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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	09-Sep-2021	First issue

1. Content

1. Content
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3. Methodology
4. Findings /Results
 - 4.1 Intertek Testing
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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 the period 7th - 27th August 2021.

This report includes inputs from Intertek Inbound Testing, Product Complaints, Qualtrics survey, Real World Performance Monitoring, CAPAs, SCARs and Variants of Concern.

3. Methodology

The methodology for data collection was established in the PMS plan PMS-0001 Revision 2, dated 29-July-2021.

(Refer to Attachment 01)

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4. Findings /Results

4.1 Intertek Testing

49 Inspection reports received between the reporting window of 7th - 27th August 2021. 4,109 samples were analysed for lateral flow performance, all of which passed. The SKU codes aligned to these samples were TK2193.

A total of 81 inspections were carried out between 7th - 27th August 2021. These 81 inspections were reflective of 59,000,000 units of TK2193 produced. Each lot contained a total of 1,000,000 units. There was a requirement for 21 lots to be re-inspected for an amber flag raised for concerns regarding the integrity of the extraction tubes. Re-inspection of the affected lot numbers found no issues with product beyond acceptable quality limit (AQL) standards.

(Refer to Attachment 02 for input report)

4.2 In-House manufacturing inspection

There were no inspection reports received by DHSC for Innova product in the specified reporting window.

(Refer to Attachment 02 for input report)

4.3 Product complaints

- DHSC has received a total of 19 complaints between 7th - 27th August 2021. 3 complaints came through Innova and 16 from MHRA (yellow card). The number of kits distributed (3s, 7s and 25s) during this period was 40.3 million.
- No lot trend was identified within this period.
- Trending category shows 7 complaints for "Faulty test results" however investigations are still going on to determine if the fault is with the kit or IT error on the website
- 10 out of 19 Complaints have had the investigation completed and are due for final review before the complaints can be closed.
- There were no new hazards identified for this reporting period.

A summary of the received complaints is below

No	Complaint category	Reportability	Investigation	Investigation results
1	1 Damaged Item	No	No trend	No further actions
2	1 Packaging error	No	No trend	No further action
3	1 empty extraction buffer sachet	No	No trend	No further action
4	1 faulty item	No	Not enough information/no trend	No further actions
5	7 Faulty test results	No	No trend/Investigations on going for 25Ts	No further action
6	1 Leakage	No	No trend	No further actions
7	3 Missing item	No	Not enough information	No further action
8	3 Not a product complaint	N/A	N/A	N/A
9	1 Unknown description	N/A	N/A	N/A

(Refer to Attachment 03 for raw data)

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4.4 Qualtrics survey

- A total of 292 reports were recorded through the Qualtrics Survey for period 7th - 27th August 2021. The number of kits distributed (3s, 7s and 25s) during this period was 40.3 million.
- No Injuries were reported.
- 67.5 % of the end user completing Qualtrics survey answered 100% of the survey questions during 7th - 27th August 2021.

Complaint category	Reportability	Investigation	Investigation results
5 Damaged items	No	No trend	No further actions
28 Missing items	No	No tend	No further actions

- Qualtrics summary - User Experience

Question	Yes	No
Swab easy to use?	299	16
Test Strip easy to use?	295	20
Easy to get sample?	287	28
Test worked as instructed?	275	40
Manual easy and clear?	304	11

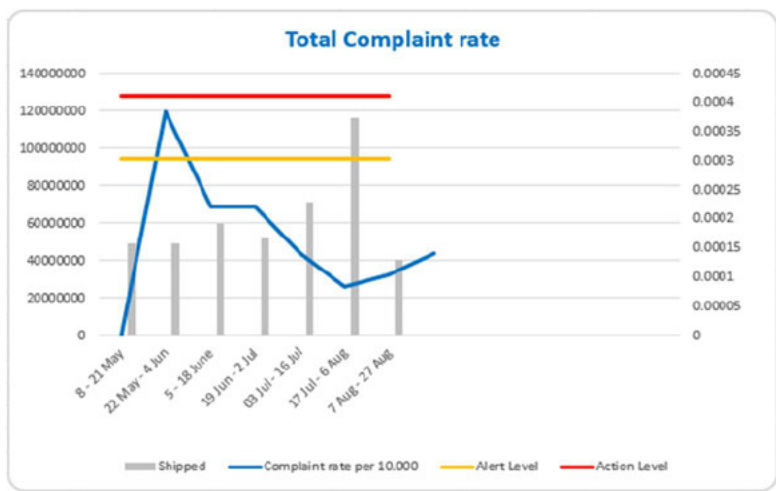
(Refer to Attachment 03, for data)

4.5 Combined Complaints Data (Yellow Card, Control Tower and Qualtrics Complaints) – Trending

This table shows the trending data for the combined LFD complaints (Yellow Card, Control Tower and Qualtrics Complaints) vs distributed LFD test kits for the last reporting periods.

