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	25 Mar 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 were no inspections carried out between the reporting period of 12/02/2022 and 11/03/2022 following conclusion of QC of the previous contract on 30/01/2022. No further Innova product has been procured during this reporting window.

(Refer to Attachment 5.1)

6.2 Receiving inspection - Intertek Testing in the UK

A total of 7,035 samples underwent validation from the 12/02/2022 until 11/03/2022, from 67 lots. From these samples, there were no red flags recorded.

(Refer to Attachment 5.2)

6.3 Product complaints & Qualtrics Survey Reports

- The number of kits distributed in this reporting period is **~ 110 Million** which is decrease of **~9.38 Million** over the previous reporting month.
- A large increase in volume of distributed DHSC Innova 3's. Approximately 60 Million of these were due to a claim from the Northern Ireland (DA) distributing to local pharmacies.

- A total of 20 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.

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

- One of the 20 complaints was defined as a reportable complaint when discussed at the weekly patient safety panel (MORE Ref: 2022/003/001/601/506).

- A total of 404 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	177	Not reportable	There was no trend observed for any particular batch.	SCAR was raised with the supplier due to increased missing item complaints
Damaged Item	22	Not reportable	There was no trend observed for any particular batch.	No further action. Complaints will be monitored for trending purposes
Faulty test results	46	Not reportable	There was no trend observed for any particular batch.	No further action. Complaints will be monitored for trending purposes
Faulty items	26	Not reportable	There was no trend observed for any particular batch.	No further action. Complaints will be monitored for trending purposes
Patient injury	3	2 Not reportable, 1 Reportable (MORE Ref: 2022/003/001/601/506)	There was no trend observed for any particular batch.	No further action. Complaints will be monitored for trending purposes
Allergic reactions	2	Not reportable	This was decided to be not reportable by the clinical team in the incident review meeting	Investigation ongoing with clinical team
Empty extraction buffer	17	Not reportable	There was no trend observed for any particular batch.	No further action. Complaints will be monitored for trending purposes
Wrong media volume	48	Not reportable	There was no trend observed for any particular batch.	No further action. Complaints will be monitored for trending purposes
Bar code/QR code issues	48	Not reportable	QR code number is not captured in order to comply with the DPIA and hence further investigations cannot be done to trace back the root cause.	Qualtrics is updated to capture QR code from 14th Mar 2022 to investigate further

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

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. **From the graph (see Figure 1), it is apparent that during this week the alert level is triggered, investigating this it was found that most of the complaints in material category was regarding missing items and QR code issue. For missing item complaints, SCAR was raised with the Innova (Refer to Section 6.11). For QR code issue, it was not possible to investigate further as Qualtrics was not capturing QR code due to DPIA agreement. Plan is in place to capture QR code from 14 Mar 2022.**
2) **Faulty Test Results:** No sub-categories exist within this category of complaints. **From the graph (see Figure 2) During this week the alert level is triggered, on investigating this it was found that no batch specific trend was observed for faulty test result complaints.**

3) **Harm & Allergy:** this includes complaints from Patient Injury and Allergic reactions as sub-categories. From the graph (see Figure 3), Harm-allergy complaints for this reporting period remained below the alert threshold.

Refer to **Attachment 2.2** for a summary of complaints trending activities to date.

