FDA authorizes marketing of Fragile X syndrome dx

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April 2020—The FDA authorized the marketing of AmplideX Fragile X Dx and Carrier Screen Kit (Asuragen). It is the first test, according to the FDA, to detect Fragile X syndrome, the most common known cause of inherited developmental delay and intellectual disability. Additionally, this test is intended for use in adults who may be carriers of genetic alterations in the *FMR1* gene.

The kit uses blood specimens from patients to measure the number of repeats of the CGG segment in the *FMR1* gene. The test can determine whether a patient has a number of CGG repeats that is considered normal, intermediate, premutation, or full mutation.

The test can also be used as an aid in the diagnosis of fragile X-associated disorders, including fragile X-associated tremor/ataxia syndrome and fragile X-associated primary ovarian insufficiency. The AmplideX Fragile X Dx and Carrier Screen Kit is not intended for use in fetal diagnostic testing, the screening of eggs obtained for in vitro fertilization prior to implantation, or standalone diagnoses of FXS.

Asuragen, 512-681-5200