Alert and Action thresholds have been established using an average derived from the last reporting periods. These thresholds will remain consistent. And will provide an ongoing benchmark for identifying trends through continual monitoring.

The data this 7th - 27th August 2021 shows an increase on the number of total/Combined complaints rates due to the reduction of distributed volume. The Percentage went above the Alert level. Complaints were monitored for this period, and there were not specific concerns.



(Refer to Attachment 03, for data)

4.6 Real World Performance Monitoring

This is the summary slide from the data provided in attachments 4, 5, and 6.

31/07/2021 to 11/08/2021

summary rates Void rates rates Variants

Device performance by service team

Service performance for period (31/07/2021 – 11/08/2021)***

Service team	No. of LFD 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	2	-	2	-	0.00%	0.00%	(Blank)	-	(Blank)
Home / Other	2,329,313	49,343	2,278,930	3,040	2.12%	0.13%	88.00%	33,479	91.90%
Private Industry	193,813	687	192,940	186	0.35%	0.10%	67.00%	460	84.60%
Public Industry	15,208	71	15,108	29	0.47%	0.19%	72.00%	51	84.30%
Schools / College	857,322	8,058	850,154	1,110	0.71%	0.13%	76.00%	4,576	92.90%
University	49,880	344	49,280	78	0.69%	0.15%	85.00%	222	85.80%
Total	3,445,338	56,503	3,384,394	4,441	1.64%	0.13%	69%	38,788	91.89%

All-time performance (25/01/2021 – 11/08/2021)***

Service team	No. of LFD 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	9	0	9	-	0.00%	0.00%	(Blank)	-	(Blank)
Home / Other	24,893,914	304,804	24,552,596	36,514	1.22%	0.15%	72.00%	220,566	90.80%
Private Industry	2,127,998	4,824	2,121,188	1,980	0.23%	0.09%	67.00%	3,238	83.10%
Public Industry	173,800	414	173,151	235	0.24%	0.14%	64.00%	267	82.80%
Schools / College	54,282,730	129,880	54,085,898	68,972	0.24%	0.12%	74.00%	98,242	84.50%
University	430,985	2,851	427,197	547	0.66%	0.13%	65.00%	1,843	88.30%
Total	81,889,046	442,753	81,340,039	106,254	0.54%	0.13%	72.76%	322,156	88.85%

* Number of confirmatory PCR where we are confident they belong to the same individual
** Confirmatory PCR rate describes the number of LFD positives with a corresponding PCR result, where the PCR result was also positive

For this reporting period that is 2 days shorter than usual***, the average void rate of 0.13% performs according to expectations. At service team level, there was no significant variance from that. Overall positivity for DHSC 3/7 self-testing was 1.64%. Positivity in Home/Other has been highest (2.12%), in line with prevalence. The confirmatory PCR rate across all services has been above expectations with an average of 91.89%.

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Actions:1 site was escalated to the Integrator team due to the confirmatory PCR rate being below the 70% threshold.

The average void rate of 0.12% performs according to expectations. The overall positive rate for the DHSC 3/7 self-test across all service teams was 1.71%. Positivity in Home/Other has been highest (2.10%), thus measuring the number of positive LFDs detected in line with prevalence. The confirmatory PCR rate across all services has been above expectations in all service teams, with an average of 93,27%.

Actions:1 site was escalated to the Integrator team due to the void rate being above the 1.2% threshold and above the lower CI of 1.2% for void rates

14/08/2021 to 27/08/2021

summary

rates

VOID rates

rates

Validities

Device performance by service team

Service performance for period (14/08/2021 – 27/08/2021)									
Service team	No. of LFD 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	3	-	3	-	0.00%	0.00%	(Blank)	-	(Blank)
Home / Other	2,323,215	48,892	2,271,864	2,659	2.10%	0.11%	74.00%	38,185	93.30%
Private Industry	181,923	689	181,052	182	0.38%	0.10%	78.00%	524	89.30%
Public Industry	13,838	83	13,838	18	0.60%	0.13%	78.00%	85	89.20%
Schools / College	800,528	7,788	791,788	998	0.97%	0.12%	81.00%	6,281	93.90%
University	41,231	283	40,898	70	0.64%	0.17%	88.00%	179	87.70%
Total	3,360,839	57,493	3,299,421	3,925	1.71%	0.12%	75%	43,214	93.27%

