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	05-Nov-2021	First issue

1. Content

2. Introduction

The purpose of this document is to summarise the Periodic Summary Report for Innova LFD kits where DHSC is the legal manufacturer for size 3s and 7s. This report covers the period 25th September to 22th October 2021 .

This report includes inputs from Intertek Inbound Testing, Product Complaints, Qualtrics survey, Real World Performance Monitoring, CAPAs, SCARs and Variants of Concern.

3. Methodology

The methodology for data collection was established in the PMS plan PMS-0001 Revision 2, dated 29-July-2021.

(Refer to Attachment 01)

4. Findings /Results

4.1 In-House manufacturing inspection at Biotime

There were no inspections carried out between the reporting period of 25th September to 22nd October 2021. This is following the conclusion of QC of the previous contract on the 30th August 2021.

No further Innova product has been procured during this reporting window.

4.2 Receiving inspection - Intertek Testing in the UK

A total of 30 "validation" reports were received during the above reporting period. A total of 2,566 samples of TK2193 tests were analysed.

A total of 77 "validation" reports were received between 22nd September to 22nd October 2021 with a total of 6,563 Innova samples processed during the specified reporting period. These samples correspond to 76,399,840 units of TK2193 produced. Of these, there were 9 instances of failure as below:

-Two instances of control line dysfunction for X2108738 which is within the batch acceptance rate outlined in contract with supplier.
-One instance of liquid not tracking the full length of the strip was found for X2108751 which was due to insufficient liquid being applied to test strip by the analyst meaning control line was not visible and within batch acceptance rate.
-Six instances of failure were found against lot number X2108753, where no control line was visible. This issue was reported though control tower and commercial teams on 13 October 2021. Warehouse is to provide samples for additional testing.

(Refer to Attachments 02 for input report)

4.3 Product complaints

- DHSC has received a total of 13 complaints between 25th September – 22nd October 2021. 12 of which from MHRA (yellow card) and 1 through control tower. The number of kits distributed (3s, 7s and 25s) during this period was 32 million.
- One complaint 2021/009/025/501/007 has been reported through the MORE Portal. Rational for non-reporting the other issues is provided below for the allergic reaction complaints. These complaints were discussed in the Incident review meetings or at the Patient safety panel and the reportability decision was documented in the minutes of the meeting as listed below.
- No lot trend was identified within this period.
- Trending category shows 5 complaints for "Faulty test results", however investigations are still going on to determine if there is a problem with the LFD kits or this can be linked to the wider issue of incorrect PCR results from a particular lab.
- 9 out of 13 Complaints have had the investigation completed and are due for final review before the complaints can be closed.
- There was one new hazard identified for the contaminated item in the kit. The reporter stated; "I have directed the patient to contact 119 immediately as per service outline and have quarantined remaining stock from the associated batch meantime until further guidance." This is a one off complaint that has been received for the LFD kits. The Risk Management File (RMF) will be updated with a new hazard ID

Source Reference (Yellow Card)	Trending Category	Reportability	MORE Reference	Investigation status	Investigations Results
2021/009/027/501/005	Wrong Media volume	Not reportable *	N/A	Complete/ No trend	No further action
2021/009/022/501/010	Wrong Media volume	Not reportable *	N/A	Complete / No trend	No further action

Source Reference (Yellow Card)	Trending Category	Reportability	MORE Reference	Investigation status	Investigations Results
2021/009/025/501/007	Allergic Reaction	Reportable	2021/010/008/601/503	Complete/ No trend	No further action
2021/009/025/501/005	Allergic Reaction	Not reportable *	N/A	Complete/ No trend	No further action
2021/010/009/501/001	Allergic Reaction	Not reportable *	N/A	Complete/ No trend	No further action
2021/009/030/401/001	Barcode issue	Not reportable *	N/A	Complete/ No trend	No further action
CSL-26178	Contaminated Item	Not reportable *	N/A	Complete/ No trend	No further action
2021/010/007/291/006	Faulty test results	Not reportable *	N/A	Ongoing	Ongoing
2021/010/008/501/003	Faulty test results	Not reportable *	N/A	Ongoing	Ongoing
2021/010/009/501/003	Faulty test results	Not reportable *	N/A	Ongoing	Ongoing
2021/010/009/501/005	Faulty test results	Not reportable *	N/A	Ongoing	Ongoing
2021/009/021/501/009	Faulty test results	Not reportable *	N/A	Ongoing	Ongoing
2021/009/023/501/001	Missing Item	Not reportable *	N/A	Complete	No further action

