FDA permits marketing of test to detect periprosthetic joint infection

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(HealthDay)—The Synovasure Lateral Flow Test Kit was granted

approval for marketing as an aid in detecting periprosthetic joint infection when evaluating patients for revision surgery, the U.S. Food and Drug Administration announced.

Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA Center for Devices and Radiological Health, said this test will help clinicians when they are assessing whether a patient should undergo revision surgery and could help to avoid unnecessary revision operations.

The Synovasure Lateral Flow Test Kit can detect human alpha defensins in patients' synovial fluid in about 10 minutes. The FDA notes that the test kit is not meant to identify a specific infection type but is an aid in determining whether infection is present. The test results should be used in combination with other clinical and diagnostic findings when determining diagnosis of infection.

Approval was based on clinical data from 305 prospective synovial fluid samples collected from patients with total knee or hip joint replacement who were being assessed for revision surgery. Researchers found that 89.5 percent of patients with an infection diagnosis based on standard-of-care criteria were also identified as positive for alpha defensins with the Synovasure Lateral Flow Test Kit.

Marketing authorization of the test kit was granted to CD Diagnostics.

More information: More Information