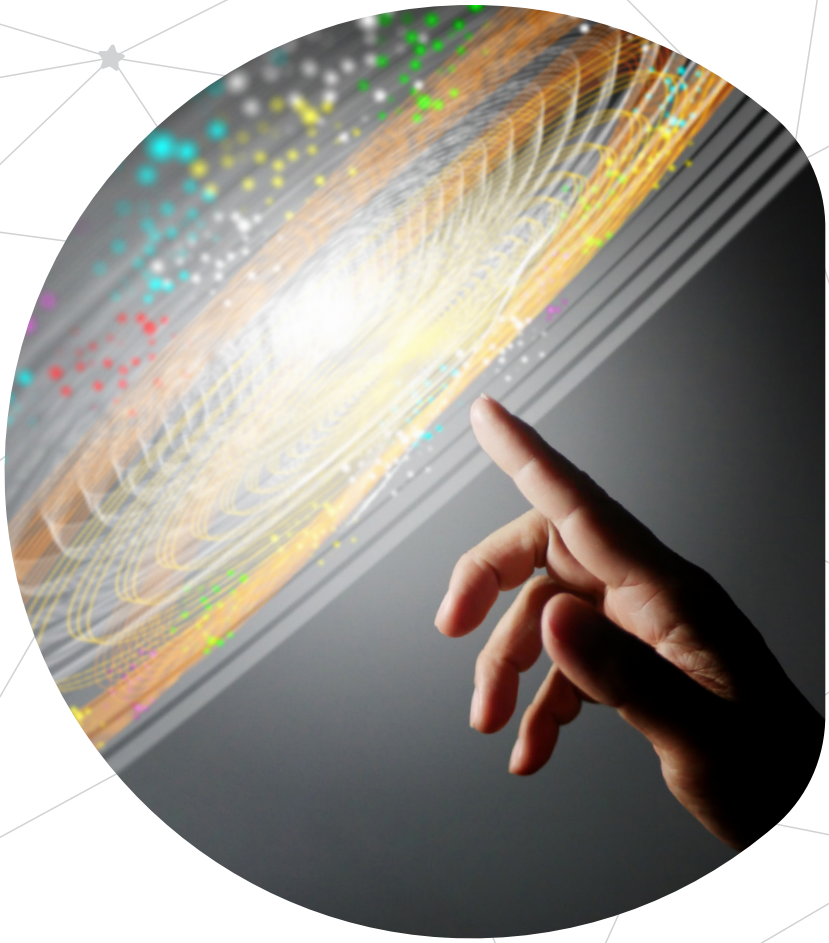

canvas Dx™

Performance Metrics and Clinical Research

canvas Dx by cognoa | **Know Now. Act Sooner.** Because knowing is the earliest intervention.

Performance Metrics

Current Device Performance

As measured in a population of patients with concern for developmental delay (n=761, autism prevalence 39%, 33% female) the Device performs as follows:

Negative Predictive Value (NPV)	Positive Predictive Value (PPV)	Sensitivity*	Specificity*
98.1% (96.1-100%)	86.9% (82.7-91.1%)	98.6% (97.1-100%)	82.8% (77.5-88.1%)

Table 1. Summary of Device Performance (*Sensitivity and Specificity measured in the determinate group)

In the 45.8% of patients for whom the device abstained from providing a determinate result for autism (also referred to as Indeterminate for autism), specialists determined the following autism and other developmental concern prevalences:

Low Indeterminates
- 10% received an autism diagnosis
- 80% had a noted risk of at least one neurodevelopmental condition other than autism

Moderate Indeterminates
- 32% received an autism diagnosis
- 87% had a noted risk of at least one neurodevelopmental condition other than autism

High Indeterminates
- 45% received an autism diagnosis
- 90% had a noted risk of at least one neurodevelopmental condition other than autism

Pivotal Study

Pivotal Study Results

The performance of the Device was evaluated in a 425-patient, 14-site, prospective, clinical study (ClinicalTrials.gov Identifier NCT04151290) that compared the Device output to a reference diagnosis based on DSM-5 criteria by a specialist clinician and corroborated with independent review by a group of specialist clinicians. All study participants and assessors were blinded to the results of the Device. Specialist clinicians were board-certified pediatric psychiatrists, pediatric neurologists, developmental-behavioral pediatricians, or psychologists with at least five years of experience diagnosing autism.

The study population included female and male patients, 18 months through 72 months of age, from a general practice population, for whom a caregiver or HCP had a concern about developmental delay. The autism prevalence in the study population was 29%.

The primary endpoints of the study were the Positive Predictive Value (PPV), the Negative Predictive Value (NPV), and the Indeterminate for autism Rate of the Device.

- **Positive Predictive Value (PPV)** - Probability that a patient identified by the Device as Positive for autism has ASD as determined by specialist clinicians.
- **Negative Predictive Value (NPV)** - Probability that a patient identified by the Device as Negative for autism does not have ASD as determined by specialist clinicians.
- **Indeterminate for autism Rate** - Rate of patients for whom the Device abstained from providing a determinate result due to there being insufficient information to render a "Positive for autism" or "Negative for autism" result.

In the 31.8% of patients for which the Device provided a definitive answer, the Device demonstrated a PPV of 80.8% with a 95% confidence interval of (70.3%, 88.8%) and a NPV of 98.3% (90.6%, 100%). There is no evidence of device performance inconsistency across sex, race/ethnicity, income, or education level.

		Clinical Reference Standard		
		ASD Positive	ASD Negative	Total Subjects
Canvas Dx	Autism Positive	63	15	78
	Autism Negative	1	56	57
	Indeterminate	58	232	290
	Total Subjects	122	303	425

Table 2. Study results comparing number of subjects in each category of Device output to clinical reference standard (specialist consensus diagnosis)

Measures	Value	95% Confidence Interval
PPV	80.8% (63/78)	70.3%, 88.8%
NPV	98.3% (56/57)	90.6%, 100%
Indeterminate for autism Rate	68.2% (290/425)	63.6%, 72.6%

Table 3. Primary Endpoints

Pivotal Study

The Device is designed to return an Indeterminate for autism result when predictive ability is low. In 68.2% of patients, the Device did not provide a determinate result because its predictive reliability was too low to be clinically meaningful using the information available. This procedure of abstaining from prediction when the model response has lower reliability is a well-understood method of risk control in machine learning algorithms.

Within the cohort of patients who received an Indeterminate for autism result, 20% were found to be positive for autism, 71% had a non-autism neurodevelopmental condition, and 9% were found to be neurotypical.

The study also measured the sensitivity and specificity of the Device as secondary endpoints.

- **Sensitivity:** Probability that a patient who specialist clinicians determine has autism is identified by the Device as having autism.
- **Specificity:** Probably that a patient who specialist clinicians determine does not have autism is identified by the Device as not having autism.

At the conclusion of the study, the Device demonstrated a sensitivity of 98.4% (91.6%, 100%) and a specificity of 78.9% (67.6%, 87.7%) in patients for whom the Device provided a determinate output.

Risks related to the study were minimal with no adverse events reported during the study.

Mandatory Reporting of Child Abuse and Neglect

Per the Federal Child Abuse Prevention and Treatment Act (CAPTA), all States require healthcare professionals to report known or suspected instances of child abuse and neglect. If you suspect or know that a child is being abused or neglected, call or text 1.800.4.A CHILD (1.800.422.4453) or consult https://www.childwelfare.gov/ and contact your local child protective services office or law enforcement agency.

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