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	09-July-2021	First issue

1. Content

2. Introduction

The purpose of this document is to summarise the fortnight post-market surveillance report for LFD where DHSC is distributor or manufacturer. This report covers period 19th June - 2nd July 2021.

This report includes inputs from Intertek Testing, Product Complaints, Qualtrics survey, Real World Performance Monitoring, CAPA and SCARs.

3. Methodology

The methodology for data collection was established in the PMS plan PMS-0001 Revision 1, dated 24-Feb-2021.

4. Findings /Results

4.1 Intertek Testing

Inspection reports received between the reporting window of 19th June - 2nd July 2021. During this time period Intertek has provided 47 reports. A total of 4,032 tests have been analysed, all of which passed inspection.

4.2 In-House manufacturing inspection

Production at Xiamen Biotime has re-started following a new Innova Contract. New SKUs has been created.

36 lots have been inspected, all of which passed. A total of 36M kits have been produced in this time period. The SKU code applicable to these products is TK2193 (identical to TK1876) (7T). For each lot, 1,000,000 tests were produced, of which, 105 tests have been ring-fenced for inspection, the reports are due to be provided.
(Refer to Attachment 02 for Intertek testing data)

4.3 Product complaints

- DHSC has received a total of 22 complaints between 19th June - 2nd July 2021. 1 came through Control tower (source University), 21 from MHRA yellow card.
- 2 complaints were received for missing items on batch X2102723.
- All received 22 Reports are open pending on complaint review for final closing. However, investigation has been completed for 16 reports and 6 ongoing investigation.
- No new hazard identified this period

A summary of the received complaints is below

No	Complaint category	Reportability	Investigation	Investigation results
1	1 Allergic reaction	Yes	Ongoing	Ongoing
2	2 contaminated item	No	No trend	No further actions
3	3 Faulty item	No	No trend	No further actions
4	5 Missing components	No	Ongoing	Ongoing
5	1 Leakage	No	No trend	No further actions
6	7 faulty test results	No	Ongoing	Ongoing
7	1 Label error	No	No trend	No further actions
8	1 Patient injury	No	No trend	No further actions
9	1Not a complaint	N/A	N/A	N/A

(Refer to Attachment 03 for raw data)

4.2 Qualtrics survey

- A total of 1037 reports were recorded through the Qualtrics Survey for period 19th June - 2nd July 2021.
- 183 out of 1037 reports referred to End User injury. Survey redirects End User to Yellow Card to report injury. However, only 21 Yellow Card reports were received in the same period.
- The Survey percentage of completion shows only 53 percent completed the whole survey and 45 percent stop completing the survey at 13% of the survey questionnaire.

Complaint category	Reportability	Investigation	Investigation results
12 Damaged items	No	No trend	No further actions
29 Missing items	No	No tend	No further actions

- Qualtrics summary - User Experience

Question	Yes	No
Swab easy to use?	378	32
Test Strip easy to use?	378	32
Easy to get sample?	375	35
Test worked as instructed?	350	60
Manual easy and clear?	384	26

(Refer to Attachment 03, for data)

4.3 Real World Performance Monitoring

No actions identified during this period.

Performance for the period (19/06/2021 – 02/07/2021)

Use Case	No. of 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	1	-	1	-	0.00%	0.00%	0.00%	-	0.00%
Home	2,794,261	42,078	2,748,237	3,946	1.51%	0.14%	69.05%	29,054	92.09%
Private Industry	295,666	715	294,672	279	0.24%	0.09%	66.43%	475	87.58%
Public Industry	26,735	54	26,649	32	0.20%	0.12%	59.26%	32	87.50%
Schools / College	4,326,688	19,919	4,302,027	4,742	0.46%	0.11%	77.08%	15,354	85.20%
University	90,729	826	89,780	123	0.91%	0.14%	59.08%	488	92.62%
Total	7,534,080	63,592	7,461,366	9,122	0.84%	0.12%	71%	45,403	89.70%

(Refer to Attachment 4,5,6,7 for data)

4.4 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.	Action plan to be updated	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	30 July 2021
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	28 Aug 2021

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
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	28 Aug 2021
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	30 July 2021
06	CAPA-21-06-0013	08-Jun-21	CAPA raised to strengthen the PMS plan and appropriate PMS activities	Action implementation stage	30 July 2021
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	30 July 2021
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	30 July 2021
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	30 July 2021
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	30 July 2021
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	06 July 2021
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	13 July 2021
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	13 July 2021
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	13 July 2021
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	13 July 2021
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	13 July 2021

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
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	13 July 2021
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	13 July 2021
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	13 July 2021
20	CAPA-21-06-0027	09-Jun-21	CAPA raised to address the issue of not sending the LFD test samples for testing to quality	Root cause investigation stage	13 July 2021
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	13 July 2021
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	30 July 2021
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	Out for action pan approval	30 July 2021
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	30 July 2021
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 Aug 2021

4.5 SCAR – Supplier Corrective Action Report

No SCARs raised for LFD in this period.

5. Conclusion

Batch issues

- No batch trending was identified during this period.

User incidence

- HSC has received a total of 22 complaints between 19th June - 2nd July 2021
- 183 out of 1037 reports referred to End User injury. Survey redirects End User to Yellow Card to report injury. However, only 21 Yellow Card reports were received in the same period. This will be address within CAPA-21-06-0011

- The Survey percentage of completion shows only 53 percent completed the whole survey and 45 percent stop completing the survey at 13% of the survey questionnaire. This will be address within CAPA-21-06-0011

Trends and analysis

- Out of 47.2 Million of distributed LFD kits, only 9.03 Million (19%) have registered their results.
- Out of 47.2 Million of distributed LFD kits, only 1037 end users (0.00198%) have used the Qualtrics survey

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.

Recall

- DHSC has not instigated a recall.

6. Actions

No new actions were identified this week.

Actions from previous week

No	Added	Action	Responsible Name/Email	Due Date	Status
1	27-May-2021	Risk management file to be updated with new hazards identified.	[redacted]	23-July-2021	ongoing

7. Attachments

Attachment 01: PMS-0001, PMS Plan for the DHSC Covit-19 LFD Devices (3 and 7 kit) Rev1, 24-Feb-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

Attachment 07: RWPM findings

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