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

MED DEV 2.12 rev 8 vigilance Guidance:

- Question A 'Has and event occurred etc.. '
- Question B Is DHSC' device cause of incident'
- Question C 'Has the event led to death or serious deterioration in health'

Complaint reference	Brief summary	Batch	A	B	C	Reportability decision (Reportable/Non reportable)
LFD-21-10-0010 2021/010/009/501/001	Acute sneezing as soon as swab applied to nostril.	X2103855	Yes	Yes	No	Non-Reportable – No issue to health or deterioration. Normal reaction to swab therefore not reportable.

Complaint reference	Brief summary	Batch	A	B	C	Reportability decision (Reportable/Non reportable)
LFD-21-10-0005 2021/009/025/501/005	Normal discomfort and couple of sneezes post nasal swab. Then gradual onset of extreme itchiness, sneezing, streaming nose, itching, sore throat, increasing over an hour and lasting for several hours afterwards.	X2011011	Yes	Yes	No	This incident was recognised as being likely due to an allergic reaction

(Refer to Attachment 03 for raw data)

4.4 Qualtrics survey

- A total of 1668 reports were recorded through the Qualtrics Survey for period 25th September to 22nd October 2021 . This data may contain reports for other brands. In order to improve the reporting for improved visibility by brand, the system has been updated and it went live on the 27 of October. The new link is NHS Test and Trace LFD Test Survey (qualtrics.com)
- The number of kits distributed (3s, 7s and 25s) during this period was 32.1 million.
- 193 Injuries were reported and in the absence of details from the reporters, these cases could not be followed up. The new system is currently going through a Data protection agreement with the system supplier, to allow reporters to provide contact details so that DHSC will be able to follow up the incidents.
- 32.4 % of the end user completing Qualtrics survey answered 100% of the survey questions during the reporting period of 25th September to 22nd October 2021 .
- 41.3 % of the reporters aborted the Qualtrics survey answering only 7% of the Survey.
- 28 reports were recorded for Damage items and 56 reports for missing items.

- Qualtrics summary - User Experience

Question	Yes	No
Swab easy to use?	372	35
Test Strip easy to use?	367	40
Easy to get sample?	338	69
Test worked as instructed?	329	78
Manual easy and clear?	376	31

(Refer to Attachment 03, for data)

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

The graph 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.

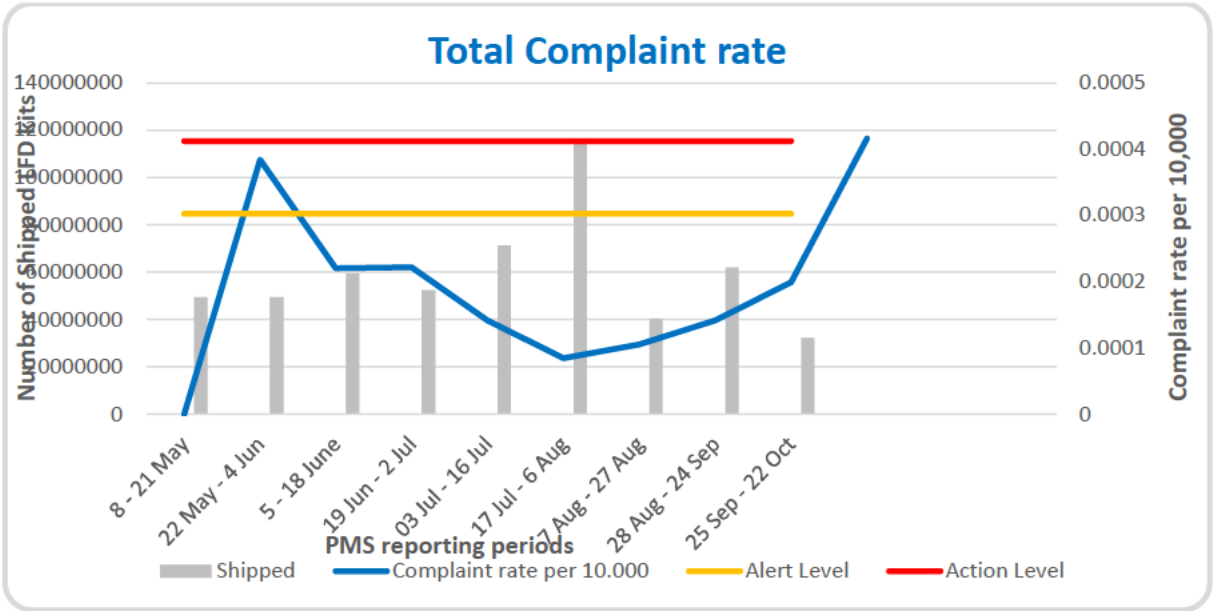
Alert and Action thresholds have been established using an average derived from the last reporting periods. These thresholds will remain consistent, and will provide an ongoing benchmark for identifying trends through continual monitoring.

