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	14 May 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 from 24th April to 7th May 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

Intertek Testing

Between the reporting period 24 April 21 – 07 May 21 there have been 94,000,000 kits produced by (Innova) Xiamen Biotime Biotechnology Co., with 94 lots produced each containing 1,000,000 test kits. Of these 94 lots, 6 were found to have QC failures, details of which are shown in Attachment 02. Following QC failure, DHSC Inbound Freight Quality Lead was notified and the lots were quarantined. Biotime conducted an full inspection of the whole lots, followed by a second re-inspection. The external inspection service was mediated by Uniserve to conduct inspections on-site at Biotime. All lots passed the second re-inspection and were released.

(Refer to Attachment 02 for Intertek testing data)

Product complaints

- Received total 59 complaints between 24th April to 7th May 2021. 2 came from Control tower and 57 from MHRA yellow card
- Reports were assessed for reportability in the PSP Patient Safety Pannel.
  Reportability assessment *(A: An even has occurred, B: The MANUFACTURER's device is suspected to be a contributory cause of the INCIDENT, C: The event led, or might have led, to one of the following outcomes: -dead or serious deterioration in state of health).* of the complaints as per MEDDEV 2 12-1 Rev8 section 5.1.1.
- Yellow card 2021/004/018/501/004 report was considered: reportable for Allergic Reaction.
- No trending observed by lot numbers.
- The updated RMF-0001 Rev3 for LFD covers all hazards for this period.

Summary of the complaint received in this period.

	Complaint category	Reportability	Investigation	Investigation results
1	9 faulty item	No	No trend	No further actions
2	1 Malfunction	No	No trend	No further actions
3	8 Missing components	No	No trend	No further actions
4	11 complaints missing complaint description	N/A	N/A	N/A
5	6 not a product complaint	N/A	N/A	N/A
6	2 User error	No	No batch number provided	No further actions
7	4 Allergic reaction complaint	1 reportable MHRA ref no: 2021/004/018/501/004	Escalated for CAPA/SCAR as trend seen	CAPA/SCAR TBC
8	2 faulty test results	No	No trend	No further actions
9	4 empty buffer sachets	No	Escalated for SCAR as trend seen	Investigation ongoing
10	12 Complaints having patient impact: sore throat, nosebleed nostril inflamed, headache, irritating throat and nose, runny nose	Not reportable	No trend	TBC
	9 faulty items	No	No trend	No further actions

(Refer to Attachment 03 for raw data)

Qualtrics survey (Public contacting 119 is provided with the Qualtric's survey Link)

- A total of 2279 complaints were recorded through the Qualtrics Survey
- Out of 2279 received Qualtric's reports, 209 reported injury. The survey redirects users to Yellow Card to report injuries. However only 57 Yellow cards were received in the same period.

No	Complaint category	Reportability	Investigation	Investigation results
1	Complaint category	Reportability	Investigation	Investigation results
2	25 Damaged items	No	No trend	No further actions
3	98 Missing items (65 missing buffer sachets or bottles)	No	Trend seen in this category for the last 6 weeks – buffer sachets/bottles	Ongoing investigation

(Refer to Attachment 03, for data)

Real World Performance Monitoring

Key actions taken by Real-world performance monitoring for Innova 3&7 Self-test report:

Escalated 6 sites as potential incidents to integrator team for further follow up due to Confirmatory PCR testing rates being below threshold (70%).

Communicated Private Industry and Public Industry use-case teams that overall Confirmatory PCR testing rates (65.2% and 0.0%) are below threshold (70%) in the self-testing setting which is currently being piloted.

Work ongoing to formally model expected device performance relative to prevalence positivity. From the next reporting period we will include a section on expected performance against prevalence.

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

CAPA and SCARs

CAPA No	Started Date	Problem statement	Status/ progress	Due date
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.	Investigation is completed. Awaiting independent latex audit outcome.	12 May 2021

CAPA No	Started Date	Problem statement	Status/ progress	Due date
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'.	CAPA action plan approval ongoing.	20 May 2021

No SCARs related to LFD products have been raised during this period

5. Conclusion

Batch issues

- No trend identified by lot number

User incidence

- Qualtrics Survey- Out of 2279 received Qualtric's reports, 209 reported injury. The survey redirects users to Yellow Card to report injuries. However only 57 Yellow cards were received in the same period.

Trends and analysis

- The high Qualtrics Survey – 98 reported missing items where 65 were related to missing Buffer Sachet or Bottle.
- Out of 75.8 Million distributed LFD kits only 10.5 Million (14 %) have registered results.
- Out of 75.8 Million distributed LFD kits only 2,279 (0.003%) have used the Qualtrics survey

PHCO: Public Health Clinical Oversight Review

- All reports are presented on the (PSP) Patient Safety Panel. PHCO representatives attend the PSP and review all the reports to assess if new CAPAs are required.

Recall

- Non instigated

6. Actions

No new actions identified this week.

Actions from previous week

No	Added	Action	Responsible Name/Email	Due Date	Status
1	16-April-2021	Risk management file to be updated with hazard for allergic reaction, latex and bleeding nose, missing	[redacted]	30-April-2021	Completed

		components an unable to continue the test.			MRF-0001 Rev3 issued (attachment 07)
2	13-April-21	Open CAPA/SCAR to address reportable incident from Yellow card 2021/004/018/501/004	[redacted]	21-May-21	Raised

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 07.1: RMF-0001 LFD Plan and Report Rev3

Attachment 07.1: RMF-0001 LFD HTM Hazard-Traceability-Matrix

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