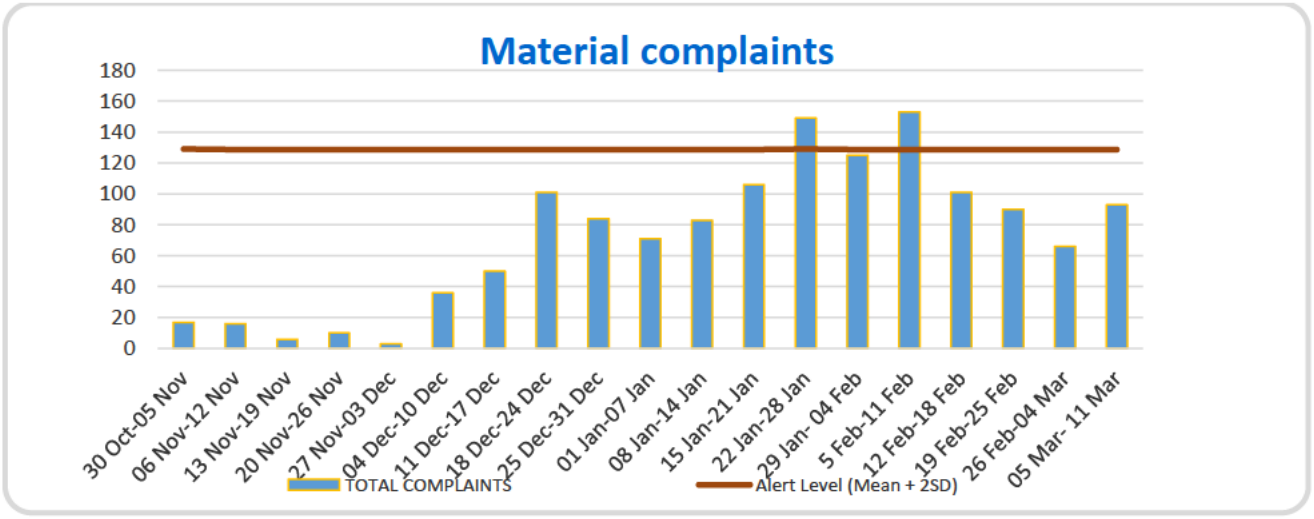


Figure 1: Material complaints weekly trending

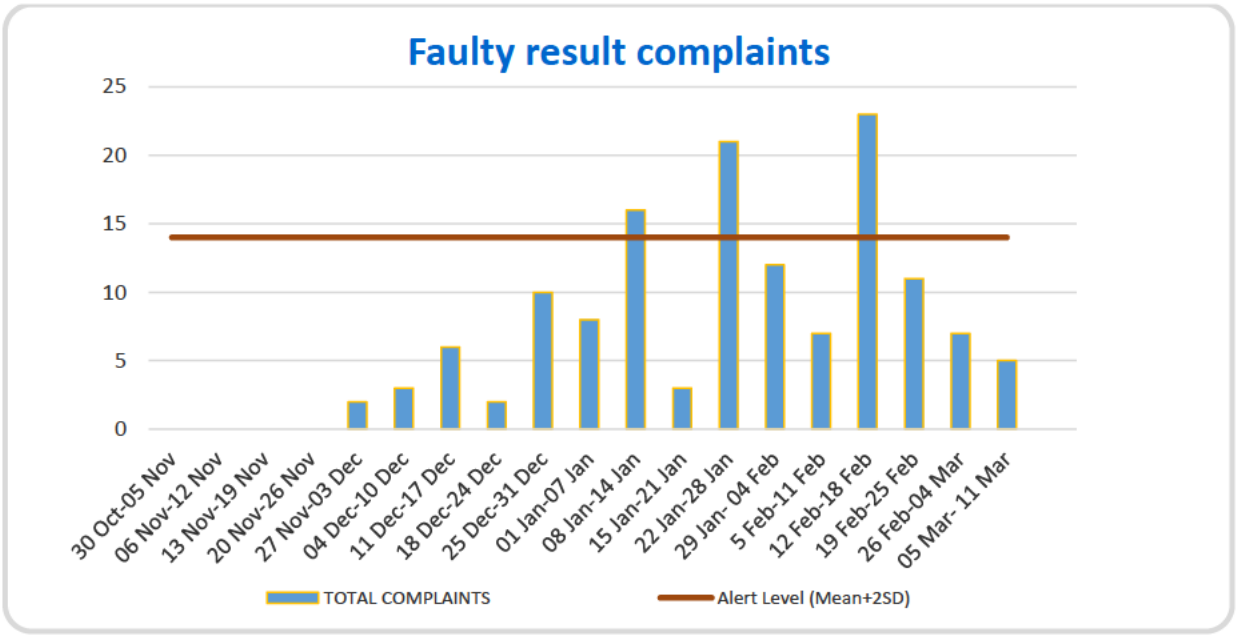


Figure 2: Faulty results complaint weekly trending

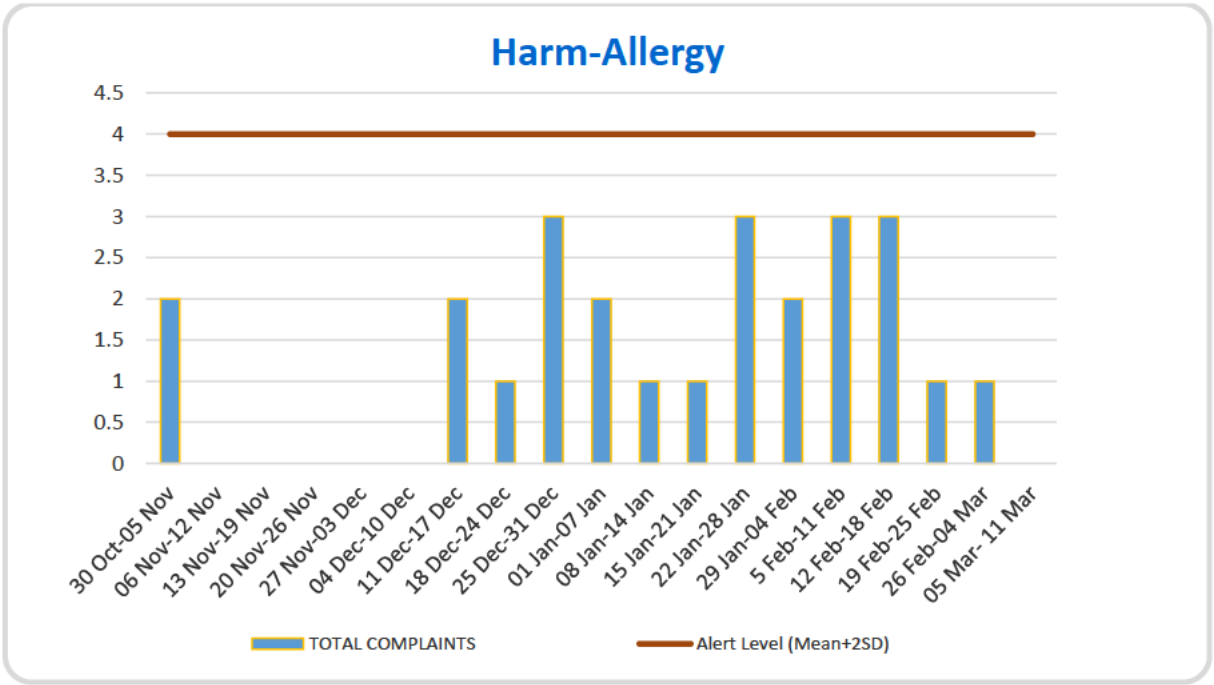


Figure 3: Harm-Allergy complaints weekly trending

(Refer to Attachment 2.2)

6.5 Qualtrics Survey (User Experience)

A total of 1266 user responses were received during this reporting window of 12th February – 11th March 2022 for all LFD products for which the DHSC is either the legal manufacturer or distributor.

54.4% of these responses were related to the DHSC LFD Products (**highlighted in green in Attachment 2.3**). 662 users completed 100% of the survey in an average time of 7.38 minutes.

A series of questions relating to the user's overall experience can be seen in **Attachment 2.3**. Satisfaction rates were predominantly above 80% for most queries relating to the useability of the LFD products, except for:

1) ***Reporting of results (Understanding of IFU):*** 74.39% satisfaction rate which is an improvement of 5.03% since the last reporting period.
2) ***Reporting of results (Difficulty of process):*** 68.05% Satisfaction rate which is an improvement of 6.1% 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 (Useability Studies)

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

The team have carried out useability 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.

