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	28-Jan-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?

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

There was a total of 200,000,000 tests of SKU2193 produced during the reporting period of 18/12/2021-14/01/2022. In line with this, 200,000,000 tests underwent inspection (200 lots). Of these lots, 1 had failed inspection on 21/12/2021 and was rejected.

(Refer to Attachment 07)

6.2 Receiving inspection - Intertek Testing in the UK

The supplier experienced several issues with logistics meaning there were several delays for the goods reaching the UK. Therefore, the first validation samples were not receipted by the laboratory until 19/01/2022 such that at the time of writing the report no validation reports have been generated.

(Refer to Attachment 7)

6.3 Product complaints & Qualtrics Survey

- The number of kits distributed in this reporting period is ~ 40.5 Million which is an increase of ~27.5 Million over the previous reporting month.

- A total of 9 complaints were received from MHRA Yellow Card and were discussed at the bi-weekly incident review meetings and weekly Patient safety panel meetings.

- Seven of those complaints were defined as non-reportable as per Med Dev 12.1 Rev 8.

- One reportable complaint (*MHRA Reference: 2021/012/024/601/001*).

- The remaining complaint is one where the reporter did not provide a description of the event; an email was sent to obtain more information from the reporter to support with the investigation and determine reportability status.

- A total of 426 user reports were received from the Qualtrics survey in this reporting window, of which 21 were defined as “not a product complaint” as they were related to service issues i.e. (issues with courier delivery etc.) and routed to the appropriate department.

- 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)

Trending category	Number of complaints	Reportability	Investigation	Further actions
Missing components	66	*Not reportable	There is a mention in the IFU directing people to call 119 in case they have some Damaged/broken or missing items. 119 team arranges to send a kit within next 24 hrs so that the person can complete the test. There was no trend observed for any batch. However, this will be taken up with the supplier to confirm any if there are any process issues.	The Quality investigations team have setup a monthly meeting with the supplier management team to discuss similar issues reported throughout the month. Once the trend is analysed supplier will be informed. A SCAR or CAPA will be raised if immediate action is required
Damaged Item	8	*Not reportable	There is a mention in the IFU directing people to call 119 in case they have some Damaged/broken or missing items. 119 team arranges to send a kit within next 24 hrs. that the person can complete the test. There was no trend observed for any batch. However, this will be taken up with the supplier to confirm any if there are any process issues.	The Quality investigations team have setup a monthly meeting with the supplier management team to discuss the similar issues reported throughout the month. Once the trend is analysed supplier will be informed. A SCAR or CAPA will be raised if immediate action is required
Faulty test results	30	*Not reportable	Since there is no trend observed for a particular batch, this might be a user error. However, we do not have the contact details to confirm this. The false negative complaints might be due to the LFD not having 100% sensitivity. Without further details it cannot be concluded that there is a product complaint	The Quality investigations team is investigating possible ways to capture QR code to confirm the users faulty test result complaints with the help of the digital reader data.
Faulty items	39	*Not reportable	There is a mention in the IFU directing people to call 119 in case they have some Damaged/broken or missing items. 119 team arranges to send a kit within next 24 hrs. so that the person can complete the test. There was no trend observed for any batch. However, this will be taken up with the supplier to confirm any if there are any process issues.	The Quality investigations team have setup a monthly meeting with the supplier management team to discuss on the similar issues reported through the month. Once the trend is analysed supplier will be informed. A SCAR or CAPA will be raised if immediate action is required
Patient injury	1	**Reportable**	**This was reported to MHRA -2021/012/024/601/001**	Monitor for similar complaints
Allergic reactions	1	*Not reportable	This was decided to be not reportable by the clinical team in the incident review meeting as it did not meet the reportability criteria set out in Med Dev 2.12 Rev 8.	Monitor for similar complaints

