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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	13-07-2022	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)
- 7. Conclusion & Risk-Benefit Determination
- 8. Recommended Actions
- 9. Attachments
- 10. Author

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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)	3
	Procedure	
PMS-0001	PMS Plan for the DHSC COVID-	2
	19 LFD device (3 and 7 kit)	
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

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 ~ **7.87 Million** which is an increase of ~**5.82 Million** over the previous reporting period.

• Twenty-four 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 24 complaints were defined as non-reportable as per Med Dev 12.1 Rev 8.

• A total of 107 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	38	Not reportable	The kits are not being procured from Innova anymore. Compared to the number of kits distributed the number of complaints is low and there is no batch trend observed	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	7	Not reportable	No action required no trend observed	Complaints will be monitored for trending purposes
Faulty test results	4	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	5	Not reportable	The kits are not being procured from Innova anymore. Compared to the number of kits distributed the number of complaints is low and there is no batch trend observed	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	21	Not reportable	The kits are not being procured from Innova anymore. Compared to the number of kits distributed the number of complaints is low and there is no batch trend observed	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	3	Not reportable	There was no trend observed for this type of complaint.	No further action. Complaints will be monitored for trending purposes.
Bar code/QR code issues	2	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	9	Not reportable	There was no trend observed for any specific type of usability issue	No further action. Complaints will be monitored for trending purposes
Reporting issue	29	Not reportable/Not a product issue	Forwarded to NHS digital for further action	No further action required

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

With the reduced testing, the volume of complaints has reduced significantly in previous reporting periods. The complaints trending activity is intended to be a dynamic process and the Action levels are periodically reviewed (as per the SOP) to reflect the volume of complaints received. This new Action level is currently in review and will calculate the average complaints from November 2021 through to June 2022. This will be reflected in the next PSR report.

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 below the trigger threshold and therefore the alert was not triggered.

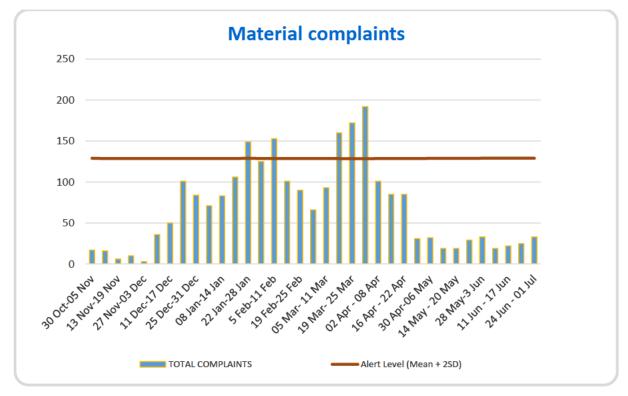
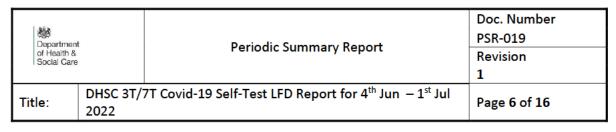


Figure 1: Material complaints weekly trending



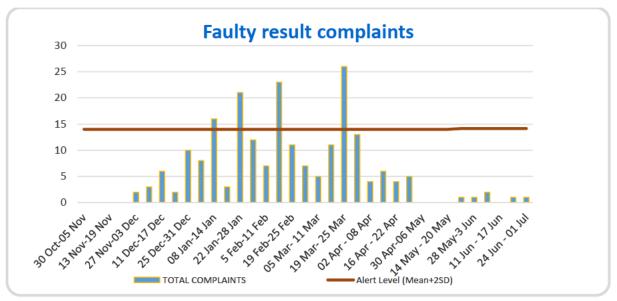


Figure 2: Faulty results complaint weekly trending

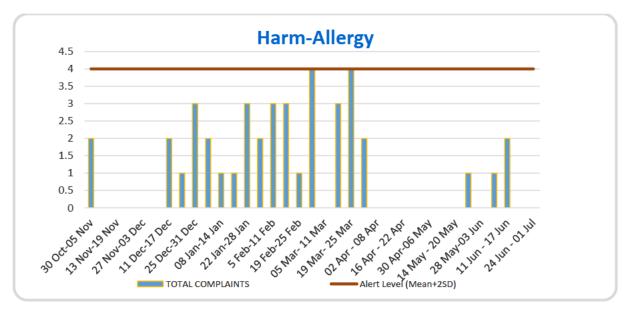


Figure 3: Harm-Allergy complaints weekly trending

(Refer to Attachment 2.2)

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6.5 Qualtrics Survey (User Experience)

A total of 574 user responses were received during this reporting window of 4^{th} Jun – 1^{st} Jul for all LFD products for which the UKHSA is either the legal manufacturer or distributor.