The data for this reporting period of 25th September to 22nd October 2021 shows a rate of 0.042% per 10,000 complaints which is above the Action limit 0.041%.

The total number of complaints has gone up and the number of LFD Kits distributed (Innova) has gone down.

The fact that most of the complaints from the Qualtrics survey are attributed to Innova might not be accurately reflect that for Innova. Citizens completing the survey were not able to distinguish clearly the Manufacturer of their kits and this results in a large set of undistinctive reports.

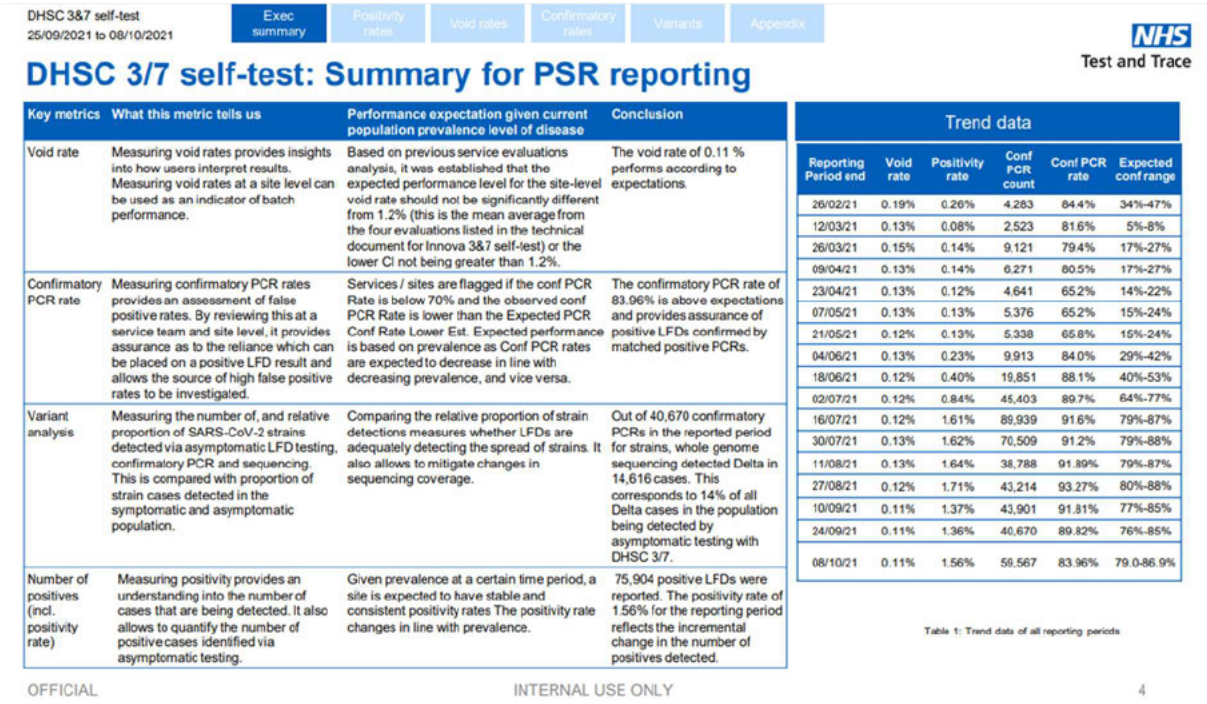
Qualtrics survey have now been reviewed and re-drafted and making it clearer for the citizens to choose the right supplier of their LFD kits when completing the survey. This came into effect from Wednesday 27th October, hence the data going forward will show true reflection of the actual number of complaints by LDF Manufacturer.