All-time performance (25/01/2021 – 27/08/2021)									
Service team	No. of LFD 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	12	0	12	-	0.00%	0.00%	(Blank)	-	(Blank)
Home / Other	27,585,259	380,890	27,184,790	39,579	1.31%	0.14%	74.00%	288,070	91.20%
Private Industry	2,336,888	5,002	2,328,872	2,192	0.24%	0.08%	89.00%	3,876	83.90%
Public Industry	189,890	508	189,127	257	0.27%	0.14%	87.00%	339	84.10%
Schools / College	55,174,055	138,539	54,987,420	88,098	0.25%	0.12%	75.00%	103,855	85.20%
University	455,589	2,888	452,078	585	0.64%	0.13%	88.00%	1,901	87.70%
Total	85,741,451	508,435	85,122,297	110,719	0.59%	0.13%	73.92%	375,841	89.46%

* Number of confirmatory PCR where we are confident they belong to the same individual

** Confirmatory PCR rate describes the number of LFD positives with a corresponding PCR result, where the PCR result was also positive

The average void rate of 0.12% performs according to expectations. The overall positive rate for the DHSC 3/7 self-test across all service teams was 1.71%. Positivity in Home/Other has been highest (2.10%), thus measuring the number of positive LFDs detected in line with prevalence. The confirmatory PCR rate across all services has been above expectations in all service teams, with an average of 93,27%.

Actions:1 site was escalated to the Integrator team due to the void rate being above the 1.2% threshold and above the lower CI of 1.2% for void rates


(Refer to Attachment 04, 05, 06 for data)

4.7 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
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.	Completed pending VOE	VOE due date: 28-Oct-21
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. Action over-due	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	Completed pending VOE	VOE Due Date: 01-Oct-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. Action overdue	08-Sep-21
06	CAPA-21-06-0013	08-Jun-21	CAPA raised to strengthen the PMS plan and appropriate PMS activities	Completed pending VOE	VOE Due date: 28-Oct-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. Overdue – In process of agreeing additional actions	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. Action Overdue	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. Action Overdue	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

No	CAPA No	Start Date	Problem statement	Status/ progress	Due date
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
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 University LFD kits failing to flow	Out for closure	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	Action implementation stage	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

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4.8 SCAR – Supplier Corrective Action Report

No SCARs raised for LFD in this period 7th - 27th August 2021. There are no open SCARs for LFD products.

4.9 Variant of Concern Data VoC

Not available this period.

4.10 Risk Management

DHSC Risk management File RMF-0001 has been updated to Revision 5.

(Refer to Attachment 07 for data)

5. Conclusion

Batch issues

- No lot trending was identified during this period.

User incidence

- DHSC has received a total of 57 total complaints between 7th - 27th August 2021 from all sources. This is a rate of 0.014 per 10,000.
- 40.2 Million were distributed (3s, 7, and 25s) LFD kits between 7th - 27th August 2021.
- No reports related to injury received from Qualtrics survey.
- 67.1% of the end users completing Qualtrics survey answered 100% of the survey questions during 7th - 27th August 2021.

Trends and analysis

- Trending category shows 7 complaints for "Faulty test results". 3 complaint investigations with no further action by DHSC and 4 complaint investigation to be conducted.
- There were no new hazards identified for this reporting period.
- DHSC has received a total of 19 complaints between 7th - 27th August 2021. 3 complaints came through Innova and 16 from MHRA (yellow card). The number of kits distributed (3s, 7s and 25s) during this period was 40.3 million.
- The number of users using the Qualtrics survey went down from 1005 last reported period to 592 end users this period 7th - 27th August 2021

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	Added	Action	Responsible Name/Email	Due Date	Status
2	15-Aug-2021	Risk management file RMF-0001.Rev4 to be updated with new hazards identified during the period	[REDACTED]	2 Sep 021	Completed CO-135 was used to

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7. Attachments

Attachment 01: PMS-0001, PMS Plan for the DHSC Covid-19 LFD Devices (3 and 7 kit) Rev2, 29-July-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: RMF Rev5 & HTM Hazard-Traceability-Matrix Rev4

	Job Title	Name	email
Compiled by	Regulatory Lead	██████████	██████████