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		First issue

1. Content

2. Introduction

The purpose of this document is to summarise the post-market surveillance report for Innova LFD kits where DHSC is distributor or manufacturer. This report covers the period 17th July - 6th August 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 Intertek Testing

49 Inspection reports received between the reporting window of 17th July - 6th August 2021. 4,109 samples were analysed for lateral flow performance, all of which passed. The SKU codes aligned to these samples were TK2193.
(Refer to Attachment 02 for input report)

4.2 In-House manufacturing inspection

Production at Xiamen Biotime re-started following a new Innova Contract. A total of 58 inspections were carried out between 17th July - 6th August 2021. These 58 inspections were reflective of 58,000,000 units produced, and no issues were raised during the production of this volume. To note, each lot contained 1,000,000 units, and SKU code for these produced kits is TK2193.

(Refer to Attachment 02 for input report)

4.3 Product complaints

- DHSC has received a total of 24 complaints between 17th July - 6th August 2021. 1 complaint came through Control tower and 23 from MHRA (yellow card). The number of kits distributed (3s, 7s and 25s) during this period was 58.1 million.
- No lot trend was identified within this period.
- Trending category shows 7 complaints for "Faulty test results" and 5 complaints for Allergic Reaction. However, during the complaint investigations, these were deemed as no trend and no further action.
- 18 out of 24 Complaints have had the investigation completed and are due for final review before the complaints can be closed.
- 7 new hazards were identified this period. These are related to Faulty test results.

A summary of the received complaints is below

No	Complaint category	Reportability	Investigation	Investigation results
1	5 Allergic reaction	No	No trend/Not enough information	No further actions
2	1 Barcode issue	No	No trend	No further action
3	3 empty extraction buffer sachet	No	Ongoing	Ongoing
4	3 faulty item	No	Not enough information/no trend	No further actions
5	7 Faulty test results	No	No trend	No further action
6	1 Label error	No	No trend	No further actions
7	1 Missing item	No	Not enough information	No further action
8	1 Patient injury	No	No trend	No further action
9	1 Not a product complaint	N/A	N/A	N/A
10	1 Unknown description	N/A	N/A	N/A

(Refer to Attachment 03 for raw data)

4.4 Qualtrics survey

- A total of 1005 reports were recorded through the Qualtrics Survey for period 17th July - 6th August 2021. The number of kits distributed (3s, 7s and 25s) during this period was 58.1 million.
- 267 out of 1005 reports referred to End User injury. Survey redirects End User to Yellow Card to report injury. However, only 23 Yellow Card reports were received in the same period.
- 268 out of 1005 reports can be categorized as complaints about the product.

- The Survey percentage of 100% completion of the survey has increased from 42.2 percent last reporting period to 80.7 percent during 17th July - 6th August 2021.
- The percentage of population dropping the survey at 13% of completeness has dropped from 56.4 percent to 18 percentage.

Complaint category	Reportability	Investigation	Investigation results
13 Damaged items	No	No trend	No further actions
47 Missing items	No	No tend	No further actions

- Qualtrics summary - User Experience

Question	Yes	No
Swab easy to use?	484	41
Test Strip easy to use?	496	29
Easy to get sample?	466	59
Test worked as instructed?	449	76
Manual easy and clear?	498	27

(Refer to Attachment 03, for data)