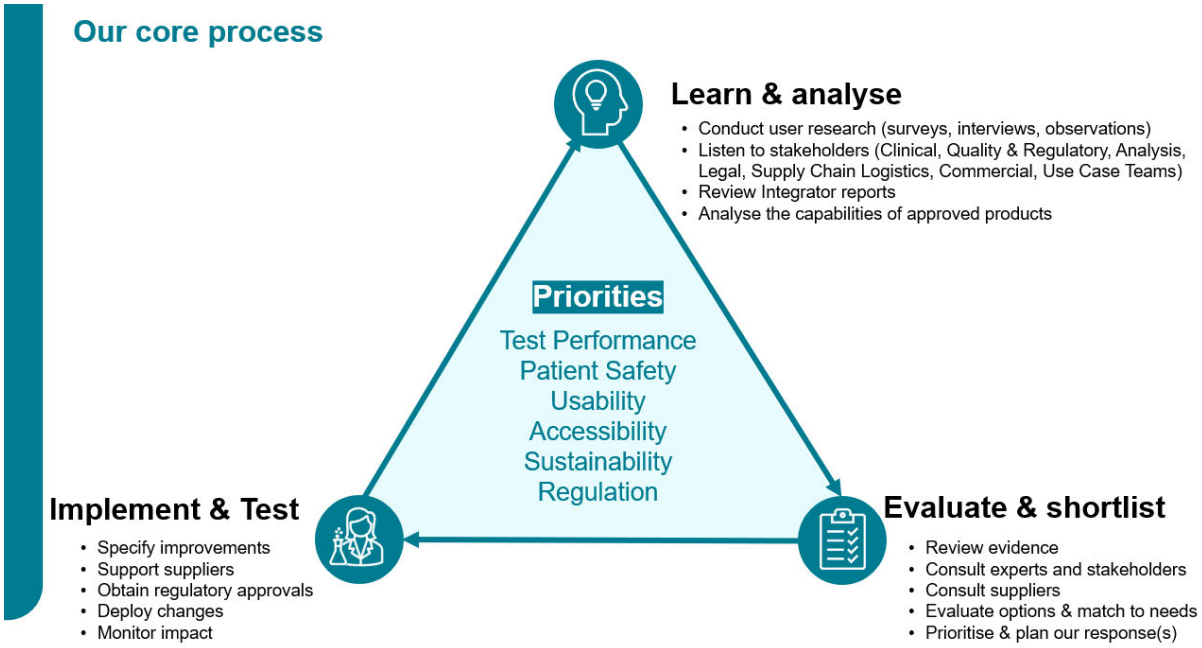


Figure 4: LFD Product Management Teams Core Process

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

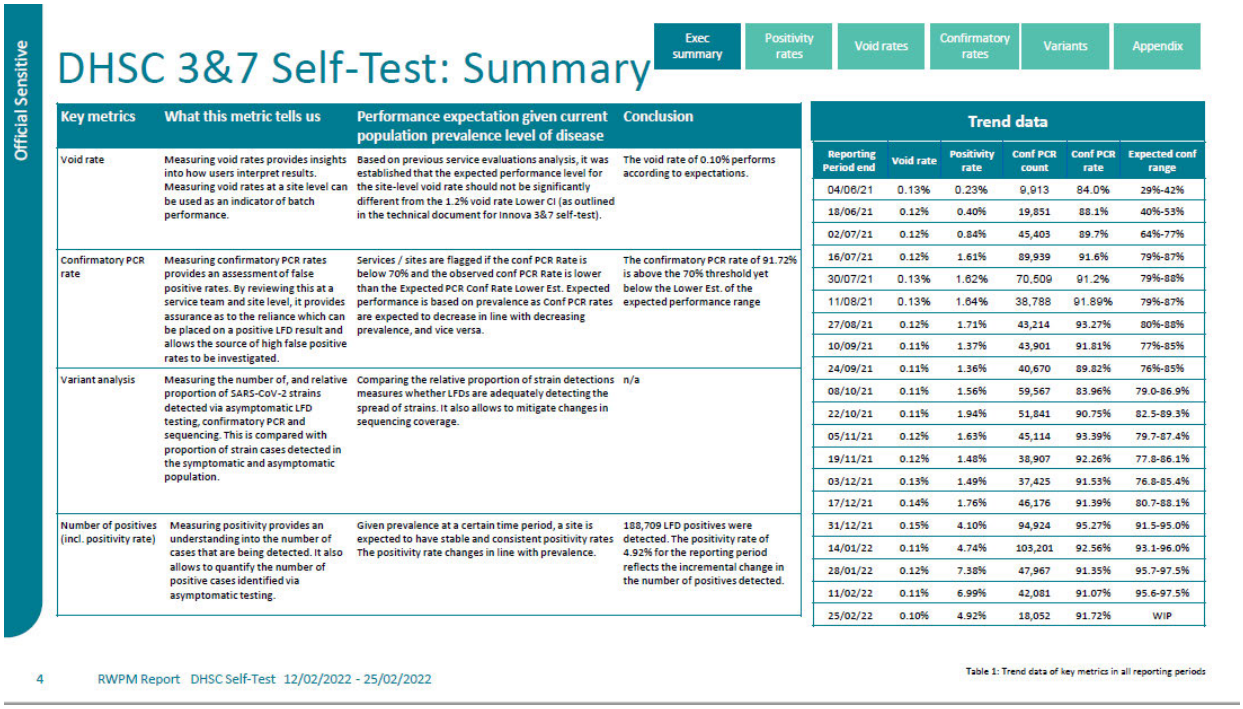
Further information on some of the findings and actions were shared in the previous report and have therefore been omitted from this submission.

