



November 7, 2022

Dates Distributed:

Lot 0004014634: 6/21/2021 to 3/16/2022

Lot 0004014635: 6/9/2021 to 2/14/2022

URGENT: VOLUNTARY MARKET WITHDRAWAL

**RE: ALLERGENIC EXTRACT – PEANUT (*Arachis hypogaea*)-
For Diagnostic Use Only**

Product Name: Peanut
Lot No. 0004014634
EXP date: 4/7/2024
Concentration: 1:10 w/v
5mL Scratch Test Vial for Diagnostic Testing

Product Name: Peanut
Lot No. 0004014635
EXP date:4/7/2024
Concentration: 1:10 w/v
10mL Test Vial for Diagnostic Testing

ALK-Abelló, Inc. has been made aware of multiple adverse events from the market resulting from diagnostic skin testing using the above product in 5mL and 10mL packaging configurations at 1:10 w/v. According to these reports, individuals who were test-negative using the above product lots subsequently experienced allergic reactions to peanut. Consequently, we are voluntarily withdrawing the lot(s) of allergenic extract diagnostic testing product(s) from the market.

Please examine your stock immediately to determine if you have any of the product lots on hand. If so, discontinue testing with the lot(s) and contact ALK's Sales Support Department at 800-325-7354 to request a product pick up to return the remaining material. We will issue credit to your account for all returned vials upon receipt. Our Sales Support department will also be able to assist with any requests for replacement products.

ALK-Abelló, Inc.
Americas Headquarters
1700 Royston Lane
Round Rock, TX
78664
T 512 251 0037
F 512 251 5882

Americas Product Supply
35 Channel Drive
Port Washington, NY
11050
T 516 767 1800
F 516 883 4572

www.alk.net/us

In order to advise the Food and Drug Administration about the effectiveness of this market withdrawal, you are requested to complete and return the enclosed form **promptly** using the pre-paid self-addressed envelope.

This voluntary market withdrawal is being made with the knowledge of the Food and Drug Administration.

Thank you for your cooperation. We regret any inconvenience this may cause you. If we can be of further assistance, please contact our Medical Affairs Department at (800) 252-9778.

Sincerely,

A handwritten signature in black ink, appearing to read 'Zahra Pooladi', with a decorative flourish at the end.

Zahra Pooladi
Director, Quality Assurance America's Region
ALK-Abelló, Inc.

PLEASE COMPLETE AND RETURN

We do not have any stock of

Allergenic Extract, Peanut

Lot No. __0004014634__

Allergenic Extract, Peanut

Lot No. __0004014635__

(Please Check)

We are returning

_____ units of Allergenic Extract, Peanut

Lot No. __0004014634__

_____ units of Allergenic Extract, Peanut

Lot No. __0004014635__

Note: Please contact ALK's Sales Support Department at 800-325-7354 to request a product pick up to return the remaining material. We will issue credit to your account for all returned vials upon receipt.

Name: _____

Address: _____

City: _____ State: _____ Zip code: _____