Empty extraction buffer	55	*Not reportable	There is a mention in the IFU directing people to call 119 in case they have some Damaged/broken or missing items. 119 team arranges to send a kit within next 24 hrs. so that the person can complete the test. There was no trend observed for any particular batch. However, this will be taken up with the supplier to confirm any if there is any process issues.	The Quality investigations team have setup a monthly meeting with the supplier management team to discuss on the similar issues reported through the month. Once the trend is analysed supplier will be informed. A SCAR or CAPA will be raised if immediate action is required
Wrong media volume	96	*Not Reportable	There is a mention in the IFU directing people to call 119 in case they have some Damaged/broken or missing items. 119 team arranges to send a kit within next 24 hrs so that the person can complete the test. There was no trend observed for any batch. However, this will be taken up with the supplier to confirm any if there are any process issues.	The Quality investigations team have setup a monthly meeting with the supplier management team to discuss on the similar issues reported through the month. Once the trend is analysed supplier will be informed. A SCAR or CAPA will be raised if immediate action is required
Bar code/QR code issues	85	*Not reportable	QR code number is not captured to comply with the DPIA, and hence further investigations cannot be done to trace back the route cause.	The Quality Investigations team are trying to check on possible ways to capture the QR code. Once this is captured NHS digital can handle these complaints
Reporting issues	24	*Not reportable	User error - People entering wrong results	The Quality investigations team will be monitoring these issues to ensure that no website issues are causing these errors.

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 Combined Complaints Data (Yellow Card, Control Tower and Qualtrics Complaints) – Trending

Figure 1 shows the trending data for the combined LFD complaints received (Yellow Card, Through Control Tower and Qualtrics Complaints) vs distributed LFD test kits for the last reporting periods.

Alert and Action thresholds were established using an average derived from the last reporting periods. These thresholds remained consistent to provide an ongoing benchmark for identifying trends through continual monitoring.

For this reporting period the total complaint rate is **0.026%** which is below the **currently** defined alert and action levels.

CAPA-21-06-0039 was raised as an action in PSR-011 for the reporting period of *23 Oct 21- 19 Nov 21* as the action level (0.041%) was exceeded at 0.071%. Initial investigations identified that no immediate containment action was required as the spike was attributed to the trending methodology. This was decision was based on four primary findings:

1) Lot specific trending process already exists as part of the Quality Investigations team Triage process. No lot specific issues were identified during this period.

2) Thresholds were set with the inclusion of data from all other brands for which DHSC is not the Legal Manufacturer. Qualtrics survey was updated to ensure reporters can select the correct supplier when reporting.

3) Volume distributed between 25 Sep - 22 Oct was 32 Million, volumes distributed for reporting period where a spike was observed was 12 Million. Volume distributed significantly dropped but complaints remained at a similar level. Data isn't normalised and there is no way of knowing when the kits were ordered vs when the complaint was received; therefore, month by month analysis against complaints isn't an accurate representation.

4) Total complaint rate over entire reporting period vs Total Distributed product were assessed, which revealed that the actual complaint rate was well below the action and alert levels.

Therefore, an additional level of analysis is now performed when drafting the PSR report, whereby the total number of complaints and total number of distributed products are assessed to ensure that the threshold is not exceeded when looking at overall volumes/reporting timescales.

Actions for the implementation of a new trending methodology have been defined in the CAPA-21-06-0039 to introduce a new trending methodology, which is currently in development. However, in the interest of continuity, the current trending methodology will not be omitted until the new trending methodology is finalised and approved internally.