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 12th February 2022 – 11th March 2022.



Official Sensitive

DHSC 3&7 Self-Test: Summary

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

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 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).	The void rate of 0.10% 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 91.72% is above the 70% threshold yet below the Lower Est. of the expected performance range
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.	n/a
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.	188,709 LFD positives were detected. The positivity rate of 4.92% for the reporting period reflects the incremental change in the number of positives detected.

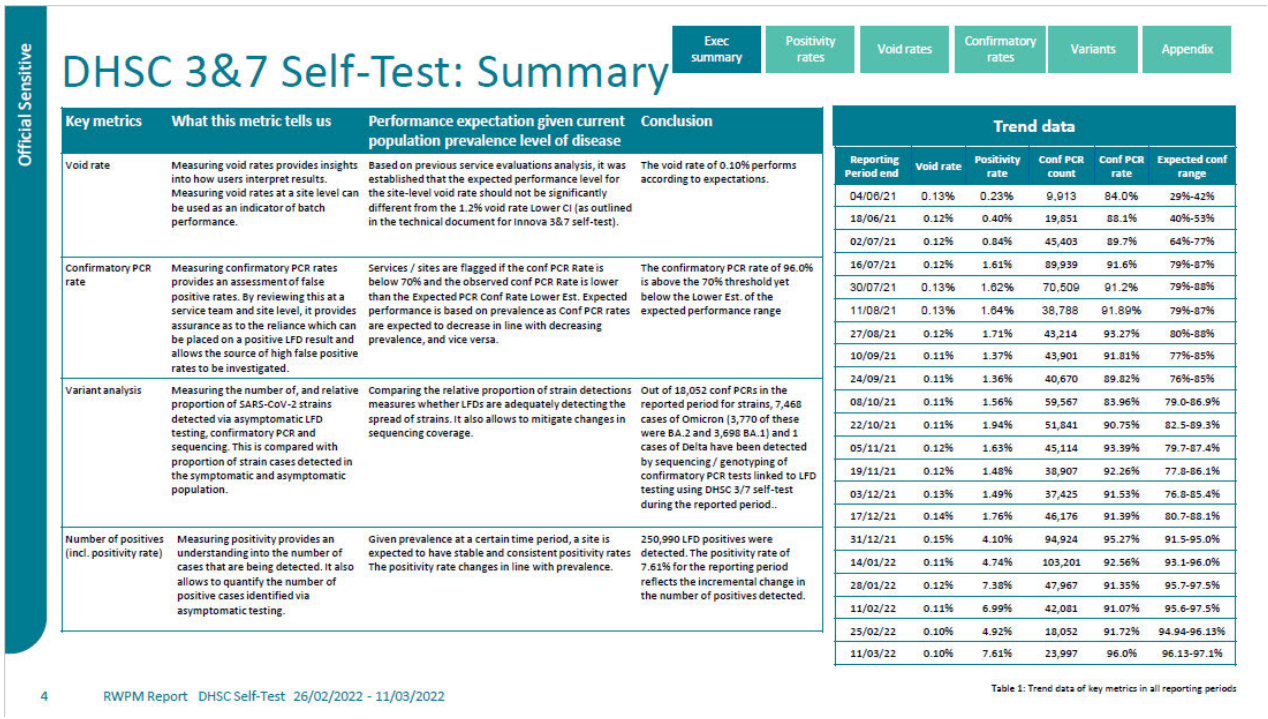
Trend data

Reporting Period end	Void rate	Positivity rate	Conf PCR count	Conf PCR rate	Expected conf range
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%
14/01/22	0.11%	4.74%	103,201	92.56%	93.1-96.0%
28/01/22	0.12%	7.38%	47,967	91.35%	95.7-97.5%
11/02/22	0.11%	6.99%	42,081	91.07%	95.6-97.5%
25/02/22	0.10%	4.92%	18,052	91.72%	WIP

