



ALABAMA  
DEPARTMENT OF FORENSIC SCIENCES

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MEMORANDUM

April 6, 2011

TO: Statewide Alabama Law Enforcement Agencies  
FROM: Mark A. Pevey, Implied Consent Laboratory Director  
RE: Sirchie DUI Blood Alcohol Collection Kit **RECALL**

Sirchie has issued a recall of **ALL UN-EXPIRED** DUI Blood Alcohol Kits. The recall is due to *potential* contamination of the supplied Povidine Iodine Prep Pad with *Elizabethkingia meningoseptica*. According to Sirchie, the suspected contaminate is contained to the inside of the Iodine Prep Pad, therefore the box can be handled safely.

**HOW YOU SHOULD RESPOND:**

- Immediately cease the use of the SIRCHIE DUI Blood Alcohol Kits you have on hand.
- Inventory all kits for;
  - Lot Number
  - Expiration Date
- Discard any Kits with an Expired Date
- **Complete the attached form and submit it directly to Sirchie for any Kits with an UN-Expired Date**
  - *Below the signature line include the following information:*
    - *Printed name, contact phone number & physical address*
  - Sirchie will notify you directly where and how to return the kits for replacement
  - There will be no cost for replacement

In the interim should you have any questions regarding DUI cases requiring a blood draw, you may contact the ADFS.

**THIS RECALL DOES NOT AFFECT SIRCHIE POST-MORTEM SAMPLE COLLECTION KITS.**

SIRCHIE Fingerprint Laboratories  
100 Hunter Place  
Youngsville, NC 27596  
1-800-356-7311  
[www.sirchie.com](http://www.sirchie.com)

March 28, 2011

**URGENT: Voluntary OTC Drug Product Sub-Recall (End User Level)  
Of Povidine Iodine Prep Pads Packaged  
With SIRCHIE Blood, Urine and DNA Collection Kits**

Dear Valued SIRCHIE Customer:

SIRCHIE was recently made aware that H&P Industries, Inc., ("H&P") had initiated a voluntary product recall of ALL LOTS of POVIDINE PREP PADS within the labeled expiration manufactured by H&P but which are private labeled for many accounts. According to H&P's recall notification letter (a copy is enclosed), H&P initiated this voluntary recall due to:

*concerns expressed by the Food and Drug Administration regarding the potential contamination of these products with an objectionable organism, Elizabethkingia meningoseptica. H&P's internal investigation also concluded a raw material component as the potential source of this contamination. This investigation was conducted as a result of the earlier ipa pad recall. Both the pvp and ipa pads use this common component.*

According to our supplier, this recall has not been classified. No additional notification will be given if this is classified as either a Class II or a Class III since the return information will be the same. The only update you will receive is if this is upgraded to a Class I recall.

We are therefore taking immediate action to notify you of the voluntary recall of Povidine Iodine Prep Pads because some of these Povidine Iodine Prep Pads may have been included in the following SIRCHIE Blood, Urine and DNA Collection Kits:

- BSC100 – Blood Alcohol Kit
- BSC50 – Blood Specimen Collection Kit
- BUK100 – Blood Alcohol/Urine Specimen Kit
- BUK200 – Blood/Urine Collection Kit
- DNA50 – Fingerstick DNA Collection Kit
- And any custom kits containing the Povidine Iodine Prep Pads.

***The affected Povidine Iodine Prep Pads in SIRCHIE kits can be identified by the names listed on the Prep Pad packaging as Triad or Triad Plus.*** The Prep Pads involved in this recall were not manufactured by SIRCHIE.

Please examine your inventory to verify if you have any of the above-mentioned kits that are currently within the SIRCHIE labeled expiration date. If so, immediately discontinue any use or distribution of the pads, immediately discontinue use or distribution of the kits, remove the kits from your shelves, and contact SIRCHIE customer service (1-800-356-7311) to coordinate the logistics of your return. Once your kits have been received, SIRCHIE will replace the Povidine Iodine Prep Pad, apply a new integrity seal, and reship your kits at no extra cost. If any of your kits are beyond the labeled expiration date identified on the package, these expired kits must not be used and should be destroyed. Please complete, sign, date, scan, email (customerservice@sirchie.com) or fax (1-800-899-8181) the enclosed SIRCHIE response form indicating that you have received this notification, checked your inventory and complied with these instructions.

H&P's "Recall--Firm Press Release"<sup>1</sup> provided the following explanation of potential health risks:

The Povidine Iodine Prep Pads are non-sterile and contain some of the same raw material as the recalled Alcohol Prep pads, and were therefore investigated by FDA and by H&P Industries for potential contamination with objectionable organisms. However, analytical testing showed the presence of objectionable organisms, namely *Elizabethkingia meningoseptica*. [H&P is] therefore taking immediate action to voluntarily recall the Povidine Iodine Prep Pads. Use of contaminated Povidine Prep Pads could lead to life-threatening infections, especially in at risk populations, including neonates, immune suppressed patients, and surgical patients. Treatment options are limited for *Elizabethkingia meningoseptica* infections. To date [H&P has] not received any reports of adverse events. Povidine Iodine Prep Pads are used to prevent infection in minor cuts, scrapes and burns and are labeled as an antiseptic for preparation of the skin prior to surgery.

If you have any general questions about the product or the recall, please contact H&P customer service at 262-538-2900 ext 2680. 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.

- **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

We apologize for any inconvenience and thank you for your attention to this urgent matter.

Sincerely,

Dan O'Neil - Recall Coordinator

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<sup>1</sup> H&P's March 15, 2011 Press Release is posted on FDA's website at <http://www.fda.gov/safety/recalls/ucm247658.htm>.

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**Please note: Only kits within the SIRCHIE labeled expiration date will have the Povidine Iodine Prep Pad replaced and reshipped with a new integrity seal. If you have any of the referenced kits beyond the labeled expiration date, do not use the expired kits and destroy the kits immediately..**

Please complete, sign, date, scan, and email or fax to:

Dan O'Neil  
Recall Coordinator  
[customerservice@sirchie.com](mailto:customerservice@sirchie.com)  
1-800-899-8181

\_\_\_\_\_ We have checked our inventory and found the following product within the SIRCHIE expiration date:

<u>Product #</u>	<u>Description</u>	<u>Lot #s</u>	<u>Quantity</u>

\_\_\_\_\_ Expired Kits have been destroyed.

\_\_\_\_\_ **WE DO NOT HAVE ANY OF THE AFFECTED ITEM**

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Agency/Company

\_\_\_\_\_  
Date