DEFENSE LOGISTICS AGENCY
TROOP SUPPORT
700 ROBBINS AVENUE
PHILADELPHIA, PENNSYLVANIA 19111-5092

DSCP-FTW
ALFOODACT 2021-038

October 5, 2021

MEMORANDUM FOR RECORD

SUBJECT: Ellume Issues Voluntary Recall of Specific Lots of Ellume COVID-19 Home Tests Due to False-Positive Results

1. **REFERENCE.** DHA-MSR 6025.01/AR 40-660/ DLAR 6025.01/NAVSUPINST 10110.8D/AFI 48-161_IP/MCO 10110.38D, DOD Hazardous Food & Nonprescription Drug Recall System, 6 September 2018.

2. **COMPANY ANNOUNCEMENT.** Digital diagnostics company Ellume announced today it is voluntarily recalling specific lots of the Ellume COVID-19 Home Test, the company's rapid, at-home COVID-19 antigen test, which was granted Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA).

There is an increased chance that tests from the affected lot numbers may give a false positive result. The voluntary recall is being taken after specific product lots reported false-positive test result rates higher than was observed in clinical testing.

The affected Ellume COVID-19 Home Tests were distributed to retailers and distributors from April-2021 through August-2021. Ellume is removing the affected product from store shelves and notifying consumers, retailers and distributors affected by the recall.

Distributors and retailers with an existing inventory of the lots being recalled should stop use and distribution and quarantine the product immediately. Distributors and retailers who have further distributed the recalled product should notify any accounts or additional locations that may have received the recalled product from them. Distributors and retailers will be contacted by Ellume with specific instructions regarding disposal or return of product.

Actions to be taken by the Consumer: Ellume is advising consumers to check whether their product is part of the affected lots and if affected, to receive further instructions via the company's website.

Consumers who attempt to use affected tests will be notified in the Ellume COVID-19 Home Test app that the test has been recalled and disabled. Consumers will be directed to www.ellumecovidtest.com/return to request a product replacement.

Ellume will directly notify via email consumers who have used an affected product and tested positive in the last 14 days. Consumers who have not already had a confirmatory test should immediately obtain one. Prior to a confirmatory test, consumers should assume they have COVID-19 and should self-isolate and take all necessary precautions.

Ellume is voluntarily conducting this recall with the knowledge of the FDA.

FDA is alerting test users, caregivers, health care personnel, and the public of the potential for false positive in association with the subject recall. For these tests, a “false positive” is a test result that indicates that a person has the virus when they do not actually have it. Negative results do not appear to be affected by the manufacturing issue.

The FDA is working closely with Ellume to assess the company’s additional manufacturing checks and other corrective steps to help ensure that the issue is resolved.

Consumer Safety Officer Note: IAW DHA-MSR 6025.01, All Food and Drug Activity (ALFOODACT) messages are issued for hazardous food, as well as nonprescription drugs, dietary supplements, ***nonprescription medical devices***, health and beauty-aid items, and pet food which may be in Military accounts. Military government retail stores were not identified in the subject recall, but company identifies DoD distributers/Institutions.

3. **PRODUCTS AFFECTED:** The affected Ellume COVID-19 Home Tests were distributed to retailers and distributors from April-2021 through August-2021.

Master Lot Number	Final Kit Lot Number	Expiration Date	Retailer/Distributor
21047-4	21047-4	February 28, 2022	Department of Defense; Institution
21047-5	21047-5	February 28, 2022	Department of Defense
21089-1	21089-1	March 31, 2022	Department of Defense; Institution
21099-1	21099-1 (AUS)	March 31, 2022	Retailer
	21099-1 (USA)	March 31, 2022	Retailer
21117-1	21117-1	April 30, 2022	Department of Defense
21124-1	21124-1	March 31, 2022	Retailer
21125-1	21125-1	April 30, 2022	Retailer
PF03X-H	PF03W-H	May 31, 2022	Retailer
	PF03V-H	May 31, 2022	Retailer
	PF03S-H	May 31, 2022	Retailer
	PF03T-H	May 31, 2022	Retailer

