FDA approves newborn screening test for DMD

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January 2020—The FDA authorized marketing of PerkinElmer's GSP Neonatal Creatine Kinase-MM kit, the first test to aid in newborn screening for Duchenne muscular dystrophy.

The GSP Neonatal Creatine Kinase-MM kit is used to measure the levels of CK-MM from dried blood samples collected from the prick of a newborn's heel 24 to 48 hours after birth. Elevated levels of CK-MM detected by the kit may indicate presence of DMD. Results showing elevated CK-MM must be confirmed using other testing methods, such as muscle biopsies and genetic and other laboratory tests.

The kit can be added to a laboratory's newborn screening panel, the FDA said in a press statement, but the authorization does not signal a recommendation for DMD to be added to the Recommended Uniform Screening Panel as a condition for which newborn screening is recommended.

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