



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

August 18, 2008

AFL 08-25

TO: Skilled Nursing Facilities
General Acute Care Hospitals
Acute Psychiatric Hospitals
Ambulatory Surgical Centers
Chronic Dialysis Clinics
End Stage Renal Dialysis Clinics
Intermediate Care Facilities
Intermediate Care Facilities for the Developmentally Disabled
Intermediate Care Facilities for the Developmentally Disabled - Habilitative
Intermediate Care Facilities for the Developmentally Disabled - Nursing

SUBJECT: Recall of Environmental Test Systems' SteriChek "Sensitive" Total Chloramines and Residual Chlorine Reagent Strips

On July 21, 2008, Hach Company, parent company of Environmental Test Systems, issued to its distributors a voluntary Expanded Recall Notification of Environmental Test Systems' **SteriChek "Sensitive" Total Chloramines and Residual Chlorine Reagent Strips**. The strips may provide inaccurate readings of dialysis fluid chlorine levels causing hemolytic anemia and related complications. A recent adverse event report indicates that inaccurate chlorine readings at a Florida dialysis center caused hemolytic anemia in 31 of 32 patients; reportedly leading to myocardial infarction in one patient. The adverse event report can be found at the FDA's website <http://www.fda.gov/search/databases.html>. Search the MAUDE database under Medical Devices, brand name SteriChek.

The California Department of Public Health is requesting that you:

1. immediately evaluate your stock of Environmental Test System's SteriChek "Sensitive" Total Chloramines and Residual Chlorine Reagent Strips.
2. ensure the affected products are removed from your facility, and
3. ensure affected products are no longer available for patient use.

The affected products were shipped on or after August 24, 2006. Please contact your supplier of these products for a list of the affected lot numbers.

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If you have questions regarding this issue, please contact Virginia Yamashiro at (916) 324-1266.

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.
Deputy Director
Center for Healthcare Quality