49.48% of these responses were related to the DHSC LFD Products (**highlighted in green in Attachment 2.3**). 275 users completed 100% of the survey in an average time of 7.98 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):** 55.37% satisfaction rate which is an improvement on the last reporting period by 2.43%.
- 2) **Reporting of results (Difficulty of process):** 37.33% satisfaction rate which is a reduction of 9.17% 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.

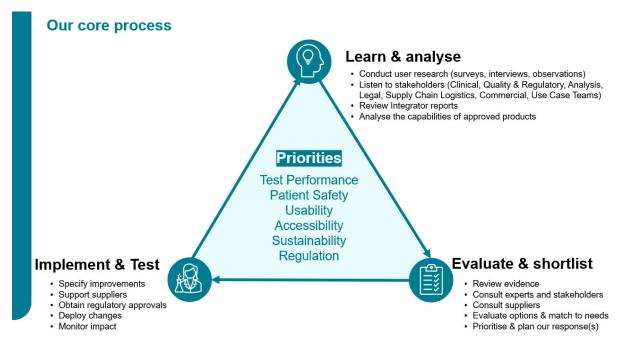


Figure 4: LFD Product Management Teams Core Process

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.

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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 7^{th} May -3^{rd} Jun 2022.

Key metrics	What this metric tells us	7s: Summary at this metric tells us Performance expectation given current population prevalence level of disease	Conclusion		Trend data				
Void rate	Measuring void rates provides insights Based on previous service evaluations analysis, it was into how users interpret results. established that the expected performance level for		Reporting Period and	Void rate	Positivity rate	Conc PCR count	LID. Centre		
			according to expectations.	18/06/2021	0.12%	0.40%	19,851	44.	
	be used as an indicator of batch			02/07/2021	0.12%	0.84%	45,403	89.	
	performance.	in the technical document for Innova 3&7 self-test).		16/07/2021	0.12%	1.61%	89,939	91	
				30/07/2021	0.13%	1.62%	70,509	91.	
				11/08/2021	0.13%	1.64%	30,700	91.	
LFD / PCR	Measuring the LFD / PCR concordance	Services / sites are flagged if the rate is below 70% and		27/08/2021	0.12%	1.71%	43,214	93.	
concordance rate	positive rates. By reviewing this at a Expected per service team and site level, it provides PCR Concrate	decreasing prevalence, and vice versa.		10/09/2021	0.11%	1.37%	43,901	91	
				24/09/2021	0.11%	1.36%	40,670	19.	
				08/10/2021	0.51%	1.54%	59,567	83.	
				22/10/2021	0.11%	2.94%	51,841	90	
				05/11/2021	0.12%	1.63%	45,114	93	
	rates to be investigated.			19/11/2021	0.12%	1.45%	38,907	92.3	
Variant analysis	Measuring the number of, and relative	ring the number of, and relative Comparing the relative proportion of strain detections	Out of 262 concurrent PCB tests in	03/12/2021	0.13%	1.49%	37,425	91.1	
variancanarysis	proportion of SARS-CoV-2 strains	on of SARS-COV-2 strains measures whether LFDs are adequately detecting the spread of strains. It also allows to mitigate changes in current PCR plus sequencing/ sequencing s	the reported period for strains, 224	17/12/2021	0.54%	1.76%	46,176	91.1	
	detected via asymptomatic LFD		the reported period to strains, 224 BA.2 were detected by sequencing / genotyping. This includes BA.4 and BA.5 which are stillflowing as sub- lineage of BA.2 in Sanger.	51/12/2021	0.15%	4.10%	94,924	95.	
	and concurrent PCR plus sequencing/			14/01/2022	0.11%	4.74%	103,201	92.5	
	genotyping. This is compared with			28/01/22	0.12%	7.38%	47,967	91.3	
	proportion of strain cases detected in			11/02/2022	0.51%	6.85%	35,658	91.0	
	the general population.			25/02/2022	0.10%	4,92%	18,597	91	
				11/03/2022	0.10%	7.67%	24,746	95.5	
				25/03/2022	0.31%	13,44%	40,572	96.3	
Number of positives		Citize exceptions to contain time, and all a starts	or control or site and determined	05/04/2022	0.10%	13.36%	17,099	95.5	
(incl. positivity rate)		Given prevalence at a certain time-period, a site is expected to have stable and consistent positivity rates	91,572 LFD positives were detected. The positivity rate of 8.58% for the	22/04/2022	0.10%	11.02%	1,640	93.5	
(mor. postowityrate)	cases that are being detected. It also	The positivity rate changes in line with prevalence.	reporting period reflects the	06/05/2022	0.09%	6.29%	638	89.3	
	allows to guantify the number of	the period of the state of the state of the state of the	incremental change in the number	20/05/2022	0.09%	5.03%	375	11.1	
	positive cases identified via		of positives detected.	03/06/2022	0.07%	4.71%	262	85	
	LFD testing.		or prostores accessed	17/06/2022	0.11%	1.115	558	21	