4 RWPM Report DHSC Self-Test 12/02/2022 - 25/02/2022

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

Figure 5: DHSC 3/7 self-test summary Period 12-Feb-2022 to 25-Feb-2022



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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 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).	The void rate of 0.10% 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 96.0% is above the 70% threshold yet below the Lower Est. of the expected performance range
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 18,052 conf PCRs in the reported period for strains, 7,468 cases of Omicron (3,770 of these were BA.2 and 3,698 BA.1) and 1 cases of Delta have been detected by sequencing / genotyping of confirmatory PCR tests linked to LFD testing using DHSC 3/7 self-test during the reported period..
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.	250,990 LFD positives were detected. The positivity rate of 7.61% 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
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%
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16/07/21	0.12%	1.61%	89,939	91.6%	79%-87%
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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%
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11/02/22	0.11%	6.99%	42,081	91.07%	95.6-97.5%
25/02/22	0.10%	4.92%	18,052	91.72%	94.94-96.13%
11/03/22	0.10%	7.61%	23,997	96.0%	96.13-97.1%

4 RWPM Report DHSC Self-Test 26/02/2022 - 11/03/2022

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

Figure 6: DHSC 3/7 self-test summary Period 26-Feb-2022 to 11-Mar-2022

(Refer to Attachments 3.1 & 3.2)

Note on omitted RWPM reports: At the beginning of March, the Real-world performance monitoring team had to implement a new dashboard when the previous one that was used came to capacity limits and was no longer publishable for reporting. In the new dashboard, there are some discrepancies in the test count associated with both the Innova 25 self-testing and Innova assisted testing reports. Even though the missing tests in these two reports can be seen in the dashboard, the dashboard is currently not coded for them to flow into the Innova 25 and Innova assisted test reports. Further dashboard development is needed before the reports can be sent out.

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.

The intention is that PMPF studies are carried out on a 6-month cadence to allow for recruitment of patients, compilation and analysis of results and completion of the final report. Conclusion from the last on-going evaluation is referenced below:

Report 2 is currently expected to be available by the end of March 2022. For this PSR report and future reports, a PMPF study tracker summary has been developed to highlight the status of future PMPF.

(Refer to Attachment 07)

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 meeting has been scheduled with the Variant of Concern Assurance Group (VOC) to discuss the monthly VOC input. An update will be available in the next reporting period.

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
06	CAPA-21-06-0013	08-Jun-21	MHRA Audit CAPA	CAPA raised to strengthen the PMS plan and appropriate PMS activities	Out for closure	**Original:** Mid Feb-22 **New:** VOE Due Mid Mar-22	Extension agreed as VOE plan for CAPA required several PSR submissions to ensure effectiveness of CAPA.
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	Open – Action plan approved.	31-Mar-22	CAPA sent out for Action plan approval.

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

6.11 SCAR – Supplier Corrective Action Report

One SCAR was raised by DHSC to Innova on 04 Mar 2022. Summary and status below:

SCAR No.	Start Date	Description	Fault Detected	Initial Response Date	Formal Response Due Date	Status
SCAR-2022-018	08-Feb-2022	This SCAR has been raised as a summary of the complaints received from end-users/patients relating to missing items within LFD kits kitted by Innova, covering the period of Dec 2021 & and Jan 2022.	Missing Component	10- Feb -2022	08-Mar-2022	Closed
SCAR-2022-025	04-Mar-2022	This SCAR has been raised as a summary of the complaints received from end-users/patients relating to missing items within LFD kits kitted by Innova, covering the period of February 2022.	Missing component	7- Mar- 2022	01-Apr-2022	Open

Table 5: SCAR Overview

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.

