Canvas Dx Prospective Clinical Validation Pivotal Study

Canvas Dx Device Description	Study Year/s	Methods	Participants	Key Findings	Peer Reviewed Publication
Algorithm V1 *Three inputs:* 1. Caregiver Questionnaire 2. Video Analyst Questionnaire 3. Healthcare Provider Questionnaire	2019- 2020	Prospective, double-blinded, active comparator multi-site clinical validation study Device output compared to consensus diagnostic agreement by two or more independent specialists. Specialists were blinded to device output and to diagnostic determination of other specialists. Conducted at 14 sites across 6 U.S states. Objectives: • Achieve a composite of PPV greater than 65% and NPV greater than 85% for the device in relation to the clinical reference standard • Measurement of the No Result rate • Measurement of sensitivity and specificity	**n=425** 36% female; 29% ASD prevalence; mean age 3.33 years (SD = 1.15) Inclusion: • 18 - 72 months • Caregiver or clinician concern for developmental delay	PPV: 81% (95% CI 70%-89%) NPV: 98% (95% CI 91%-100%) 68% No Result rate (95% CI 64%-73%) In subjects for whom the Device rendered a determinate output (ASD positive or ASD negative) sensitivity was 98% (95% CI 92%-100%) and specificity was 79%(95% CI 68%-88% No significant differences in Device performance were found across participant's sex, race/ethnicity, income, or education level.	Megerian, J. T. et al. (2022) Evaluation of an Artificial Intelligence-Based Medical Device for Diagnosis of Autism Spectrum Disorder. NPJ .Digit. Med. 10.1038/s41746-022-00598-6