canvas Dx™
by cognoa

Indications for Use

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Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism

Spectrum Disorder (autism) for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider. The device is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic process. The device is for prescription use only (Rx only).

Contraindications

There are no contraindications to using Canvas Dx.

Precautions, Warnings

The Device is intended for use by healthcare professionals trained and qualified to interpret the

results of a behavioral assessment examination and to diagnose autism. The Device is intended for use in conjunction with patient history, clinical observations, and other clinical evidence the HCP determines are necessary before making clinical decisions. For instance, additional standardized testing may be sought to confirm the Device output, especially when the Device result is not Positive or Negative for autism.

Canvas Dx is intended for patients with caregivers who have functional English or Spanish capability (8th grade reading level or above) and have access to a compatible smartphone with an internet connection in the home environment.

The Device may give unreliable results if used in patients with other conditions that would have excluded them from the clinical study. Among those conditions are the following:

- Suspected auditory or visual hallucinations or with prior diagnosis of childhood onset schizophrenia
- Known deafness or blindness
- Known physical impairment affecting their ability to use their hands
- Major dysmorphic features or prenatal exposure to teratogens such as fetal alcohol syndrome
- History or diagnosis of genetic conditions (such as Rett syndrome or Fragile X)
- Microcephaly
- History or prior diagnosis of epilepsy or seizures
- History of or suspected neglect
- History of brain defect injury or insult requiring interventions such as surgery or chronic medication

The Device evaluation should be completed within 60 days of the time it is prescribed because neurodevelopmental milestones change rapidly in the indicated age group.