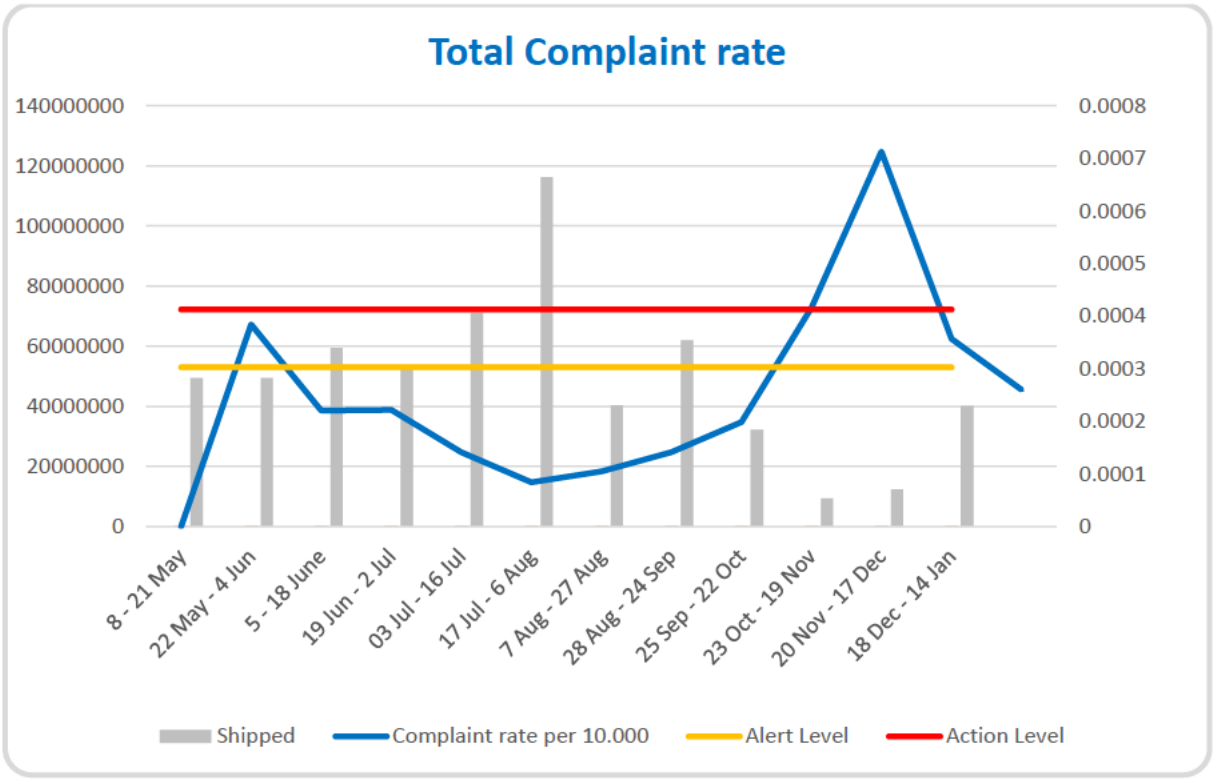


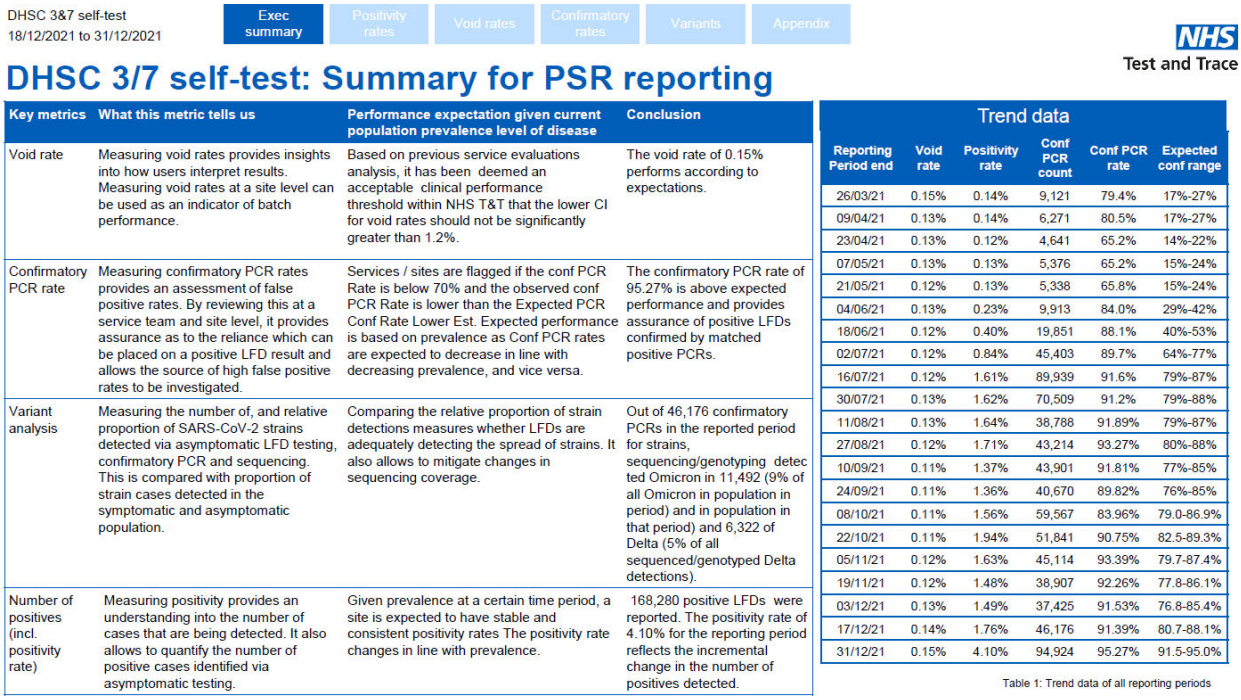
Figure 1: Graph showing total complaints vs distribution with action & alert levels set

(Refer to Attachment 02)

6.5 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 18th December 2021 – 14th January 2022



DHSC 3&7 self-test
18/12/2021 to 31/12/2021

Exec summary | Positivity rates | Void rates | Confirmatory rates | Variants | Appendix

