DOCUMENT VERIFICATION

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REVISION HISTORY

Rev.	Effective Date	Changes Made to Document
1	25-Jun-2021	First issue

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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 5th-18th June 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

During this time period we have received 73 Inspection reports and a total of 6,118 tests have been analysed.

Of these, there was one instance where a test failed inspection. The reason for this failure was due to improper seating of the test strip in the cassette such that the control and test lines of the test strips were misaligned with the markings printed to the cassette. As this was 1 in 105 tests affected for this particular LOT#, no action has been taken as this falls within acceptable quality limit (AQL) for defective product.

Production at Xiamen Biotime ceased on 30th April 2021 due to completion of contract, therefore there were not in-house inspections carried out in this reporting window and will be no inspections for the foreseeable.

(Refer to Attachment 02 for Intertek testing data)

4.2 Product complaints

- DHSC has received a total of 14 complaints between 5th-18th June 2021. 1 came through Control tower (source University), 12 from MHRA yellow card and 1 raised to address the Innova Medical Group Recall in the USA.
- The Innova Medical Group Recalls Unauthorized SARS-CoV-2 Antigen Rapid Qualitative Test with Risk of False Test Results in the USA. This recall was identified by FDA as Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death. DHSC recorded this event as reportable and raised 3 CAPAs to address this event. CAPA-21-06-0031, CAPA-21-06-0032 and CAPA-21-06-0033
- No batch trending was identified during this period.
- 13 Reports are open pending on complaint review for final closing. However, investigation has been completed for all 13 reports with not further actions. Investigation is ongoing for 1 complaint.
- The Innova Medical Group recall was recorded as New Hazard. As misbranding was not covered in the RMF-0001 Rev3.

New Hazard identified this period

DHSC Complaint number	Trending Category
Complaint-21-06-0816	Misbranding

- A summary of the received complaints is below

No	Complaint category	Reportability	Investigation	Investigation results
1	1 empty extraction buffer sachet	No	No trend	No further actions
2	2 Faulty item	No	No trend	No further actions
3	1 damaged item	No	No trend	No further actions
4	5 Missing components	No	No trend	No further actions
5	1 Misbranding	Yes	Complete	CAPA-21-06-0031, CAPA-21-06-0032, CAPA-21-06-0033
6	1 faulty test results	No	No trend	No further actions
7	1 Barcode issue	No	No trend	No further actions
8	1 Patient injury	TBC	No trend	No further actions
9	1 unknown	No	No trend	No further actions

(Refer to Attachment 03 for raw data)

4.3 Qualtrics survey

- A total of 1252 reports were recorded through the Qualtrics Survey during the same period 5-18 Jun 2021.
- 127 out of 1252 reports referred to End User injury. Survey redirects End User to Yellow Card to report injury. However, only 12 Yellow Card reports were received in the same period.
- 19 out of 69 reports for missing items where related to the Buffer Sachet or Bottle.
  Qualtrics summary table:

Complaint category	Reportability	Investigation	Investigation results
17 Damaged items	No	No trend	No further actions
69 Missing items	No	No tend	No further actions

- Qualtrics summary- User Experience

Question	Yes	No
Swab easy to use?	371	42
Test Strip easy to use?	374	39
Easy to get sample?	357	56
Test worked as instructed?	347	66
Manual easy and clear?	384	29

(Refer to Attachment 03, for data)

4.4 Real World Performance Monitoring

Findings: 1 site was escalated as potential incident to integrator team due to void rate with confidence interval.

Performance for the period (05/06/2021 – 18/06/2021)

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**
Home	2,361,927	18,858	2,339,780	3,289	0.80%	0.14%	71.07%	13,403	91.35%
Private Industry	150,003	231	149,660	112	0.15%	0.07%	59.74%	138	78.99%
Public Industry	27,696	44	27,610	42	0.16%	0.15%	47.73%	21	66.67%
Schools / College***	4,265,762	8,271	4,252,744	4,747	0.19%	0.11%	73.58%	6,086	81.04%
University	61,734	333	61,342	59	0.54%	0.10%	60.96%	203	89.16%
Total	**6,867,122**	**27,737**	**6,831,136**	**8,249**	**0.40%**	**0.12%**	**72.00%**	**19,851**	**88.10%**

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

4.5 CAPA

- A number of 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	18 June 2021

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
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.	Out for CAPA actions plan review	30June 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
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

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
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
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	Out for approval for closure	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	Out for action pan approval	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

4.6 SCAR – Supplier Corrective Action Report

No SCARs raised for LFD in this period.

5. Conclusion

- A new hazards was identified related to misbranding (USA LFD Innova recall). This hazard was not covered in the LFD RMF-0001 Rev3

Batch issues

- No batch trending was identified during this period.

User incidence

- The Innova Medical Group Recall in the USA was recorded as reportable event and 3 CAPAs were opened to address this event. CAPA-21-06-0031, CAPA-21-06-0032 and CAPA-21-06-0033
- Qualtrics Survey data shows 127 reports were related to injury to End User. Although the Survey redirects End User to Yellow Card to report the incident; only 12 reports were received through the Yellow card within the same period.

Trends and analysis

- The higher number of Qualtrics' reports are for missing components with 69 reports, where 19 are related to missing buffer sachet or bottle.
- Out of 59.5 Million of distributed LFD kits, only 8.1 Million (14 %) have registered their results.
- Out of 59.5 Million of distributed LFD kits, 1,252 (0.00210%) 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. However following the Identified recall by FDA as a Class I for Innova Medical Group Recalls unauthorized SARS-CoV-2 Antigen Rapid Qualitative Test with Risk of False Test Results. DHSC has raised CAPAs to investigate and cover actions

6. Actions

Beside the CAPA opened. 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 this period of time.	[redacted]	11-Jun-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]