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-July-21	First issue

1. Content

2. Introduction

The purpose of this document is to summarise the post-market surveillance report for Innova LFD kits where DHSC is distributor or manufacturer. This report covers period 26th June - 16th July 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

Inspection reports received between the reporting window of 3rd Jul - 16th July 2021. DHSC received 39 validation reports against Innova product. In total, for this reporting window 3,360 samples were analysed for lateral flow performance, all of which passed. The SKU codes aligned to these samples were a mixture of TK1752 and TK1876.

4.2 In-House manufacturing inspection

Production at Xiamen Biotime re-started following a new Innova Contract. New SKUs was created TK2193. A total of 42 inspections were carried out between 26th June – 2nd July 2021. This was the end of production on the Innova's most recent contract. These 42 inspections were reflective of 42,000,000 units produced, and no issues were raised during the production of this volume. Lot quantity is 1,000,000 units.

(Refer to Attachment 03, Reference Data tab)

4.3 Product complaints

- DHSC has received a total of 13 complaints between 26th June - 16th July 2021. 1 came through Control tower (Unknown source), 14 from MHRA yellow card.
- No lot trend was identified.
- All complaints are open although investigation has been completed for 10 of these complaints.
- No new hazard identified this period.

A summary of the received complaints is below

No	Complaint category	Reportability	Investigation	Investigation results
1	1 Faulty item	No	No trend	No further actions
2	1 Missing components	No	Ongoing	Ongoing
3	5 faulty test results	No	No trend	Not enough information to investigate
4	1 Leakage	No	No trend	No further actions
5	4 not a product complaint	No	N/A	N/A
6	1 Patient injury	Yes	No trend	No further actions

(Refer to Attachment 03 for raw data)

4.2 Qualtrics survey

- A total of 2312 reports were recorded through the Qualtrics Survey for period 26th June - 16th July 2021.
- 313 out of 1037 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.
- The Survey percentage of completion shows only 42.2 percent completed the whole survey and 56.4 percent stop completing the survey at 13% of the survey questionnaire.

Complaint category	Reportability	Investigation	Investigation results
15 Damaged items	No	No trend	No further actions
54 Missing items	No	No tend	No further actions

- Qualtrics summary - User Experience

Question	Yes	No
Swab easy to use?	703	51
Test Strip easy to use?	720	34
Easy to get sample?	687	67
Test worked as instructed?	683	71
Manual easy and clear?	719	35

(Refer to Attachment 03, for data)

4.3 Real World Performance Monitoring

No actions identified during this period.

03/07/2021 to 16/07/2021

NHS Test and Trace

DHSC 3/7: Summary for PSR reporting

Key metrics	What this metric tells us	Performance expectation given current population prevalence level of disease	Conclusion
Void rate	Measuring void rates provides insights into how users interpret results. Measuring void rates at a site level can be used as an indicator of batch performance.	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.	The void rate of 0.12% out-performs expectations for DHSC 3/7.
Confirmatory PCR rate	Measuring confirmatory PCR rates provides an assessment of false positive rates. By reviewing this at a service team and site level, it provides assurance as to the reliance which can be placed on a positive LFD result.	Based on service evaluations analysis, it was established that sites are flagged if the conf PCR Rate is below 70%, and the conf PCR Rate is lower than the Expected PCR Conf Rate Lower Est. Conf PCR rates are expected to decrease in line with decreasing prevalence, and vice versa.	The confirmatory PCR rate of 91.6% outperforms expectations and provides assurance for LFD positives.
Variant analysis	Measuring the number of, and relative proportion of SARS-CoV-2 strains detected via a combination of asymptomatic LFD testing, confirmatory PCR testing policy and sequencing.	We are continuing to monitor the device for its ability to detect different types of strains through testing in the asymptomatic population. Statistical analysis is work-in-progress.	LFD testing in the asymptomatic population detected 14,973 cases of Delta and 64 other strains.
Positivity	Measuring positivity provides an understanding into the number of cases that are being detected. It also allows to quantify the number of incremental cases identified via asymptomatic testing.	Given the prevalence at a certain time period, a site is expected to have stable and consistent positivity rates. Positivity rate increases in line with prevalence.	The positivity rate of 1.61% for the reporting period is on the increase in line with prevalence.

Trend data

MHRA Reporting Period end	Void rate	Positivity rate	Conf PCR count	Conf PCR rate	Expected conf rate
26/02/21	0.19%	0.26%	4,283	84.4%	WIP
12/03/21	0.13%	0.08%	2,523	81.6%	
26/03/21	0.15%	0.14%	9,121	79.4%	
09/04/21	0.13%	0.14%	8,271	80.5%	
23/04/21	0.13%	0.12%	4,641	85.2%	
07/05/21	0.13%	0.13%	5,376	85.2%	
21/05/21	0.12%	0.13%	5,338	85.8%	
04/06/21	0.13%	0.23%	9,913	84.0%	
18/06/21	0.12%	0.40%	19,851	88.1%	
02/07/21	0.12%	0.84%	45,403	89.7%	
16/07/21	0.12%	1.61%	89,939	91.6%	

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

4.4 CAPA

- The below 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.	Closed	30 July 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.	Action implementation stage	30 July 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	08-Sep-21
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	08-Sep-21
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	08-Sep-21
06	CAPA-21-06-0013	08-Jun-21	CAPA raised to strengthen the PMS plan and appropriate PMS activities	Action implementation stage	08-Sep-21
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	08-Sep-21
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	08-Sep-21
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	08-Sep-21
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	08-Sep-21
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	09-Sep-21
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	09-Sep-21
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	09-Sep-21
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	09-Sep-21
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	09-Sep-21

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
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	09-Sep-21
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	09-Sep-21
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	09-Sep-21
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	09-Sep-21
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	09-Sep-21
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	09-Sep-21
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	Closed	11-Sep-21
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	11-Sep-21
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	Action implementation stage	11-Sep-21
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-Sep-21

4.5 SCAR – Supplier Corrective Action Report

No SCARs raised for LFD in this period 26th June - 16th July 2021.

5. Conclusion

Batch issues

- No batch trending was identified during this period.

User incidence

- DHSC has received a total of 13 complaints between 26th June - 16th July 2021
- 183 out of 1037 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. This will be address within CAPA-21-06-0011.

- The Survey percentage of completion shows only 42.2 percent completed the whole survey and 56.4 percent stop completing the survey at 13% of the survey questionnaire. This will be address within CAPA-21-06-0011.

Trends and analysis

- 13 reports were received out of 71.3 Million of distributed LFD kits between 26th June - 16th July 2021.
- 2,312 end user out of 71.3 Million of distributed LFD kits between 26th June - 16th July 2021, 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.

6. Actions

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 during the period 8th May to 16th July	[redacted]	20-Aug-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]