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	28-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 8th- 21st 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 of 8th May 2021 – 21st May 2021 there were a total of 48 Intertek reports received by the DHSC, all of which passed validation.

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)

Product complaints

- Received total 30 complaints between 8th to 21st May 2021. 2 came through Control tower (Home testing and unknown report location) and 28 from MHRA yellow card.

- All reports were assessed and found not reportable. Reportability assessment *(A: An event 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: -death or serious deterioration in state of health).* of the complaints as per MEDDEV 2 12-1 Rev8 section 5.1.1.
- 3 complaints were received for a single lot X2011012 for the TK1573 packed in 25s units. The complaints were related to damaged item and the third event did not have information so it could not be classified.
- Events were reported from use cases: home test and workplace mainly.
- 3 events are not covered in the RMF-0001 Rev3. RMF needs to be reviewed for inclusion of this new hazard situations

Yellow card	Hazard	Hazard situation	Harm
2021/005/011/501/002	Chemical	Allergic reaction after testing	Tingling and numb hand
2021/005/013/401/684	Chemical	Unpleasant chemical taste from the swab	Exposure to Chemicals
2021/005/016/501/001	Chemical	Allergic reaction after testing	Lost memory

No	Complaint category	Reportability	Investigation	Investigation results
1	2 faulty items	No	No trend	No further actions
2	2 Faulty test results	No	Not enough info to investigate	No further actions
3	1 leakage	No	No trend	No further actions
4	6 Missing components	No	No trend	No further actions
5	7 complaints missing complaint description	-	-	-
6	4 Not a product complaint	No	No trend	No further actions
7	1 Packaging error	No	No trend	No further actions
8	4 Damaged items	No	No trend	No further actions
9	3 Patient injury	No	No trend	No further actions
10	1 Allergic reaction complaint	No	Complete	CAPA-21-04-0005

(Refer to Attachment 03 for data)

<u>Qualtrics survey</u>

- A total of 1959 complaints were recorded through the Qualtrics Survey
- 175 out of 1959 complaints received reported injury to user. Survey redirects user to Yellow Card to report injury

Complaint category	Reportability	Investigation	Investigation results
26 Damaged items	No	No trend	No further actions
85 Missing items	No	No tend	No further actions

User Experience

Question	Yes	No	N/A	Total
Swab easy to use?	1297	60	602	1959
Test Strip easy to use?	1302	55	602	1959
Easy to get sample?	1282	75	602	1959
Test worked as instructed?	1263	94	602	1959
Manual easy and clear?	1308	49	602	1959
Total	6452	333	3010	

(Refer to Attachment 03, for data)

Real World Performance Monitoring

Performance for the period (08/05/2021 – 21/05/2021)

Use Case	No. of Tests	No. of Positives	No. of Negatives	No. of Voids	Positivity rate	Void Rate	Matched Conf PCR count *	Conf PCR rate**
CTP	28	0	28	0	0.00%	0.00%	N/A	N/A
Schools / College	5,027,103	4,764	5,017,071	5,268	0.09%	0.10%	2,565	64.0%
Private Industry	239,942	183	239,525	234	0.08%	0.10%	51	47.1%
Public Industry	10,374	2	10,361	11	0.02%	0.11%	N/A	N/A
Home / Other Self	2,416,617	4,905	2,407,999	3,713	0.2%	0.15%	2,716	67.9%
University	11,049	20	11,016	13	0.18%	0.12%	6	66.7%
Total	**7,705,113**	**9,874**	**7,686,000**	**9,239**	**0.13%**	**0.12%**	**5,338**	**65.8%**

Positivity

Measuring positivity provides an understanding into the number of cases that are being detected using LFD devices and has been used for internal decision-making purposes.

Measuring positivity variance is a way of identifying spikes in positivity. While this is not an issue, it could be used as an indicator of potential batch performance problems.

Positivity variance also allows identification of sites with positivity rates significantly different than the overall positivity in the reporting period.

Assumptions:

Sites with less than 20 tests in the reporting period were excluded for a more robust variance measure

Void Rate

Measuring void rates at the use-case level provides insights into how users interpret results.

Measuring void rates at a site level can be used as an indicator of batch performance.

Assumptions:

- Based on previous service evaluations analysis it was established that the expected performance level for the site-level void rate should not be significantly different from 1.2% rate (as outlined in the technical document for Innova 3&7 self-test) with additional statistical control parameters being used for the population.
- To avoid flagging small sites it has been removed any sites that carried out less than 20 tests

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

CAPA and SCARs

CAPA No	Start 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.	Out for final review and closure	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'.	Out for CAPA actions plan review	20 May 2021

SCARs related to LFD products have been raised during this period

SCAR No	Start Date	Problem statement	Status/ progress	Due date
SCAR-2021-036	17-May-21	Empty extraction buffer sachets	Closed Supplier response received on 21-May-21	21 May 2021

5. Conclusion
    - LFD Production at Xiamen Biotime ceased on 30th April 2021 due to completion of contract with DHSC.
    - New hazards were identified related to chemical hazard and different reactions to the harm listed currently in the RMF.

Batch issues

- 3 complaints were received for a single lot X2011012 for the TK1573 packed in 25s units. The complaints were related to damage item and the third event did not have information so it could not be classified.
- Unable to identify any trending by batch on the Qualtrics data.

User incidence

- No reportable events were found this reporting period.
- Qualtrics Survey – 175 out of 1959 complaints received reported injury to user. Survey redirects user to Yellow Card to report injury. However only 28 yellowcard reports were received in the same period of time.

Trends and analysis

- The higher number of Qualtrics' reports are for missing components with 85 reports, where 44 are related to missing buffer sachet or bottle.

Public Health and Clinical Review

- Public Health and Clinical reviewed events related to allergies for clarification on the reportability during the PSP Patient Safety Pannel.

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	27-May-2021	Risk management file to be updated with new hazards identified this period of time.	[redacted]	11-Jun-2021	Action realised

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