



## **URGENT MEDICAL DEVICE RECALL**

August 31, 2011

We need to let you know that Alere San Diego, Inc. is initiating a voluntary recall of Strep A products in the cassette and twist formats. This voluntary recall does not include the dipstick format.

Our shipping records indicate that you have received the following affected product. If you have any unused product remaining, immediately discontinue all use and discard it in accordance with your local regulations.

- **CONSULT™ Diagnostics Strep A Cassette (25T) PN 5004, PSS Item # 184558**
- **CONSULT™ Diagnostics Strep A Cassette (50T) PN 5009, PSS Item # 184559**
- **CONSULT™ Diagnostics Strep A Twist PN 5005, PSS Item # 184560**
- **Acceava® Strep A Twist® Cassette PN 92004, PSS Item # 207300**
- **Clearview® Strep A Exact II Cassette PN 92003, PSS Item # 177924**

Through testing it was determined that this product may have an elevated incidence of false positive results. A false positive test result could lead to the administration of antibiotics that are unnecessary. This exposes the patient to potential side effects or allergic reactions. These are rarely serious and are usually resolved with discontinuation of the medication. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. A Health Hazard Evaluation by a medical advisor has concluded that the overall health risk is low. If you have questions about previously reported unexpected Strep A test results, please consult your medical advisor. We are investigating the cause for the elevated number of false positive results.

Please retain this letter for your records as documentation that you have received this information. Please follow the directions and return the attached Verification Form.

Please refer to the attached "Strep A Test Cassette and Twist Field Correction Frequently Asked Questions (FAQs)" for additional information including substitute products.

### **CUSTOMER REQUIRED ACTION**

- **Discontinue use and/or sale of the product.**



- **Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation.**
- **If you have forwarded the product to another laboratory, please provide a copy of this letter to them.**
- **Contact your local PSS Distribution Center to arrange for the return of your remaining inventory and to obtain credit.**

We sincerely apologize for any inconvenience this recall may have caused. Should you have any technical questions or need additional information, please contact Alere Technical Services at 866-216-0094.

For questions on obtaining credit please contact your local PSS Branch.

Sincerely,

Dennis King  
Senior Director  
Quality Assurance  
PSS World Medical, Inc