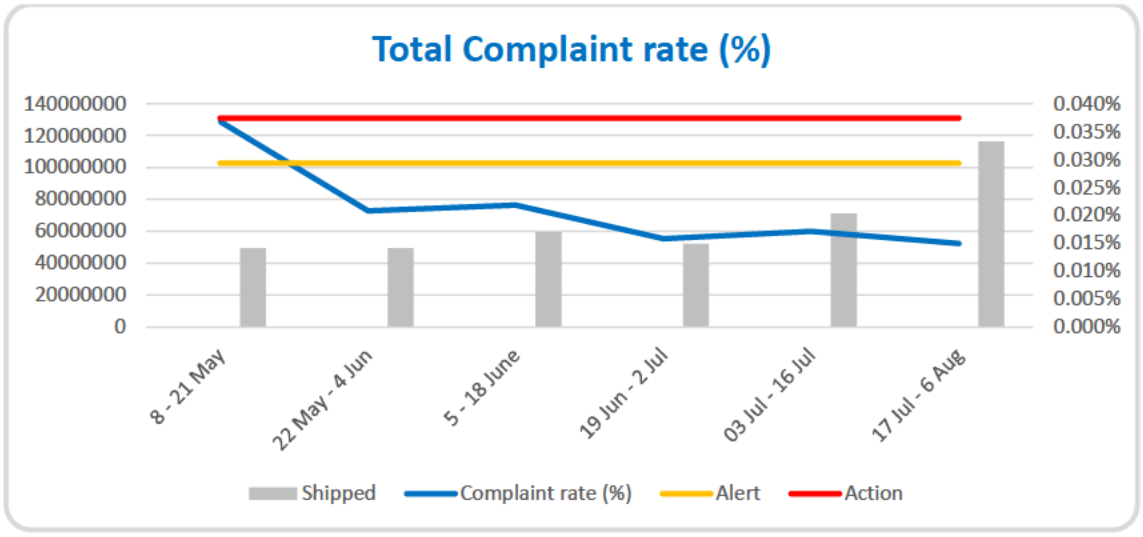
4.5 Combined Complaints Data (Yellow Card, Control Tower and Qualtrics Complaints) – Trending

This table shows the trending data for the combined LFD complaints (Yellow Card, Control Tower and Qualtrics Complaints) vs distributed LFD test kits for the last 6 reporting periods.

Alert and Action thresholds have been established using an average derived from the last 6 reporting periods. These thresholds will remain consistent, and will provide an ongoing benchmark for identifying trends through continual monitoring.

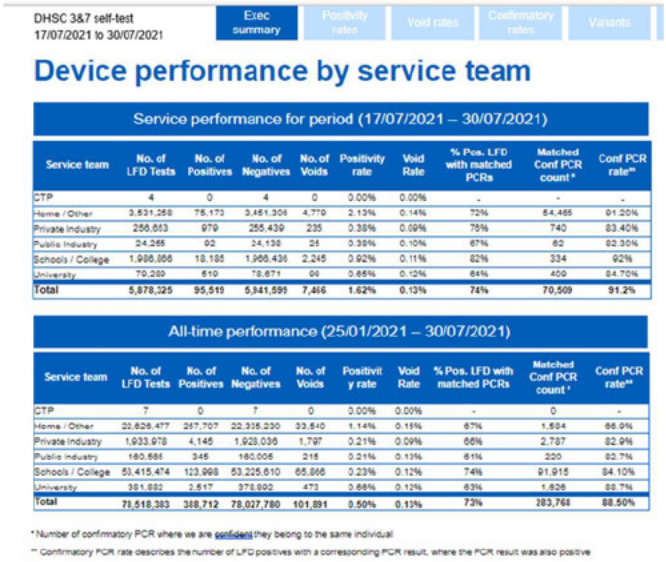
The data shows a consistent downward trend in the complaint rate, and that the complaint rate has remained below the defined thresholds for Alert & Action. We have identified that the combined data for the period 8-21 May falls above the Alert level. This is linked to how the average has been calculated. We have monitored the complaints for this period, and have no concerns.

Please see attachment 04 for the full data report.



4.6 Real World Performance Monitoring

This is the summary slide from the data provided in attachments 5 ,6 , and 7.



DHSC 3&7 self-test
17/07/2021 to 30/07/2021

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

Device performance by service team

Service performance for period (17/07/2021 – 30/07/2021)

Service team	No. of LFD Tests	No. of Positives	No. of Negatives	No. of Voids	Positivity rate	Void Rate	% Pos. LFD with matched PCRs	Matched Conf PCR count *	Conf PCR rate**
CTP	4	0	4	0	0.00%	0.00%	-	-	-
Home / Other	3,531,258	75,173	3,451,306	4,779	2.13%	0.14%	72%	54,466	91.20%
Private Industry	256,653	979	255,439	235	0.38%	0.09%	75%	740	83.40%
Public Industry	24,265	92	24,138	25	0.38%	0.10%	67%	62	82.30%
Schools / College	1,966,866	18,185	1,966,436	2,245	0.92%	0.11%	82%	334	92%
University	70,269	610	70,671	99	0.85%	0.12%	64%	409	84.70%
Total	**5,878,325**	**95,519**	**5,941,595**	**7,466**	**1.62%**	**0.13%**	**74%**	**70,509**	**91.2%**