(Refer to Attachment 03, for data)

4.6 Real World Performance Monitoring

This is the summary slide from the data provided in attachments 04 for 3 and 7 self-test



DHSC 3&7 self-test
25/09/2021 to 08/10/2021

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 was established that the expected performance level for the site-level void rate should not be significantly different from 1.2% (this is the mean average from the four evaluations listed in the technical document for Innova 3&7 self-test) or the lower CI not being 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 83.96% is above expectations 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 40,670 confirmatory PCRs in the reported period for strains, whole genome sequencing detected Delta in 14,616 cases. This corresponds to 14% of all Delta cases in the population being detected by asymptomatic testing with DHSC 3/7.
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.	75,904 positive LFDs were reported. The positivity rate of 1.56% 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
26/02/21	0.19%	0.26%	4,283	84.4%	34%-47%
12/03/21	0.13%	0.08%	2,523	81.6%	5%-8%
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%

Table 1: Trend data of all reporting periods

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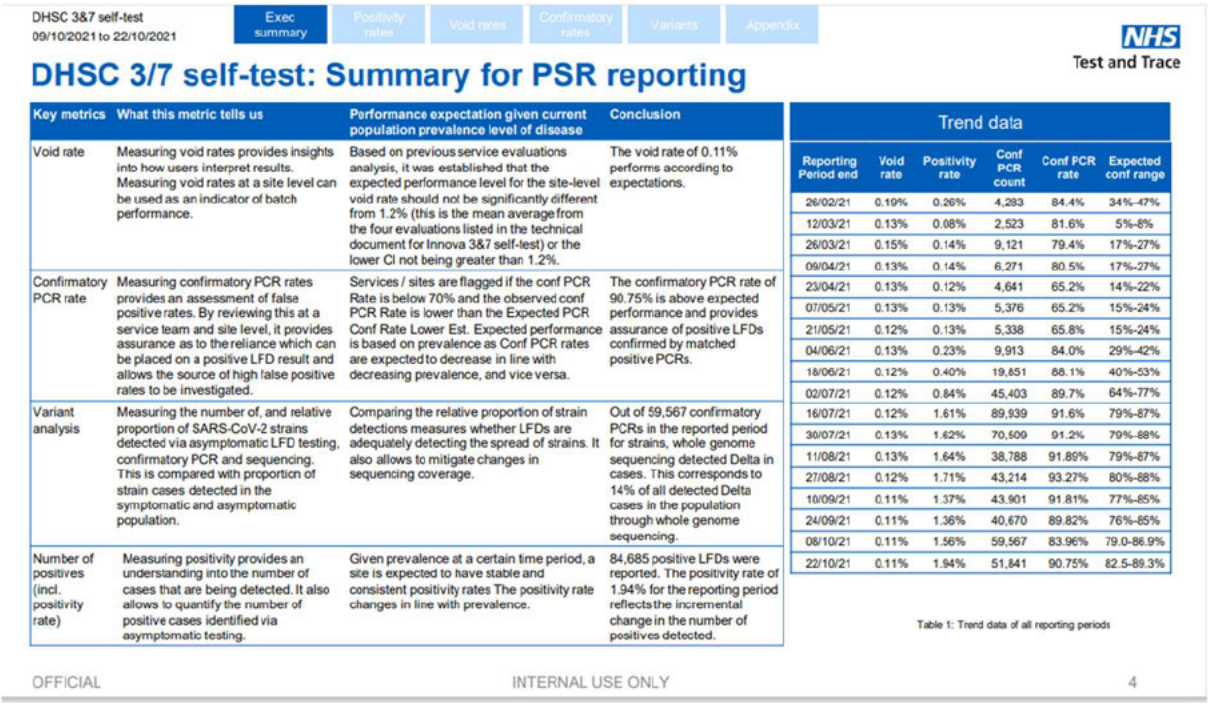