The March update was conducted 07 March 2022. Two articles were retrieved from the safety and performance search, whilst zero were retrieved from the SOTA search. One article was found relevant for the Medboard SOTA search.

During first pass review, one article was excluded from the safety and performance search due to lack of relevant to the target device. One new article was considered for inclusion in any performance evaluation report.

A study by ***Deeks et al*** was designed to investigate the proportion of LFT's that produce negative results in those with high risk of infectiousness from SARS-COV-2, to investigate the impact of the stage and severity of disease and to compare the predictions made by influential mathematical models with findings of empirical studies. The authors concluded that the proportion of infectious people with SARS-COV-2 missed by LFTs is substantial enough to be of clinical importance. The proportion missed varied between settings because of different viral load distributions and is likely to be highest in those without symptoms. Key models have substantially overestimated the sensitivity of LFTs compared with empirical data. **(Ref Attachment 6, Page 47/48, 202203-01Deeks et al).**

It is important to note that this publication has been challenged by several author(s). It is also important to note that this publication has been considered and addressed by UKHSA scientists and public health practitioners; a response to the editor was submitted on **4th March 2022 by Quilty et al**[1].

For the Medboard SOTA search on similar devices, one article was deemed to be relevant for inclusion. A study by ***Rodgers et al*** titled "Detection of SARS-COV-2 variants by Abott Molecular, antigen, and serological tests" was retrieved from the Journal of clinical virology (2022). The objectives of the study were to evaluate the capacity of Abott molecular, antigen and serologic assays to detect circulating SARS-COV-2 variants, including all current variants of concern (VOC): B1.1.7 (alpha), B1.351 (beta), P.1 (gamma) and B1.617.2 (delta). Results were consistent with in silico predictions. Each molecular and antigen assay detected VOC virus cultures with equivalent sensitivity to the WA1 control strain. The author concluded that these data confirm variant detection for 11 SARS-COV-2 assays, which is consistent with each assay target region being highly conserved. Importantly alpha, beta, gamma and delta VOCs were detected by molecular and antigen assays, indicating that these tests may be suitable for widescale use where VOCs predominate. **(Ref Attachment 6, Page 62, E4.27).**

(Refer to Attachment 06)

[1] SARS-CoV-2 antigen lateral flow tests for detecting infectious people: linked data analysis | The BMJ

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 6** and summarised in this section.

It is noted that performance of the device demonstrated a Void Rate of **0.10%** for the period between 12th Feb 2022 to 25th Feb 2022 and 0.10% for the period between 26th Feb 2022 to 11th Mar 2022, which performs according to expectations and is below the threshold of **1.2%.**

The confirmatory PCR rate of **91.72%** between the period of 12th Feb – 25th Feb 2022 and **96.0%** between the period of 26th Feb 2022 and 11th Mar 2022 which are above expected performance and provides assurance of positive LFDs confirmed by matched positive PCRs.

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 evident.

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

New literature was found which is relevant for inclusion and requires assessment. This was assessed and It is important to note that several scientists and public health practitioners have challenged the modelling of this article and provided a response to the editor on 04 Mar 2022, a link to this can be found in Section 6.13. New Medboard SOTA literature was identified in Section 6.3 for this reporting period. This data was favourable for LFD technologies detection of VOCs.

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. PMPF ongoing evaluation report 2 is expected imminently and will be summarised in this report once approved.	**Section 6.7** **Section 6.8**
d) Do users experience any usability issues?	No	Satisfaction rates are above 70% with regards to useability 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 been raised against Innova/Biotime. Immediate containment action not deemed necessary as the risk on patient safety is minimal.	**Section 6.4** **Section 6.11**

Table 6: 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
N/A	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: QP08-F02 LFD Hazard Traceability Matrix v.01 Issued 22.12.2021
Attachment 05: Inbound Freight Data for Reporting Period 15012022-11022022 (Attachments 5.1 & 5.2)
Attachment 06: Literature Search Report - Lateral Flow Device 202203withoutpapers
Attachment 07: PMCPF Study Tracker (Mar-2022)

10. Author

	Job Title	Name	Email
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