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

Figure 5: DHSC 3/7 self-test summary Period 4th Jun to 17th Jun 2022

Key metrics	What this metric tells us	Performance expectation given current population prevalence level of disease	Conclusion		т	rend data		
Void rate	Measuring void rates provides insights	Based on previous service evaluations analysis, it was	The void rate of 0.14% performs	Reporting Period end	Void rate	Positivity rate	Conc PCR count	UD/I
	into how users interpret results.	established that the expected performance level for	according to expectations.	18/06/2021	0.12%	0.40%	19,851	88.1
		the site-level void rate should not be significantly		02/07/2021	0.12%	0.84%	45,403	89.3
	be used as an indicator of batch	different from the 1.2% void rate Lower CI (as outlined		16/07/2021	0.12%	1.61%	89,939	91.
	performance.	in the technical document for Innova 3&7 self-test).		30/07/2021	0.13%	1.62%	70,509	91.
				11/08/2021	0.13%	1.64%	38,788	91.
				27/08/2021	0.12%	1.71%	43,214	93.
LFD / PCR	Measuring the LFD / PCR concordance	Services / sites are flagged if the rate is below 70% and lower than the Expected Concordance Rate Lower Est.	The LFD / PCR concordance rate of 91% is above the performance	10/09/2021	0.115	1.37%	43.901	91.
concordance rate	rate provides an assessment of false positive rates. By reviewing this at a	Expected performance is based on prevalence as LFD / threshold of 70%. And according to	24/09/2021	0.11%	136%	40,670	89.	
	service team and site level, it provides	PCR Concrates are expected to decrease in line with		59,567	83.			
	assurance as to the reliance which can	decreasing prevalence, and vice versa.		22/10/2021	0.11%	1.94%	51,841	90
	be placed on a positive LFD result and			05/11/2021	0.12%	1.63%	45.114	93.
	allows the source of high false positive			19/11/2021	0.12%	1.48%	38.907	92.
	rates to be investigated.			03/12/2021	0.13%	1.49%	45,403 83,319 70,509 18,788 43,214 43,201 43,201 43,201 43,201 53,547 53,547 53,547 53,547 53,547 53,547 53,547 53,547 53,547 53,547 54,545 103,301 47,947 13,558 115,577 24,746 40,577 24,746 40,577 11,049 14,588	91.
Variant analysis	Measuring the number of, and relative	Comparing the relative proportion of strain detections	Out of 558 concurrent PCR tests in	17/12/2021		46.176	91.	
0.0000000000000000000000000000000000000	proportion of SARS-CoV-2 strains		so allows to mitigate changes in case of BA.1 and S21 BA.2 were detected by sequencing /	31/12/2021	0.15%	4 10%		95
		spread of strains. It also allows to mitigate changes in		14/01/2022	0.11%	4.74%	103,201	92.
	plus sequencing / genotyping. This is	sequencing coverage.		28/01/22	0.12%	7.38%	47,967	91
		mparad with proportion of strain genotyping. This includes BA.4 and set of the general BA.5 which are still flowing as sub- lineage of BA.2. Interpret to the general sub- lineage of BA.2.		11/02/2022	0.11%	6.85%	35,658	91
				25/02/2022	0.10%	4.92%	18,597	91.
			0.10%	7.67%	24,746	25.		
			25/03/2022	0.11%	13.44%	40 572	96.	
				08/04/2022	0.10%	13.36%	17.099	95.
Number of positives	Measuring positivity provides an	Given prevalence at a certain time-period, a site is	165,402 LFD positives were	22/04/2022	0.10%	11.02%		93.
(incl. positivity rate)	understanding into the number of		detected. The positivity rate of	06/05/2022	0.09%	6.29%		89.
Second second contraction of the	cases that are being detected. It also	The positivity rate changes in line with prevalence.	13.31% for the reporting period	20/05/2022	0.09%	5.03%	375	88.
	allows to quantify the number of		reflects the incremental change in	03/06/2022	0.07%	4.71%	262	85
	positive cases identified via		the number of positives detected.	17/06/2022	0.11%	8.58%	558	91
	LFD testing.			01/07/2022	0.14%	13.31%	1.109	91

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

Figure 6: DHSC 3/7 self-test summary Period 18th Jun to 1st Jul 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	Awaiting VOE results
27	CAPA- 22- 01- 0041	05- Jan- 2022	PMS Activities	CAPA raised due to batch of 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 27th June 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 **0.14%** for the period between 4th Jun to 17th Jun 2022 and 0.07% for the period between 18th Jun to 1st Jul 2022, which performs according to expectations and is below the threshold of **1.2%**.

The LFD/PCR concordance rate was **91.60%** between the period of 4th Jun to 17th Jun 2022 and **91.0%** between the period of 18th Jun to 1st Jul 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 postmarket 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	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

10. Author

	Job Title	Name	Email
Compiled by	Post Market Surveillance Manager		