All-time performance (25/01/2021 – 30/07/2021)

Service team	No. of LFD Tests	No. of Positives	No. of Negatives	No. of Voids	Positivity rate	Void Rate	% Pos. LFD with matched PCRs	Matched Conf PCR count *	Conf PCR rate**
CTP	7	0	7	0	0.00%	0.00%	-	0	-
Home / Other	22,626,477	257,707	22,335,230	33,540	1.14%	0.15%	67%	1,584	66.9%
Private Industry	1,933,978	4,145	1,928,036	1,797	0.21%	0.09%	66%	2,787	82.9%
Public Industry	180,586	345	180,006	215	0.21%	0.13%	61%	220	82.7%
Schools / College	53,415,474	123,998	53,225,610	65,866	0.23%	0.12%	74%	91,915	84.10%
University	381,882	2,517	378,892	473	0.66%	0.12%	63%	1,628	88.7%
Total	**78,518,383**	**388,712**	**78,027,780**	**101,891**	**0.50%**	**0.13%**	**73%**	**283,768**	**88.50%**

* Number of confirmatory PCR where we are confident they belong to the same individual

** Confirmatory PCR rate describes the number of LFD positives with a corresponding PCR result, where the PCR result was also positive

Summary:

- The average void rate is 0.13% and remains below the 1.2% threshold.
- Overall positivity for the period was 1.62%.
- Positivity in Home/Other self-testing has been highest (2.13%), and this is in line with overall prevalence.
- The Confirmatory PCR rate across the services has been above expectations, with an average of 91.2%. This is above the threshold of 70%
- 4 sites have been escalated to the Integrator Team due to void rates above the 1.2% threshold. The Integrator Team will undertake further investigation, and CAPAs will be raised if this is the appropriate next steps. CAPAs raised linked to RWPM data are tracked by the Regulatory and Quality Team, and reported in section 4.7 of this report.

4.7 CAPA

- The below CAPAs were opened to address:
  - MHRA Audit on the 25-26 May
  - RWPM Real World Performing Monitoring findings
  - Innova Medical Group Recall in the USA

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
01	CAPA-21-04-0005	14-April-21	This CAPA is raised to address 3 yellow card complaints reported to DHSC by MHRA related to Latex allergy after using the LFD test kit.	Closed	30 July 2021
02	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.	Action implementation stage	Extension date: 27-Aug-21
03	CAPA-21-06-0010	08-Jun-21	CAPA raised to address the discrepancies/inconsistencies between the IFUs, leaflets and online information.	Action implementation stage	08-Sep-21
04	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	Action implementation stage	08-Sep-21
05	CAPA-21-06-0012	08-Jun-21	CAPA raised to address inconsistencies in the reporting criteria for the complaints which require clinical input.	Action implementation stage	08-Sep-21
06	CAPA-21-06-0013	08-Jun-21	CAPA raised to strengthen the PMS plan and appropriate PMS activities	Action implementation stage	08-Sep-21
07	CAPA-21-06-0014	08-Jun-21	CAPA raised to address the lack of regulatory clinical performance resource and oversight of PMPF studies	Action implementation stage	08-Sep-21
08	CAPA-21-06-0015	08-Jun-21	CAPA raised to address the non-conformities identified in LFD risk management process related to lack of communication between diff organization for risk assessment, lack of literature review for risk benefit evaluation and lack of risk control measure in Hazard traceability matrix	Action implementation stage	08-Sep-21
09	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	Action implementation stage	08-Sep-21
10	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	08-Sep-21
11	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	09-Sep-21
12	CAPA-21-06-0019	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	09-Sep-21