PF057-H	PG07T-H	May 31, 2022	Retailer
	PG07Q-H	May 31, 2022	Retailer
	PG082-H	May 31, 2022	Retailer
	PG07R-H	May 31, 2022	Retailer
	PG07S-H	May 31, 2022	Retailer
PF05W-H	PF05M-H	May 31, 2022	Retailer
	PF05E-H	May 31, 2022	Retailer
	PF05Y-H	May 31, 2022	Retailer
	PF05H-H	May 31, 2022	Retailer
	PF05J-H	May 31, 2022	Retailer
PF069-H	PF06J-H	May 31, 2022	Retailer
	PF06D-H	May 31, 2022	Retailer
	PF06B-H	May 31, 2022	Retailer
	PF06C-H	May 31, 2022	Retailer
PF06E-H	PF06G-H	April 30, 2022	Retailer
	PF068-H	April 30, 2022	Retailer
	PF066-H	April 30, 2022	Retailer
	PF067-H	April 30, 2022	Retailer
PF06N-H	PF06P-H	May 31, 2022	Retailer
	PF06R-H	May 31, 2022	Retailer
	PF06Q-H	May 31, 2022	Retailer
PF06Z-H	PG07X-H	June 30, 2022	Retailer
	PF070-H	June 30, 2022	Retailer
	PG07Z-H	June 30, 2022	Retailer
	PF071-H	June 30, 2022	Retailer
	PG074-H	June 30, 2022	Retailer
PG080-H	PG084-H	June 30, 2022	Retailer
	PG081-H	June 30, 2022	Retailer
PG08H-H	PF065-H	May 31, 2022	Retailer
	PF060-H	May 31, 2022	Retailer
PH08X-H	PH08Y-H	May 31, 2022	Retailer

***Immediately discontinue issue/use/sale of products and place on medical hold. Contact your supplier for disposition instructions.*

4. **PRODUCT LABELS/PICTURES:**

5. **CONTACT INFORMATION.** Consumers can find instructions for the replacement of the impacted Ellume COVID-19 Home Tests at www.ellumecovidtest.com/return. Consumers can contact the Ellume Product Support Team at 1-888-807-1501 (9 a.m. to 5 p.m. ET, Monday through Friday) to arrange a replacement. If consumers have questions unrelated to this recall, to report an adverse event or product complaint, contact the Ellume Customer Support Team at 1-888-885-6121 (9 a.m. to 9 p.m. ET, Monday through Friday, 10 a.m. to 6 p.m. ET, Weekends).

FDA MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

6. **POSITIVE AND NEGATIVE FINDINGS.**

a. **Army Veterinary Services and Air Force Public Health Personnel:** Report negative and positive findings in the Veterinary Service Information Management System (VSIMS) Subsistence Recalls application. If you are not in one of these two groups, please use the instructions below (paragraphs b-d).

b. **Navy**:

1) SHIPS AT SEA: Must report positive and negative findings to supporting Veterinary Service unit. Are authorized to destroy or dispose of recalled products utilizing the procedures and reporting requirements outlined in NAVSUP P-486 Paragraph 5302 and 6000(4), to include completion of a DD Form 200 and Standard Form 364. Procedures for completing the DD Form 200 are found in NAVSUP P-486 Paragraph 6001. Procedures for completing Standard Form 364 are found in NAVSUP P-486 Paragraph 5300(2)(c).

2) SHIPS IN PORT/HOMEPORTED/ASHORE GALLEYS: Supporting Veterinary Service unit will conduct inspection and report positive and negative findings in VSIMS Subsistence Recalls application. Contact the appropriate DLA Account Manager via Regional NAVSUP Fleet Logistics Center (NAVSUP FLC) to arrange pickup of recall items. Contact your supporting (NAVSUP FLC) for any issues regarding PV Pickup. Proceed with the same guidance as above.

c. **Defense Logistics Agency (DLA) Contractors**: Report positive and negative findings to your Contracting Officer, Contracting Specialist, TVLS, and dscpconssafofc@dla.mil within 72-hours.

Positive Response Information required: (Vendor must provide all the following information):

1) ALFOODACT 2021-XXX
2) DLA Contract Number:
3) Unit of Measure:
4) Quantity Currently in Stock:
5) List of customers that received product AND (a-h) for each customer:
    a) Customer name and location:
    b) DLA Purchase Order Number:
    c) Vendor Invoice Number:
    d) Item Stock number (LSN, NSN):
    e) Quantity Shipped:
    f) Date Shipped:
    g) Value of Affected Product:
    h) Amount of credit due:

d. **AAFES, MWR, NEX, MCCS, DeCA, DLA**, **dining facilities, and all other agencies,** report your findings in accordance with the procedures outlined by your agency.

7. If you know of others who need to receive Subsistence Recall messages, click here to Subscribe. If you no longer need to receive Subsistence Recall messages, click here to Unsubscribe.

8. Previous recalls are available on the DLA-TS Food Safety Office website, click here.

9. Point of contact for ALFOODACT messages is the undersigned at commercial telephone 267-584-6952/DSN: 312-444-2678, or dscpconssafofc@dla.mil.

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MARIVIC J. BROWN
Chief Warrant Officer 4, U.S. Army
Consumer Safety Officer