

A test to detect methicillin-resistant *Staphylococcus aureus* (MRSA) and *S aureus* (SA) has been recalled by the manufacturer based on an increasing number of complaints about false negatives for MRSA, the US Food and Drug Administration (FDA) announced yesterday.

The voluntary class 1 recall of the *Xpert MRSA/SA Blood Culture Assay*, manufactured by Cepheid, based in Sunnyvale, California, covers all kits made and distributed from October 21, 2008, through June 21, 2010. The product has been distributed to hospital laboratories worldwide.

Because the test has the rare potential to generate false-negative MRSA results, patients with MRSA infections may receive incorrect treatment or delayed care, according to an alert sent by MedWatch, the FDA's safety information and adverse event reporting program. So far, 1 adverse event has been reported to the agency through its medical device reporting process.

In a July 1 press release announcing the recall, Cepheid stated that the test does not need to be returned to the company. Customers can continue to use the product and report results of MRSA positive/SA positive as such. However, when customers obtain a result of MRSA negative/SA positive, the company recommends conducting further antimicrobial susceptibility testing using an FDA-cleared method for an accurate MRSA finding.

An ongoing "failure investigation" by Cepheid has identified the emergence of novel MRSA strain types as one cause of the false negatives, the company stated. The investigation has yet to fully determine the remaining causes of the erroneous results.

Customers with questions about the recall can contact the Cepheid Technical Support at 1-888-838-3222.

More information on the recall is available on the FDA's [MedWatch Web site](#).

To report adverse events or quality issues related to the Cepheid Xpert MRSA/SA test, contact MedWatch by telephone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at <http://www.fda.gov/medwatch>, or by mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, Maryland 20852-9787.