DHSC 3&7 self-test
09/10/2021 to 22/10/2021

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 was established that the expected performance level for the site-level void rate should not be significantly different from 1.2% (this is the mean average from the four evaluations listed in the technical document for Innova 3&7 self-test) or the lower CI not being 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 90.75% 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 59,567 confirmatory PCRs in the reported period for strains, whole genome sequencing detected Delta in cases. This corresponds to 14% of all detected Delta cases in the population through whole genome sequencing.
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.	84,685 positive LFDs were reported. The positivity rate of 1.94% 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
26/02/21	0.19%	0.26%	4,283	84.4%	34%-47%
12/03/21	0.13%	0.08%	2,523	81.6%	5%-8%
26/03/21	0.15%	0.14%	9,121	79.4%	17%-27%
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07/05/21	0.13%	0.13%	5,376	65.2%	15%-24%
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18/06/21	0.12%	0.40%	19,851	88.1%	40%-53%
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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%

Table 1: Trend data of all reporting periods

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(Refer to Attachment 04, 05, 06 for data)

4.7 CAPA

- Extension has been approved for overdue CAPAs and new completion dates are listed in the table below.
- A summary of the CAPA by Status for this reporting period is below.

CAPA Status	No
Completed	0
Implementation	3
Investigation	10
VOE	6
Total	19

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date	Reason for extension if overdue
01	CAPA-21-04-0006	21-April-21	Process for investigating and following through the product quality related incidents by opening CAPAs across the test and trace programme.	Complete pending VOE	VOE due: 04-Nov-21	N/A
02	CAPA-21-06-0010	08-Jun-21	CAPA raised to address the discrepancies/inconsistencies between the IFUs, leaflets and online information.	Action implementation stage. 1 Action Overdue – Extension being requested until 31/10.	08-Sep-21 **Extension approved until 27-Dec-21**	Additional work needed for action plans
03	CAPA-21-06-0011	08-Jun-21	CAPA raised to address the lack of unified complaints system for receiving direct complaints under the design and responsibility of DHSC	Complete Pending VOE	VOE due: 04-Nov-21	N/A
04	CAPA-21-06-0013	08-Jun-21	CAPA raised to strengthen the PMS plan and appropriate PMS activities	Complete pending VOE	Voe Due: 13-Nov-21	N/A
05	CAPA-21-06-0016	08-Jun-21	CAPA raised to address the non-conformities identified in SCAR process related to poorly defined proposed corrective action plan and lack of effectiveness check for SCAR-2021-026	Complete pending VOE	Voe Due: 13-Nov-21	N/A
06	CAPA-21-06-0017	08-Jun-21	CAPA raised to address the lack of evidence identified in LFD technical file to demonstrate whether the tests continue to be fit for purpose and that they meet the intended performance stated by DHSC.	Action implementation stage. Overdue – Awaiting Sign off of documents.	08-Sep-21 **Extension approved until 27-Dec-21**	Additional work needed for action plans

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date	Reason for extension if overdue
07	CAPA-21-06-0018	09-Jun-21	CAPA raised to address the schools supply issues and schools are having to cease testing due to supply shortages	Root cause investigation stage	27-Dec-21	N/A
08	CAPA-21-06-0019	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	27-Dec-21	N/A
09	CAPA-21-06-0020	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	27-Dec-21	N/A
10	CAPA-21-06-0021	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	27-Dec-21	N/A
11	CAPA-21-06-0022	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	27-Dec-21	N/A
12	CAPA-21-06-0023	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	27-Dec-21	N/A
13	CAPA-21-06-0024	09-Jun-21	CAPA raised to address the high false positive rate for LFD 25S identified at [redacted]	Root cause investigation stage	27-Dec -21	N/A
14	CAPA-21-06-0025	09-Jun-21	CAPA raised to address the high false positive rate for LFD 3s and 7s identified at [redacted]	Root cause investigation stage	27-Dec-21	N/A
15	CAPA-21-06-0026	09-Jun-21	CAPA raised to address the high false positive rate for LFD 3s and 7s identified at [redacted]	Root cause investigation stage	27-Dec-21	N/A
16	CAPA-21-06-0027	09-Jun-21	CAPA raised to address the issue of University LFD kits failing to flow	Out for closure- Has been sent back to owner for changes.	09-Sep-21 Overdue – Chased progress awaiting update to be able to close	N/A
17	CAPA-21-	09-Jun-21	CAPA raised to address the issue registering the test results from OLT and schools	Root cause investigation stage	27-Dec-21	N/A

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date	Reason for extension if overdue
	06-0030					
18	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	Linked to CAPA 21-06-0011	11-Sep-21	N/A
19	CAPA-21-06-0034	18-Jun-21	CAPA raised to address the Non-conformity identified regarding the IFUs supplied with the LFD 25s kits	Linked to CAPA 21-06-0010.	28-Sep-21	N/A

4.8 SCAR – Supplier Corrective Action Report

No SCARs raised for LFD in this period 25th September to 22nd October 2021.

