

Table 5: Implementation of an Algorithm Threshold Update

Canvas Dx Device Description	Update Year	Methods	Subjects	Updated Performance Metrics	Peer Reviewed Publication
<p>Algorithm V2</p> <p>Three inputs:</p> <ol style="list-style-type: none"> Caregiver Questionnaire Video Analyst Questionnaire Healthcare Provider Questionnaire 	2022	<p>Two datasets were used for the decision threshold modification process, namely the pivotal trial data set and a pre-pivotal data set, providing 722 samples total. Of these 70% (504) were used for training and 30% (218) for testing, ensuring that no training data appear in the test set. The test dataset broadly mirrored U.S. population demographics across race, ethnicity, and socio-economic status. All children in the combined dataset were reflective of the Canvas Dx intended use population (concern for developmental delay, aged 18-72 months). A balance of sex, age and diagnosis was maintained in the threshold optimization data set. Optimization focused on decreasing the No Result rate while ensuring other performance metrics remained comparable to those achieved in the pivotal trial.</p>	<p>n=722</p> <p>28% autism, 22% neurotypical, 50% other developmental delay, mean age 3.6 years, 39% female</p> <p>Inclusion:</p> <ul style="list-style-type: none"> 18 - 72 months Caregiver or clinician concern for developmental delay 	<p>Performance metrics following decision threshold optimization: PPV 87.5% (95% CI 81.7-96.7) NPV 95.6% (95% CI 93.8-98.4)</p> <p>33.5% No Result rate (95% CI 29.5-38.5)</p> <p>In subjects for whom the device rendered a determinate output (ASD positive or ASD negative) sensitivity was 84.8% (95% CI 75.5- 94.3) and specificity was 96.4% (95% CI 94.4-99.0)</p> <p>No significant differences in Device performance were found across participant's sex, race/ethnicity, income, or education level.</p> <p>The optimized thresholds significantly reduced the device's abstention rate while maintaining a comparable NPV, PPV, and determinate group sensitivity and specificity to that observed in the validation trial.</p>	<p>Shannon, J. et al. Optimizing a de novo artificial intelligence-based medical device under a predetermined change control plan: Improved ability to detect or rule out ASD in general pediatric settings. J. Am. Acad. Child Adolesc. Psychiatry 61, S242-243 (2022).</p>