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Latex allergy test cleared for marketing.

The first laboratory test to help identify people suspected of having allergic reactions to latex received marketing clearance from FDA last March 24. The test, which measures latex antibodies in blood, is not for screening, but it can help prevent future reactions in latex-sensitive people by alerting them to avoid exposure.

A natural rubber used for medical devices such as catheters and surgical gloves, latex can cause allergic reactions ranging from minor skin reddening to fatal anaphylactic shock. Allergic reactions can occur in sensitive people whenever latex comes in contact with the body, even with no apparent prior signs or allergy symptoms.

Latex sensitivity affects an estimated 1 percent of the population, including up to 15 percent of health workers and others exposed to latex regularly, and 34 to 100 percent of people with spina bifida, who are repeatedly exposed to latex tips on enema bottles during treatment.

FDA based its approval on clinical data showing that the test accurately detected latex sensitivity in 87 to 94 percent of those with an allergy. Previously, diagnoses were based on a physical examination and a history of allergic reaction after latex exposure.

The new test, the AlaSTAT Latex-Specific IgE Allergen Test Kit, can be performed in a hospital laboratory using patient blood specimens. Results are available in a few hours.

Diagnostic Products Corporation of Los Angeles makes the test kits.