NHS Test and Trace

DHSC 3/7 self-test: Summary for PSR reporting

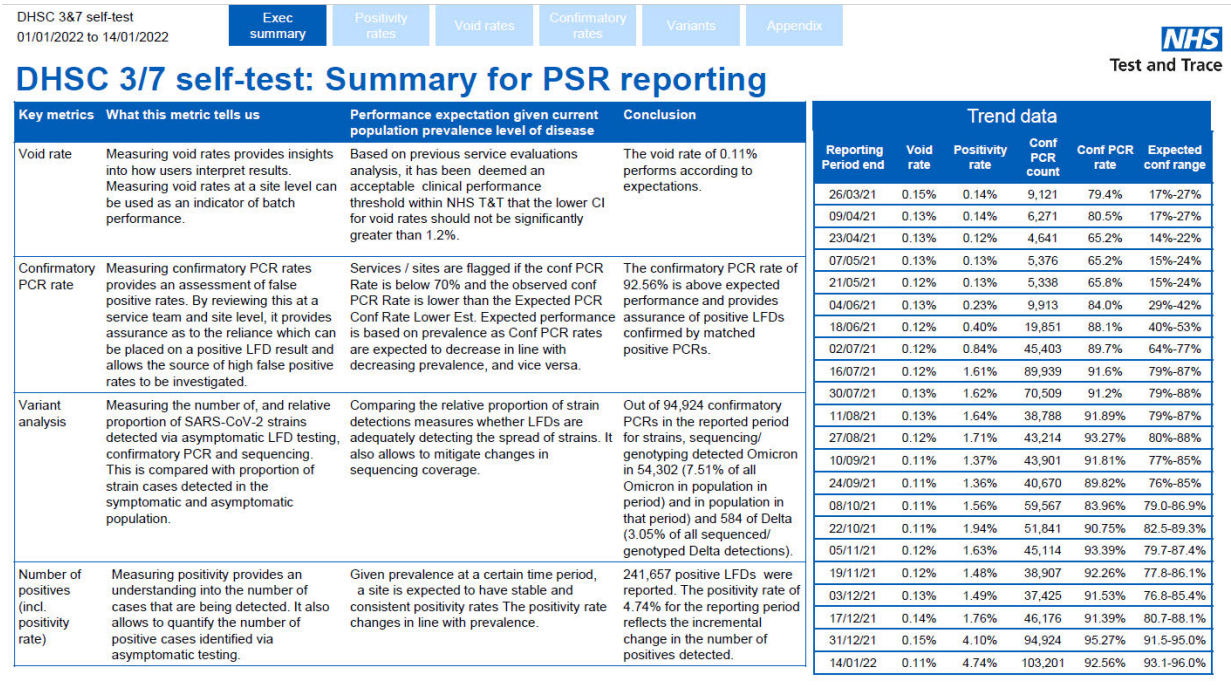
Key metrics	What this metric tells us	Performance expectation given current population prevalence level of disease	Conclusion
Void rate	Measuring void rates provides insights into how users interpret results. Measuring void rates at a site level can be used as an indicator of batch performance.	Based on previous service evaluations analysis, it has been deemed an acceptable clinical performance threshold within NHS T&T that the lower CI for void rates should not be significantly greater than 1.2%.	The void rate of 0.15% performs according to expectations.
Confirmatory PCR rate	Measuring confirmatory PCR rates 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 conf PCR Rate is below 70% and the observed conf PCR Rate is lower than the Expected PCR Conf Rate Lower Est. Expected performance is based on prevalence as Conf PCR rates are expected to decrease in line with decreasing prevalence, and vice versa.	The confirmatory PCR rate of 95.27% is above expected performance and provides assurance of positive LFDs confirmed by matched positive PCRs.
Variant analysis	Measuring the number of, and relative proportion of SARS-CoV-2 strains detected via asymptomatic LFD testing, confirmatory PCR and sequencing. This is compared with proportion of strain cases detected in the symptomatic and asymptomatic 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.	Out of 46,176 confirmatory PCRs in the reported period for strains, sequencing/genotyping detec ted Omicron in 11,492 (9% of all Omicron in population in period) and in population in that period) and 6,322 of Delta (5% of all sequenced/genotyped Delta detections).
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 asymptomatic 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.	168,280 positive LFDs were reported. The positivity rate of 4.10% for the reporting period reflects the incremental change in the number of positives detected.

Trend data

Reporting Period end	Void rate	Positivity rate	Conf PCR count	Conf PCR rate	Expected conf range
26/03/21	0.15%	0.14%	9,121	79.4%	17%-27%
09/04/21	0.13%	0.14%	6,271	80.5%	17%-27%
23/04/21	0.13%	0.12%	4,641	65.2%	14%-22%
07/05/21	0.13%	0.13%	5,376	65.2%	15%-24%
21/05/21	0.12%	0.13%	5,338	65.8%	15%-24%
04/06/21	0.13%	0.23%	9,913	84.0%	29%-42%
18/06/21	0.12%	0.40%	19,851	88.1%	40%-53%
02/07/21	0.12%	0.84%	45,403	89.7%	64%-77%
16/07/21	0.12%	1.61%	89,939	91.6%	79%-87%
30/07/21	0.13%	1.62%	70,509	91.2%	79%-88%
11/08/21	0.13%	1.64%	38,788	91.89%	79%-87%
27/08/21	0.12%	1.71%	43,214	93.27%	80%-88%
10/09/21	0.11%	1.37%	43,901	91.81%	77%-85%
24/09/21	0.11%	1.36%	40,670	89.82%	76%-85%
08/10/21	0.11%	1.56%	59,567	83.96%	79.0-86.9%
22/10/21	0.11%	1.94%	51,841	90.75%	82.5-89.3%
05/11/21	0.12%	1.63%	45,114	93.39%	79.7-87.4%
19/11/21	0.12%	1.48%	38,907	92.26%	77.8-86.1%
03/12/21	0.13%	1.49%	37,425	91.53%	76.8-85.4%
17/12/21	0.14%	1.76%	46,176	91.39%	80.7-88.1%
31/12/21	0.15%	4.10%	94,924	95.27%	91.5-95.0%

