MedicalXpress

First newborn screening test approved for rare immune disorder

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(HealthDay)—The first test to screen for Severe Combined Immunodeficiency (SCID) in newborns has been approved by the U.S. Food and Drug Administration.

Some 40 to 100 cases of SCID are identified each year among newborns in the United States, the federal Centers for Disease Control and Prevention says. The group of disorders is caused by genetic defects that influence infection-fighting immune cells. While babies with SCID appear normal at birth, they typically develop deadly infections within a few months, the FDA said in a news release. Death commonly occurs during the infant's first year without early detection and treatment.

The EnLite Neonatal TREC Kit uses a few drops of blood from the baby's heel to look for traits that can help identify SCID. The FDA said it recommends that all states screen newborns for SCID, among other genetic, endocrine and metabolic disorders.

In clinical testing involving 6,400 newborn-blood samples, the new test correctly identified all 17 samples from newborns confirmed to have SCID, the FDA said.

The new test should not be used to screen for other SCID-like syndromes, the FDA said.

The test is produced by a Finnish subsidiary of PerkinElmer, based in Waltham, Mass.

More information: The FDA has more about this approval.