 Department of Health & Social Care	PMS REPORT	Doc. Number PMSR001
		Revision 1
Title: LFD Report for 10-23 April 2021		Page 1 of 4

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	30-April-2021	First issue

1. Content

1. Content
2. Introduction
3. Methodology
4. Findings /Results
5. Conclusion
6. Actions
7. Attachments

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 10th-23rd-April-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

A sample size of the 66 lots were tested. Lot quantity range from 1 million units to 4 million units. Samples tested for performance positive control, Negative control and control line test. All sample passed the test. All tested devices performed as expected.

(Refer to Attachment 02 for Intertek testing data)

Product complaints

- Received total 15 complaints between 10th Apr-23rd Apr 2021. 3 came from Control tower and 11 from MHRA yellow card
- All 14 reports Complaints were considered: Not reportable following assessment (*A: An even has occurred, B: The MANUFACTURER's device is suspected to be a contributory cause of the INCIDENT, C:*

 Department of Health & Social Care	PMS REPORT	Doc. Number PMSR001
		Revision 1
Title: LFD Report for 10-23 April 2021		Page 2 of 4

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

- No trending observed by lot numbers.
- Events were reported from home test and LTS Local Testing Sites mainly.
- New hazard was identified for missing components and unable to progress with the test.

Complaint category	Reportability	Investigation	Investigation results
2 Complaints related to swab causing abscess on surface of tonsil/tongue	To be discussed	No trend	No further actions
1 complaint regarding concern of cotton-tipped swab for users having cotton allergy	No	No trend	No further actions
1 barcode issue	No	No trend	No further actions
3 empty buffer sachet	No	Trend seen for this category for last 2 months.	SCAR TBC
3 misaligned LFD strip	No	No trend	No further actions
2 Missing components	No	No trend	No further actions
2 complaints missing complaint description	Not a complaint	Not a complaint	Not a complaint


(Refer to Attachment 03 for data)

Qualtrics survey

- A total of 2004 complaints were recorded through the Qualtrics Survey
- 214 out of 2004 complaints received reported injury to user. Survey redirects user to Yellow Card to report injury

Complaint category	Reportability	Investigation	Investigation results
19 Damaged items	No	No trend	No further actions
145 Missing items	No	Trend seen in this category for the last 6 weeks – buffer sachets/bottles	SCAR- TBC
94 Usability	No	No trend	No further actions

(Refer to Attachment 3, for data)

 Department of Health & Social Care	PMS REPORT	Doc. Number PMSR001
		Revision 1
Title: LFD Report for 10-23 April 2021		Page 3 of 4

Real World Performance Monitoring

Key points reviewed during the Patient Safety Panel, next steps to be agreed:

1. Escalated 1 site ([REDACTED]) as potential incidents to integrator team due to void rate with confidence intervals above our pre-defined threshold. The site was already flagged in the report dated 20/04/2021.
2. Escalated 2 sites ([REDACTED]) as potential incidents to integrator team due to Confirmatory PCR testing rates being below threshold (70%).
3. Escalate to Private Industry and Public Industry use case teams that overall Confirmatory PCR testing rates (50.0% and 0.0%) are below threshold (70%) in the self-testing setting which is currently being piloted.
4. Work ongoing to formally model expected device performance All-time performance (25/01/2021 – 23/04/2021) relative to prevalence positivity. The performance for Innova 3&7 self-testing for the period is outlined

(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	Latex Allergies	Investigation. Awaiting independent latex audit outcome.	12 May 2021
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'.	Investigation phase 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 – 214 out of 2004 complaints received reported injury to user. Survey redirects user to Yellow Card to report injury.

 Department of Health & Social Care	PMS REPORT	Doc. Number PMSR001
		Revision 1
Title: LFD Report for 10-23 April 2021		Page 4 of 4

Trends and analysis

- The high Qualtrics Survey – 145 reported missing items where 80 were related to missing Buffer Sachet or Bottle.

Public Health and Clinical Review

- Public Health and Clinical reviewed requested for event related Allergies for clarification on the reportability.

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 components an unable to continue the test.	[REDACTED]	30-April-2021	On track RMF out for DHSC review
2	16-April-2021	CAPA to be opened to record Real World Performance monitoring actions	[REDACTED] [REDACTED]	19-April-2021	Complete CAPA-21-04-0006

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