Table 1: Trend data of all reporting periods

Figure 2: DHSC 3/7 self-test summary Period 18-Dec-2021 to 31-Dec-2021



DHSC 3&7 self-test
01/01/2022 to 14/01/2022

Exec summary | Positivity rates | Void rates | Confirmatory rates | Variants | Appendix

NHS Test and Trace

DHSC 3/7 self-test: Summary for PSR reporting

Key metrics	What this metric tells us	Performance expectation given current population prevalence level of disease	Conclusion
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 has been deemed an acceptable clinical performance threshold within NHS T&T that the lower CI for void rates should not be significantly greater than 1.2%.	The void rate of 0.11% performs according to expectations.
Confirmatory PCR rate	Measuring confirmatory PCR rates 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 conf PCR Rate is below 70% and the observed conf PCR Rate is lower than the Expected PCR Conf Rate Lower Est. Expected performance is based on prevalence as Conf PCR rates are expected to decrease in line with decreasing prevalence, and vice versa.	The confirmatory PCR rate of 92.56% is above expected performance and provides assurance of positive LFDs confirmed by matched positive PCRs.
Variant analysis	Measuring the number of, and relative proportion of SARS-CoV-2 strains detected via asymptomatic LFD testing, confirmatory PCR and sequencing. This is compared with proportion of strain cases detected in the symptomatic and asymptomatic 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.	Out of 94,924 confirmatory PCRs in the reported period for strains, sequencing/ genotyping detected Omicron in 54,302 (7.51% of all Omicron in population in period) and in population in that period) and 584 of Delta (3.05% of all sequenced/ genotyped Delta detections).
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 asymptomatic 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.	241,657 positive LFDs were reported. The positivity rate of 4.74% for the reporting period reflects the incremental change in the number of positives detected.

Trend data

Reporting Period end	Void rate	Positivity rate	Conf PCR count	Conf PCR rate	Expected conf range
26/03/21	0.15%	0.14%	9,121	79.4%	17%-27%
09/04/21	0.13%	0.14%	6,271	80.5%	17%-27%
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30/07/21	0.13%	1.62%	70,509	91.2%	79%-88%
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17/12/21	0.14%	1.76%	46,176	91.39%	80.7-88.1%
31/12/21	0.15%	4.10%	94,924	95.27%	91.5-95.0%
14/01/22	0.11%	4.74%	103,201	92.56%	93.1-96.0%

Figure 3: DHSC 3/7 self-test summary Period 01-Jan-2022 to 14-Jan-2022

(Refer to Attachments 3 & 4)

6.6 CAPA

- Since the last reporting period the DHSC Quality team have closed 11 CAPA's.
- Refer to Table 3 for a CAPA Status Overview
- Refer to
- Table 4 for List of open CAPA's and current progress and due dates.

CAPA Status	No
Completed	00
Implementation	00
Investigation	00
VOE	02
Open	01
Total	**03**

Table 3: CAPA Status Overview

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date	Reason for extension if overdue
06	CAPA-21-06-0013	08-Jun-21	CAPA raised to strengthen the PMS plan and appropriate PMS activities	Complete pending VOE	Voe Due: Mid Feb 2022	N/A
23	CAPA-21-06-0032	11-Jun-21	CAPA raised to demonstrate DHSC's compliance towards nonconformity identified in Innova USA voluntary recall notice with regards to QMS requirements	Complete pending VOE	Out for closure	N/A
26	CAPA-21-06-0039	26-Nov-21	CAPA raised due to a spike in LFD complaints taking them over the acceptable threshold	Open	31-Mar-22	N/A

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

6.7 SCAR – Supplier Corrective Action Report

No SCARs raised for DHSC LFDs in this reporting period of 18th December to 14th January 2022.