4.9 Risk Management

LFD Risk management File is RMF-0001 Revision 5 and HTM Hazard traceability Matrix Rev4.

DHSC is currently updating the QOP08 for Risk management process. The update of the LFD RMF with the new hazard identified during the complaint's investigation for the last period and for this reporting period will be included in the revised RMF templates.

5. Conclusion

- There has not been any manufacturing of the devices during this reported period and there is no new contract with Biotime at the moment.

Batch issues

- 9 failures identified from the sample size inspected out of 76. Million units. The main issue was related to "control line was not visible" on lot X2108753 with 6 failures, further testing will be conducted. The event has been reported through Control tower And this is to be included into the ISO13485 QMS non-conforming process. An action will be raised in this report to ensure that the non-conformities found during inspection are included in the QMS non conforming system.

User incidence

- DHSC has received a total of 13 complaints between 25th September – 22nd October 2021. 12 from MHRA (yellow card) and 1 through control tower. The number of kits distributed (3s, 7s and 25s) during this period was 32 million.
- There were 3 complaints for Allergic reaction, 2 of them were classified as non-reportable because the event did not lead to death or serious deterioration in the health of the end user.
- Investigation for the reportable complaint 2021/009/025/501/007 has been completed. There was no trend of this type of complaint, hence CAPA/SACR was not required. The complaint will be closed and monitored for trending purposes.

- There was one new hazard identified for the contaminated item in the kit. The reporter stated, "I have directed the patient to contact 119 immediately as per service outline and have quarantined remaining stock from the associated batch meantime until further guidance." This is a one off complaint that has been received for the LFD kits. However, the RMF will be updated with a new hazard ID. An action will be raised in this PRS report to include this New hazard in the LFD RMF together with the hazard highlighted in the PSR-009.

Trends and analysis

- Results of 34% of the distributed LFD size 3s, 7s and 25s 32.1 million were registered.
- The Void Rate of 0.11 % remain consistence as per the previous report. Results are according to expectations and below the 1.2% threshold.
- Confirmatory PCR Rate of 87.35% average of the whole period is above the expected performance 70% threshold.
- Overdue CAPAs have been extended to a more realistic time for completion. 3 in Implementation, 10 Investigation and 6 VOE.
- No SCARs raised for LFD in this period 25th September to 22th October 2021

PHCO: Public Health Clinical Oversight

- Reports where actual harm was identified as patient injure were presented at the (PSP) Patient Safety Panel meeting. Meeting is attended by multiple functions including PHCO, Quality and Regulatory, Integrator.

Recall

- DHSC has not instigated a recall.

6. Actions

No	Added	Action	Responsible Name	Due Date	Status
1	04-Oct-2021	Add 2 new hazards to Risk management file. Hazard identified during this period 28th Aug to 24thSep and the hazard for period 25th Sept to 22nd Oct.	[redacted]	19-Nov-21	Open action
2	04-Oct-2021	Raise Non-conformity within the ISO13485 QMS for findings during the Intertek Testing and reported to Control Tower CSL-25062 in period 28th Aug to 24thSep and 9 failures found for control of line not visible on lot X2108753 for period 25th Sept to 22nd Oct.	[redacted]	19-Nov-21	Open Action
3	04-Oct-2021	Investigation and action needed on overdue CAPAs	[redacted]	26th Oct-2021	Completed Extension dates approved for individual CAPAs

7. Attachments

Attachment 01: PMS-0001, PMS Plan for the DHSC Covit-19 LFD Devices (3 and 7 kit) Rev2, 29-July-2021
Attachment 02: Intertek testing Report
Attachment 03: DHSC PSR – Complaints & Qualtrics data
Attachment 04: RWPM Innova 3s and 7s
Attachment 05: RWPM Innova 25s
Attachment 06: RWPM Innova Assisted

	Job Title	Name	email
Compiled by	Regulatory Lead	[redacted]	[redacted]