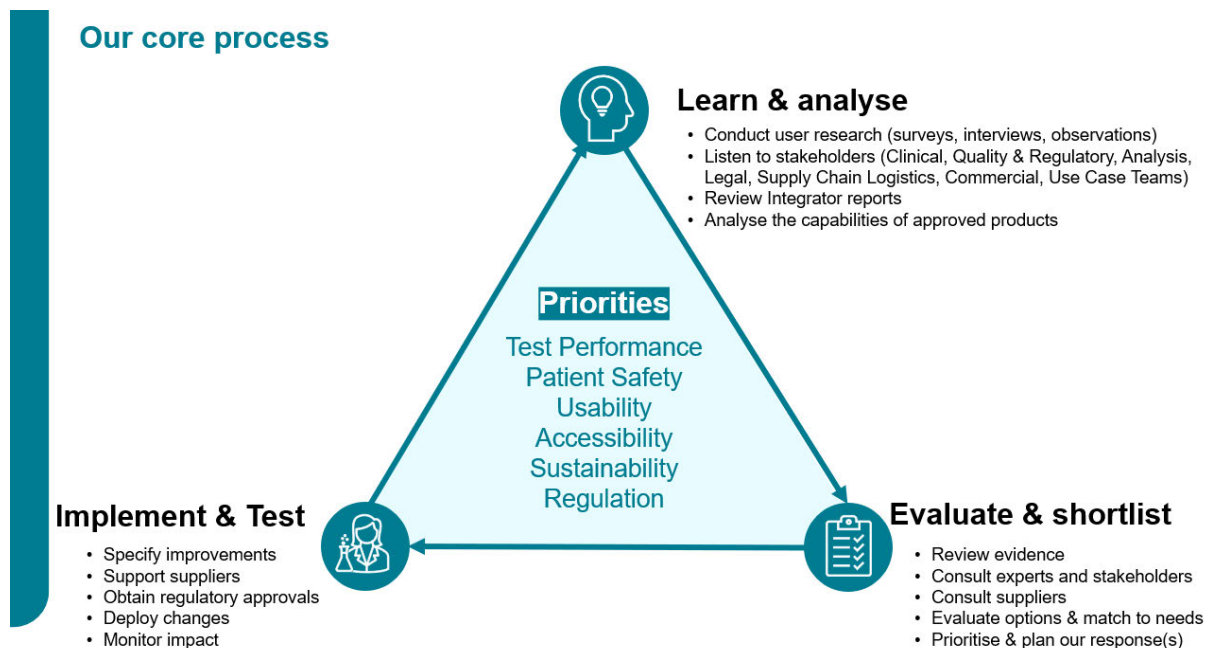


Figure 4: LFD Product Management Teams Core Process

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 7th May – 3rd Jun 2022.