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
13	CAPA-21-06-0020	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	09-Sep-21
14	CAPA-21-06-0021	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	09-Sep-21
15	CAPA-21-06-0022	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	09-Sep-21
16	CAPA-21-06-0023	09-Jun-21	CAPA raised to address the high void test for LFD identified at [redacted]	Root cause investigation stage	09-Sep-21
17	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	09-Sep-21
18	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	09-Sep-21
19	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	09-Sep-21
20	CAPA-21-06-0027	09-Jun-21	CAPA raised to address the issue of University LFD kits failing to flow	Out for closure	09-Sep-21
21	CAPA-21-06-0030	09-Jun-21	CAPA raised to address the issue registering the test results from OLT and schools	Root cause investigation stage	09-Sep-21
22	CAPA-21-06-0031	11-Jun-21	CAPA raised to demonstrate DHSC'S compliance towards nonconformity identified in Innova USA voluntary recall notice with regards to Public Health Risk Assessment and clinical performance data	Closed	11-Sep-21
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	Action implementation stage	11-Sep-21
24	CAPA-21-06-0033	11-Jun-21	CAPA raised to demonstrate DHSC's compliance towards nonconformity identified in Innova USA voluntary recall notice with regards to Supplier Management	Action implementation stage	11-Sep-21
25	CAPA-21-06-0034	18-Jun-21	CAPA raised to address the Non-conformity identified regarding the IFUs supplied with the LFD 25s kits	Action implementation stage	28-Sep-21

4.8 SCAR – Supplier Corrective Action Report

No SCARs raised for LFD in this period 17th July - 6th August 2021. There are no open SCARs for LFD products.

4.9 Variants of Concern

The routine laboratory assessment suggesting a lower sensitivity of the DHSC 3/7 self test LFD did not translate into a difference in real-world performance within asymptomatic LFD testing or select surge testing sites operating a paired LFD-PCR testing regime.

The DHSC 3/7 self test LFD remains suitable for deployment as part of the asymptomatic testing programme to identify infectious individuals in the population and to reduce onward transmission risk at a local and national population level. There is no difference in performance in its ability to detect the Delta variant in comparison to the Alpha variant.

Full report attachment 8

4.10 Risk Management

DHSC Risk management File RMF-0001 has been updated to Revision 4 in order to address new hazard raised from Complaints since 8th May to 16th July 2021.

5. Conclusion

Batch issues

- No lot trending was identified during this period.

User incidence

- DHSC has received a total of 292 complaints between 17th July - 6th August 2021 from MHRA Yellow Card, Control Tower and Qualtrics out of 58.1 Million of distributed (3s, 7, and 25s) LFD kits between 17th July - 6th August 2021.
- 267 out of 1005 reports received from Qualtrics referred to End User injury. The survey redirects the End User to MHRA Yellow Card to report an injury. However, only 23 Yellow Card reports were received in the same period. This will be addressed within CAPA-21-06-0011.
- The percentage of End Users accessing the Qualtrics Survey, and fully completing the survey (100 % completion) has increased from 42.2 percent last reporting period to 80.7 percent during 17th July - 6th August 2021.
- The percentage of End Users who leave the survey having only completed 13% of the survey has dropped from 56.4 percent of End Users to 18 percent of End Users.

Trends and analysis

- Trending category shows 7 complaints for "Faulty test results" and 5 complaints for Allergic Reaction. However, during the complaint investigations, these were deemed as no trend and no further action.
- 7 new hazards were identified this period. These are related to Faulty test results
- 24 Complaint reports were received via Yellow Card and Control Tower out of 58.1 Million of distributed (3s, 7, and 25s) LFD kits between 17th July - 6th August 2021.
- 1005 end users have used the Qualtrics survey out of 58.1 Million of distributed LFD kits between 17th July - 6th August 2021

PHCO: Public Health Clinical Oversight

- Public Health Clinical Oversight reviewed events for clinical input and clarification on the reportability during the PSP Patient Safety Panel.
- The PSR Report has been reviewed and signed off by the Test and Trace Clinical Oversight Group.

Recall

- DHSC has not instigated a recall.

6. Actions

No	Added	Action	Responsible Name/Email	Due Date	Status
1	27-May-2021	Risk management file to be updated with new hazards identified during the period 8th May to 16th July	[redacted]	20-Aug-21	Completed
2	15-Aug-2021	Risk management file RMF-0001.Rev4 to be updated with new hazards identified during the period 17th July - 6th August 2021	[redacted]	2 Sep 021	Open

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: Trending data – Kits Distributed vs total complaints
Attachment 05: RWPM Innova 3s and 7s
Attachment 06: RWPM Innova 25s
Attachment 07: RWPM Innova Assisted

Attachment 08: Variant of Concern Report

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