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	11-Jun-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 22nd May to 4th 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

Intertek Testing

Between the reporting this period there were a total of 98 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 18 complaints between 22nd May to 4th June 2021. 3 came through Control tower (Home testing, LST and Workplace report location) and 15 from MHRA yellow card.

- 3 out of 18 Reports are pending on assessment due on the 10Jun2021 during the Patient Safety Pannel. The other 15 reports were 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.
- 2 complaints were received for a single lot X2102319 for the TK1572 packed in 7 units. Both of the complaints were classified under different trending categories. One was assigned to: "Not a product complaint" because the End User is just informing of the results from positive LFD and a confirmatory Positive PCR the day after. The second complaint was classified as "patient injury" however it was found not reportable because there was not deterioration of the patient health.
- All reports are open pending on complaint review for final closing. However investigation has been completed for 15 reports with not further actions. Investigation is ongoing for the other 3 complaints.
- 2 events were not covered in the RMF-0001 Rev3. RMF needs to be reviewed for inclusion of this new hazard situations

Source Reference (Yellow Card)	Actual Harm	Trending Category
2021/005/023/501/001	Reaction to Medicinal Component of Device	Patient Injury
2021/005/025/501/010	Epistaxis- Nose bleed	Patient Injury

- A summary of the received complaints is below

No	Complaint category	Reportability	Investigation	Investigation results
1	2 empty extraction buffer sachet	No	No trend	No further actions
2	1 Faulty item	No	Ongoing	TBC
3	1 Contaminated kit	No	No trend	No further actions
4	4 Missing components	No	No trend	No further actions
5	2 Not a product complaint	No	No trend	No further actions
6	2 faulty test results	No	No trend	No further actions
7	1 Leaky extraction tube	No	No trend	No further actions
8	3 Patient injury	No	No trend	No further actions
9	2 unknown	No	No trend	No further actions
10	2 empty extraction buffer sachet	No	No trend	No further actions

(Refer to Attachment 03 for data)

Qualtrics survey

- A total of 843 reports were recorded through the Qualtrics Survey
- 117 out of 843 reports reported injury to End User. Survey redirects End User to Yellow Card to report injury.
- 29 out of 68 reports for missing items where related to the Buffer Sachet or Bottle.

Complaint category	Reportability	Investigation	Investigation results
9 Damaged items	No	No trend	No further actions
68 Missing items	No	No tend	No further actions

- User Experience

Question	Yes	No	Total
Swab easy to use?	316	42	358
Test Strip easy to use?	327	31	358
Easy to get sample?	305	53	358
Test worked as instructed?	301	57	358
Manual easy and clear?	337	21	358
Total	1586	204	

(Refer to Attachment 03, for data)

Real World Performance Monitoring

Performance for the period (22/05/2021 – 04/06/2021)

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**
CTP	250	0	249	1	0.00%	0.40%	N/A	N/A	N/A
Schools / College	3,329,826	4,412	3,321,738	3,676	0.13%	0.11%	69%	3,084	81.8%
Private Industry	226,198	170	225,833	195	0.08%	0.09%	49%	84	61.9%
Public Industry	14,214	12	14,192	10	0.08%	0.07%	33%	4	100.0%
Home / Other Self	2,461,511	9,042	2,448,890	3,779	0.37%	0.15%	67%	6,017	95.4%
University	31,891	78	31,782	31	0.24%	0.10%	51%	40	87.5%
Total	**6,063,890**	**13,714**	**6,042,484**	**7,692**	**0.23%**	**0.13%**	**67%**	**9,913**	**84.0%**

- Escalated 3 sites as potential incidents to integrator team due to void rate with confidence interval above our pre-defined threshold.
- Escalated 4 sites as potential incidents to integrator team due confirmatory PCR rate below our pre-defined threshold.

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

CAPA and SCARs

- CAPA Summary

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	18 June 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	30June 2021

- No SCARs raised for LFD between 22nd May and 4th June.

5. Conclusion
    - New hazards were identified related to reaction to medicinal component of device and Epistaxis – nose bleed. These are to be added to the current RMF.

Batch issues

- 2 complaints were received for a single lot X2102319 for the TK1572 packed in 7 units. However these were classified under different trending categories.
- Unable to identify any trending by batch on the Qualtrics data.

User incidence

- No reportable events were found this reporting period.
- Qualtrics Survey data shows 117 reports were related to injury to End User. Although the Survey redirects End User to Yellow Card to report the incident; only 15 reports were received through the Yellow card within the same period of time.

Trends and analysis

- The higher number of Qualtrics' reports are for missing components with 68 reports, where 29 are related to missing buffer sachet or bottle.
- Out of 49.4 Million of distributed LFD kits only 7.3 Million (15 %) have registered results.
- Out of 49.4 Million of distributed LFD kits only 843 (0.001706%) have used the Qualtrics survey
- Out of 49.4 Million of distributed LFD kits only 861 reports were received. This is 0.001743%.

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	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