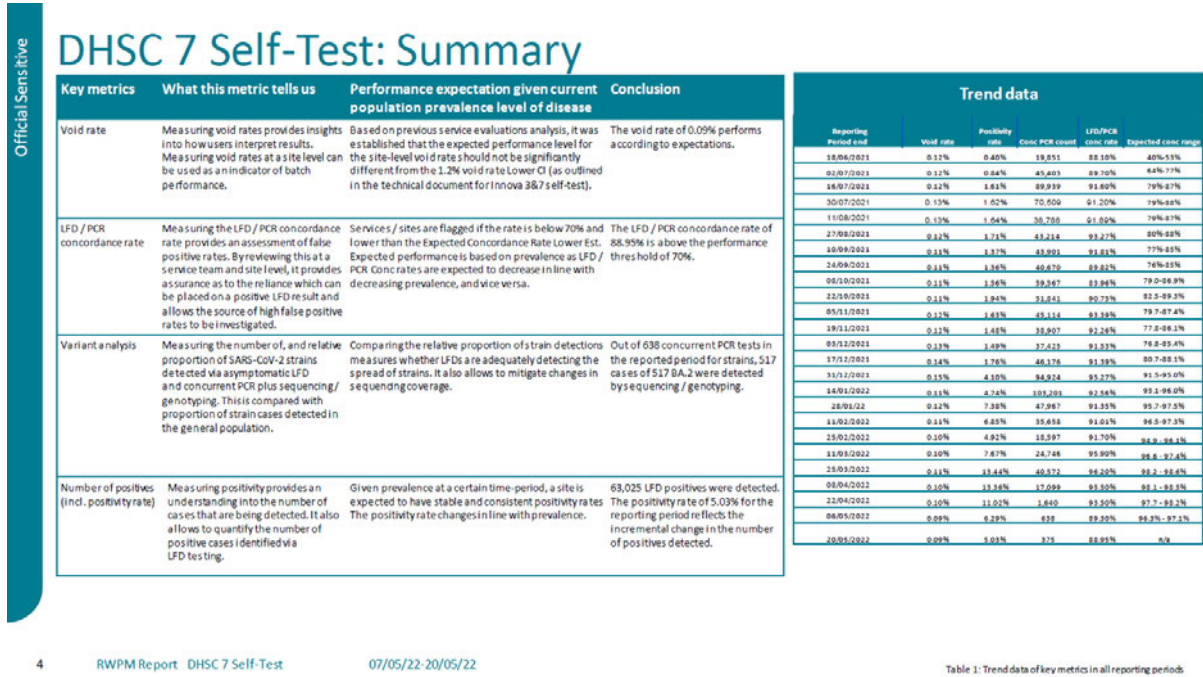


Figure 5: DHSC 3/7 self-test summary Period 7th May to 20th May 2022

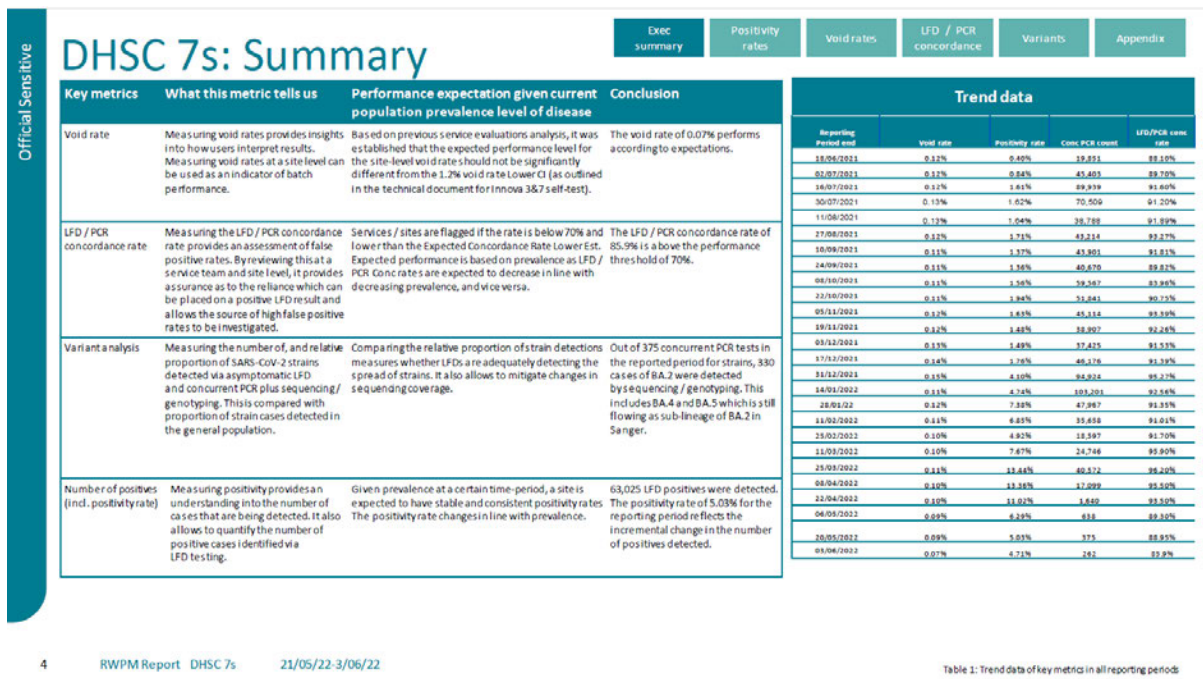



Figure 6: DHSC 3/7 self-test summary Period 23rd Apr to 06-May-2022

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(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.

PMPF Report 2 was submitted to the MHRA 15th Apr 2022, titled “BIOTIME ongoing evaluation and DHSC 3&7 self-test post-market clinical performance follow-up report 2” and published on 14 Apr 2022 and covering the period 22 May 2021 – 21 Sep 2021.

PMPF Report 3 is currently in progress and further communication regarding proposed submission date will be communicated to the MHRA in upcoming reports.

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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. No new updates were received in time for this reporting window.

A cross-functional VOC meeting has now been setup and the MHRA and the Regulatory & Quality team are in attendance. Due to the recent structural and workforce changes at the UKHSA, there has been some inevitable delays in assessing appropriate VOC inclusion in the PSR. However, this is in progress and further updates will be provided via the periodic summary report submission.

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
VOE	01
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	Complete pending VOE	VOE due 1 st July 2022	N/A
27	CAPA-22-01-0041	05-Jan-2022	PMS Activities	CAPA raised due to batch of SureScreen kits failing Intertek validation.	Open	30-June-2022	Due date has been extended due to the volume of SCLSOP's that need updating for CAPA to be effective.

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

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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.

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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.

The June update was conducted 31st May 2022. No new articles were determined to be relevant from neither the SOTA or safety and performance search.

(Refer to Attachment 07)

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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 **0.09%** for the period between 7th May 2022 to 20th May 2022 and 0.07% for the period between 21st May 2022 to 3rd June 2022, which performs according to expectations and is below the threshold of **1.2%**.

The LFD/PCR concordance rate was **88.95%** between the period of 7th May 2022 to 20th May 2022 and **85.9%** between the period of 21st May 2022 to 3rd June 2022 which are above expected performance and provides assurance of positive LFDs confirmed by matched positive PCRs.

PMPF Report 2 was submitted to the MHRA 15th Apr 2022, titled “BIOTIME ongoing evaluation and DHSC 3&7 self-test post-market clinical performance follow-up report 2” and published on 14 Apr 2022 and covering the period 22 May 2021 – 21 Sep 2021. 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. Report 3 is currently in planning and findings will be reported upon publication.


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.

No new relevant literature was found and no new Medboard SOTA literature was identified in Section 6.3 for this reporting period.

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

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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.

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8. Recommended Actions

No	Added	Action	Responsible Name	Due Date	Status
1	19 May 2022	Raise a non-conformance report to capture the issue with one lot of LFD identified as part of the Intertek validation report.	██████████	16 June 2022	Closed – failure was within AQL limits, no further action deemed to be required. Lot number will be monitored against complaints received.

9. Attachments

- Attachment 01: PMS-0001, PMS Plan for the DHSC Covid-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: Intertek Validation Reports – 07 May – 03 June 2022
- Attachment 07: Literature Search Report - Lateral Flow Device 202204 without papers

10. Author

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