JANT PHARMACAL CORPORATION
LABORATORY & POINT OF CARE DIAGNOSTICS

URGENT MEDICAL DEVICE (IVD) RECALL: Accutest URS 4, 10, 11 (lot specific)

Dear Customer,

The purpose of this letter is to advise you that our manufacturing partner has requested us to participate in a voluntary recall, which includes the following Accutest Urine Reagent Strips, which contain a protein reagent pad on the strip.

The affected product catalog number and lot numbers are listed below:

Catalog #:UA774; Accutest URS 4
Lot# N2306014, Expiration Date: 05/31/2025

Catalog #:UA710B / UA824B; Accutest URS 10
Lot# N2306013, Expiration Date: 05/31/2025

Catalog #:UA711 / UA924; Accutest URS 11
Lot# N2306012, Expiration Date: 05/31/2025

Issue Description: The reason for the voluntary recall is that Urinary Reagent Strip products listed above have shown reduced sensitivity and potential false negative results for the Protein test.

Impact on Results: Reduced sensitivity and potential false negative results may be generated, which could lead to a delay in the identification of potential kidney diseases or their evaluation and/or other conditions associated with elevated protein levels in urine.

The results of the assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings. Please discuss this letter with your medical director.

Customer Actions: Because of the above reasoning, we are requesting that you:

- Immediately examine your inventory and quarantine products subject to recall.
- Stop the sale of the identified lot number(s) of these products immediately.
- Stop or cease use of the identified lot number(s) of these products immediately.
- Recall products in the market.
- Ship recalled products to Jant Pharmacal by requesting a return authorization form within 1 month of this notice (OR dispose of the product and provide proof of destruction (records, pictures, etc.)

ADDRESS:

Jant Pharmacal Corp.
Attn: QC Manager
16530 Ventura Blvd Ste 512
Encino, CA 91436-5062
USA

- Use **Appendix I** to record the inventory report of the affected lots and send it back to Jant Pharmacal.
- Inform the end-user or sub-distributor at once of this recall and the required actions.

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• 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 (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

*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

Resolution: You may request unaffected replacement products at no charge. We apologize for the inconvenience this situation may cause.

Please contact Jant Pharmacal Corporation if you have any additional questions or concerns regarding this notification.

Telephone: 800.676.5565 or (818) 986-8530

Email: info@jantdx.com

This recall is being made with the knowledge of the Food and Drug Administration.

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Appendix I

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed **Jant Pharmacal Urgent Medical Device Recall** (UMDR) URS24001 dated 08-30-2024. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Appendix I immediately contact your Jant Pharmacal point of contact (representative) or *info@jantdx.com*.

Return this completed form as per the instructions provided at the bottom of this page.

1. Have you read and understood the instructions provided in this letter.	Yes ☐	No ☐
2. Do you have the affected product on hand? Please check inventories before answering.	Yes ☐	No ☐
3. Were affected Site Personnel notified.	Yes ☐	No ☐
4. Was a copy of the letter retained and posted with the current product labeling.	Yes ☐	No ☐

If the answer to the question #2 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		**State:**	**Zip Code:**
Phone:		**Country:**	

Product Code & Lot Number	Number of Tests	Date Disposed or Shipped to Jant Pharmacal	Comments

Please send a scanned copy of the completed form via email to: **info@jantdx.com.** We apologize for the inconvenience this situation may cause.

JANT PHARMACAL CORPORATION 16530 VENTURA BOULEVARD, SUITE 512, ENCINO, CALIFORNIA 91436

PHONE: 800.676.5565 818.986.8530 FAX: 818.986.0235 info@jantdx.com www.jantdx.com