Type 1 diabetes test gets FDA go-ahead

By: SHERRY BOSCHERT, Clinical Endocrinology News Digital Network | August 21, 2014

The Food and Drug Administration has announced (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm410830.htm) that it is allowing marketing of a novel diagnostic test to help differentiate type 1 diabetes from other diseases by detecting zinc transporter 8 autoantibody.

The immune systems of many people with type 1 diabetes generate zinc transporter 8 autoantibody (ZnT8Ab), a substance not produced by people with type 2 diabetes or gestational diabetes.

The new enzyme-linked immunosorbent assay to detect ZnT8Ab in a patient’s blood, when used with other tests and patient clinical information, may help some patients with type 1 diabetes get more timely diagnosis and treatment, the FDA announced. The agency reviewed the test through the de novo premarket regulatory pathway for low- to moderate-risk medical devices that are not substantially equivalent to a device already on the market.

The test detected ZnT8Ab in 65% of 323 patients with diagnosed type 1 diabetes and incorrectly gave a positive result in less than 2% of 246 blood samples from patients diagnosed with other kinds of diabetes, other autoimmune disorders, or other clinical conditions, according to clinical trial data reviewed by the FDA.

“Early treatment of type 1 diabetes is important in helping to prevent further deterioration of insulin-producing cells,” Alberto Gutierrez, Ph.D., said in an FDA statement. "This test can help patients get a timely diagnosis and help start the right treatment sooner,” said Dr. Gutierrez, director of the Office of In Vitro Diagnostics and Radiological Health in the FDA’s Center for Devices and Radiological Health.

A negative result from the ZnT8Ab test does not rule out type 1 diabetes, and the test should not be used to monitor the stage of diabetes or a patient’s response to treatment, the FDA cautioned.

The test is manufactured by Kronus Market Development Associates, Star, Idaho.