SML Distribution LLC

March 20, 2022

MEDICAL DEVICE RECALL

Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Dear Device Customer/Distributor,

(1) Purpose of this letter

The purpose of this letter is to advise you that SML Distribution LLC is voluntarily recalling ALL LOTS of the Skippack Medical Lab SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold).

(2) Reason for the Voluntary Recall:

The product is not authorized, cleared or approved by the FDA for marketing and distribution in the US.

(4) Risk to Health:

It is important that tests are validated because false results can impact the individual patient and broad public. False positive results from diagnostic tests, for example, can lead to unnecessary quarantine and testing resources. False negative results can lead to lack of appropriate treatment for the individual and further spread of COVID-19.

To date no false positives or negatives have been reported to us.

(5) Actions to be taken by the Customer/User:

Please immediately return all unused product to 1625 Lincoln Ave., Tyrone Pa 16686. Once you return the unused product and we inventory same, we will refund monies paid to us from the purchaser within 60-90 days.

If you have further distributed the product, we ask that you also take cooperative measures to perform a recall from all purchasers and report the outcome back to us so that we may share with the FDA.

There are certainly alternative rapid antigen tests for COVID-19 on the market that are FDA authorized or cleared and may be used in the meantime.

Please contact us with any questions, concerns, or product returns of any recalled goods purchased that are listed and subject to this voluntary recall by contacting us via e-mail at techsupport@smldistribution.com.

(6) Product and Distribution Information: The lot #'s, production dates, and expiration dates of the lots recalled are listed below in **Table 1**.

TABLE 1

DATE:	LOT #:	EXPIRATION:
1/5/2022	UL-AG-2110-05-Q	10/15/2023
1/10/2022	UL-AG-2111-02-Q	11/15/2023
1/18/2022	UL-AG-2112-01-Q	12/15/2023
1/19/2022	UL-AG-2112-02-Q	12/15/2023
2/1/2022	UL-AG-2201-03-Q	1/15/2024

The subject product is the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold), a photo of which is below.

(7) Type of Action by the Company:

SML Distribution LLC is taking the steps to voluntarily recall the product from the marketplace until such time as it obtains necessary authorization to distribute same.

(8) OTHER INFORMATION:

- Contact information for questions: E-mail techsupport@smldistribution.com. Telephone 888-209-4406
- Attachments of Acknowledgement and Product Replacement Forms (separate sheets)

Authorized by:

Christopher W. Nagle

Name: (Print)

Signature:

Vice President

Title:

Contact Information: Please call us Monday through Friday, 9:00 AM to 4:30 PM, Eastern Time at 888-209-4406.

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.