

Subject: Voluntary Recall of HACH SteriChek " Sensitive" Total Chloramines and Residual Chlorine Reagent Strips that may have been shipped to your facility.



California Dialysis Council

1904 Naomi Place • Prescott, AZ 86303 • Phone: 928-717-1156 • Fax: 928-441-3857



Voluntary Recall of HACH SteriChek " Sensitive" Total Chloramines and Residual Chlorine Reagent Strips that may have been shipped to your facility.

See attached notice from HACH

**NEWS
UPDATE**

This information is communicated to your facility at the request of the Centers for Medicare and Medicare Services.

Please take time to:

- Read this important recall notification
- Review your inventory and check to see if you have any test strips from the product code and lot numbers listed on the t
- Take immediate action to pull the product from your stock and follow the directions for returned goods that are included the recall notification
- Pass this information on to your home hemodialysis departments
- Instruct your home hemodialysis patients to check their inventory for these test strips and return them to you immediate (they may need to obtain replacement strips from the unit)
- Share this recall notification with your Medical Director so that they may share the information with the acute dialysis services if appropriate



July 21, 2008

EXPANDED RECALL NOTIFICATION

Hach Company is expanding its voluntary recall of SteriChek "Sensitive" Total Chloramines and Residual Chlorine Reagent Strips that may have been shipped to your office.

We are conducting the recall because further investigation has shown that there have been other lots that have not satisfied our QC standards. In particular, our testing has shown inconsistencies in identifying levels of total chlorine and free chlorine. Such inconsistencies may result in inaccurately high or low readings. As a commitment to our customers, we are recalling all products and lot numbers identified on the attached table that may have been shipped to you on or after August 24, 2006. Please review this table to determine if you have any of these lot numbers in your inventory.

If you have any of this product in your inventory, immediately return it to Hach Company as follows:

1. First contact customer service to receive a return authorization.
2. Acquire return labels from Hach Company.
3. Affix the label to the product.
4. Send the product to the following address:

**Hach Company
100 Dayton Rd
Ames, IA 50010**

Please affix the labels received from Hach Company to your product for proper processing of your return.

In addition, we ask for your assistance in completing the enclosed **Return Form** and returning it to the above address or faxing it to 515-956-3820.

This recall is being conducted to the end user level therefore we request you notify your customers to return the products listed in the attached table. We are asking the distributors to consolidate all returned product from your customers and ship to Hach Company.

Any product that you have in stock with the above-mentioned lot number will be replaced with similar product code 811902, Total Chlorine DPD Test kit at no charge or credited to your account. Please contact Customer Service at 1-800-548-4381 ext. 3560 directly to handle the arrangements for a quick return and replacement.

We sincerely apologize for the inconvenience this causes you and your patients. Hach Company continues to strive to be a leader in quality products and we have made prompt system improvements to eliminate this type of problem from reoccurring.

Thank you for your patience and support.

Sincerely,

Diane Draper
Manager, Regulatory Affairs



MINNTECH
14605 28TH AVE NORTH
PLYMOUTH, MN 55447

RETURN FORM

SteriChek "Sensitive" Total Chloramines and Residual Chlorine
Expanded RECALL

<u>Product Description, Product Code</u>	<u>Lot Number</u>	<u>Quantity Returned*</u>
SteriChek Total Chloramines and Residual Chlorine, 811909 & 812144	_____	_____
Sensitive Total Chlorine Reagent Strips, 821972	_____	_____
Please use additional lines to record product description & code, lot and qty.		
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

* Please indicate the quantity/quantities of SteriChek "Sensitive" Total Chloramines and Residual Chlorine returned to Hach Company.

We have checked our inventory and were unable to locate the above-mentioned product.

Contact Person (Please Print)

Signature

Date

Please return by fax or mail to:

Hach Company
100 Dayton Road
Ames IA 50010
Attention: Diane Draper
Fax Number: 515-956-3820