6.8 Risk Management

LFD Risk management File (RMF) was updated to RMF-0001 Revision 5 and HTM Hazard traceability Matrix Rev5 ***(Refer to Attachment 6)***. The RMF updated to new template for compliance with ISO 14971:2019

Two new Hazards were identified during this reporting period as part of the continual monitoring through post-market surveillance activities ***(Refer Attachment 2 – "Events Trending" Tab).*** These hazards were reported to the Risk Management team by the Quality Investigations team. Initial feedback indicates that these are hazards have previously been identified (see Table 5) . An action will be raised in this report and an update provided in the upcoming reporting period.

DHSC Complaint Number	Brief Description of Event	Expected Hazard ID after initial assessment	Confirmation that new risk identified in PMS is already captured in HTM
LFD-21-12-0025	User experiences hypersensitivity to extraction buffer after accidental exposure.	AI01 & HI50	TBC – Action raised in this PSR and sent to Risk Management Team. **(See Section 8)**
LFD-22-01-0007	Duplicate QR codes received within the same box.	HI73	

Table 5: New risks identified in current reporting period.

6.9 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.

For the update search conducted in January 2022, one article was received (from the safety and performance search). During first pass review, this article was excluded due to lack of relevance to the target device. Therefore, no new articles were considered for inclusion in the literature review ***(Refer to Attachment 08, Page 16, Figure 3).***

No new articles were retrieved from the SOTA search, however in this report the SOTA search from November 2021 is included as this was omitted from previous submissions ***(Refer to Attachment 09).***

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.

It is noted that performance of the device demonstrated a Void Rate of 0.15% for the period between 18 Dec to 31 Dec 21 and 0.11% for the period between 01 Jan 2022 to 14 Jan 2022, which performs according to expectations and is below the threshold of 1.2%.

The confirmatory PCR rate of 95.27% between the period of 18 Dec – 31 Dec 2021 and 92.56% between the period of 01 Jan 2022 and 14 Jan 2022 which are above expected performance and provides assurance of positive LFDs confirmed by matched positive PCRs.

Two new Hazards were identified during this reporting period as part of the continual monitoring through post-market surveillance activities. These hazards were reported to the Risk Management team by the Quality Investigations team. Initial feedback indicates that these are hazards have previously been identified, however an action is raised in this report and an update will be provided in the next report.

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

No new literature or SOTA information were identified in Section 6.3 for this reporting period, therefore no new evidence is apparent to challenge the evidence presented in previous reports. LFDs remain quick and cost-effective means of rapid mass testing during the on-going pandemic and that the device continues to meet its intended purpose.

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

No emerging issues or safety signals identified, but opportunities for improvement were noted and actions are assigned in Section 8.

As a 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	21-Jan-2022	Two new hazards identified during this reporting window to be assessed and added to the Hazard Traceability Matrix (if applicable). An update to be provided prior to the next reporting period.	[redacted]	16-Feb-2022	Open
2	06-Dec-2021	Raise Quality Alert for 68 reports under complaint categories "Missing", "Media Volume"," Empty Sachet", "Damaged" and "Contamination".	[redacted]	19-Jan-2022	Completed

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
Attachment 03: RWPM Innova 3s and 7s
Attachment 04: RWPM Innova 25s
Attachment 05: RWPM Innova Assisted
Attachment 06: QP08-F02 LFD Hazard Traceability Matrix v.01 Issued 22.12.2021
Attachment 07: Inbound Freight Report – 18/01/2021 – 14/01/2022
Attachment 08: Literature Search Report - Lateral Flow Device 20220119
Attachment 09: 2021-11-25_Medboard Search report for SOTA of LFD.V2

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