

**Table 4: Canvas Dx Prospective Clinical Validation Pivotal Study**

Canvas Dx Device Description	Study Year/s	Methods	Participants	Key Findings	Peer Reviewed Publication
<p><b>Algorithm V1</b></p> <p>Three inputs:</p> <ol style="list-style-type: none"> <li>Caregiver Questionnaire</li> <li>Video Analyst Questionnaire</li> <li>Healthcare Provider Questionnaire</li> </ol>	2019- 2020	<p>Prospective, double-blinded, active comparator multi-site clinical validation study</p> <p>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.</p> <p>Conducted at 14 sites across 6 U.S states.</p> <p>Objectives:</p> <ul style="list-style-type: none"> <li>Achieve a composite of PPV greater than 65% and NPV greater than 85% for the device in relation to the clinical reference standard</li> <li>Measurement of the No Result rate</li> <li>Measurement of sensitivity and specificity</li> </ul>	<p><b>n=425</b></p> <p>36% female; 29% ASD prevalence; mean age 3.33 years (SD = 1.15)</p> <p>Inclusion:</p> <ul style="list-style-type: none"> <li>18 - 72 months</li> <li>Caregiver or clinician concern for developmental delay</li> </ul>	<p>PPV: 81% (95% CI 70%-89%) NPV: 98% (95% CI 91%-100%)</p> <p>68% No Result rate (95% CI 64%-73%)</p> <p>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%)</p> <p>No significant differences in Device performance were found across participant's sex, race/ethnicity, income, or education level.</p>	<p>Megerian, J. T. et al. (2022) Evaluation of an Artificial Intelligence-Based Medical Device for Diagnosis of Autism Spectrum Disorder. <i>NPJ Digit. Med.</i> 10.1038/s41746-022-00598-6</p>