

FDA clears lysosomal storage disorder test

September 2018—PerkinElmer has received FDA 510(k) clearance for its NeoLSD MSMS kit, an in vitro diagnostic that uses tandem mass spectrometry to screen for six lysosomal storage disorders in newborns via a single dried blood spot sample. The kit is intended for the quantitative measurement of the activity of the enzymes acid β -glucocerebrosidase, acid sphingomyelinase, acid α -glucosidase, β -galactocerebrosidase, α -galactosidase A, and α -L-iduronidase in dried blood spots from newborn babies. The test enables early diagnosis of LSDs including Gaucher, Niemann-Pick A/B, Pompe, Krabbe, Fabry, and MPS I.

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