



**canvas Dx<sup>TM</sup>**

AND SUPPORTING SOFTWARE

# User Guide

for Healthcare Providers (HCPs)



**canvas Dx** | Because Knowing is the First Step.  
by cognoa

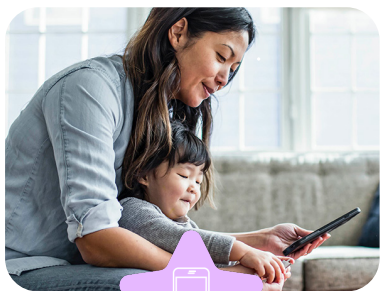
# Table of Contents

Thank you for choosing Canvas Dx, the first FDA authorized diagnostic device that equips you to reliably diagnose or rule out autism in young children and better plan for next steps.

<b>Product Description</b> .....	<b>1</b>
<b>Overview</b> .....	<b>2</b>
<b>The Healthcare Provider Portal</b> .....	<b>3</b>
Setup .....	3
Dashboard .....	5
Adding New Patients .....	5
Understanding the 'Next Step' column.....	6
<b>Completing the HCP Questionnaire</b> .....	<b>7</b>
<b>Device Result</b> .....	<b>8</b>
Accessing & Customizing .....	8
Device Result .....	9
Detailed Report .....	10
Downloading the Report .....	10
<b>Appendices</b> .....	<b>11</b>
Indications for Use .....	11
Minimum Technical Requirements.....	12
When to Prescribe .....	13
Discussing Canvas Dx with Caregivers.....	14
Tips for Successful Completion .....	15
<b>Integrating Canvas Dx into practice</b> .....	<b>16</b>
Clinical Case Studies.....	16
Case Study 1.....	16
Case Study 2 .....	25
Case Study 3 .....	33
Performance Metrics.....	40
Pivotal Study .....	41
Device Algorithm Performance Modification Process .....	43
Algorithm Update.....	44
Contact & Support .....	45

# Product Description | Rx only

Canvas Dx is a prescription diagnostic device designed to support healthcare providers to diagnose or rule out Autism Spectrum Disorder (hereafter referred to as autism) in patients 18 months through 72 months of age. Canvas Dx utilizes a machine-learning algorithm that receives independent inputs from caregivers, trained analysts, and healthcare professionals (see Fig 1). If there is enough information to make a reliable determination, Canvas Dx produces an output that the patient likely does or does not have autism.



## Parent/caregiver questionnaire

Caregiver uses smartphone to answer a brief questionnaire about the child's behavior.



## Two home videos of the child

Caregiver uses smartphone to record and upload two short home videos of the child. Videos are securely transmitted to a portal where trained analysts\* identify key features.



## HCP questionnaire

HCP independently answers a short questionnaire on key developmental behaviors using the HCP portal.



## Algorithm Analysis and Classification for autism



Positive | Negative | Indeterminate



### Canvas Dx Detailed Report

Individualized child development report capturing strengths & challenges across domains to better inform next steps

Fig 1

\*Trained professionals with at least a Master's degree from professional backgrounds including psychology, occupational therapy, physical therapy, speech-language pathology, special education or a related field, and have more than 5 years working with children with autism.

# Overview

## Healthcare Provider Workflow



Video: click or scan QR code to the right  
[Introduction to Canvas Dx for Healthcare Providers](#)

- 1 Prescribe Canvas Dx for children meeting indications for use\*
  - Concern for developmental delay – and –
  - 18–72 months
- 2 Complete the HCP questionnaire

Once caregiver and video analyst inputs are also completed, you will be notified that a result is available to view.
- 3 View, customize and download the Canvas Dx result and Detailed Report\*\*

POSITIVELY FOR AUTISM Result Date: Apr 11 2023 [Download Result](#)

Device Result Caregiver Input HCP Answers Detailed Report

### Canvas Dx Detailed Report

#### Detailed Report

NAME	SEX	DOB
JJ	Male	2021-01-01

**Testing**

Canvas Dx was completed on 2023-03-14 when JJ was 2 year 3 months old.

Canvas Dx is an FDA authorized Diagnostic device for autism that has been clinically validated for use in children with developmental delay concerns aged 18 through 72 months. Canvas Dx captures input from a parent/caregiver questionnaire, a healthcare provider questionnaire, and behavioral observations of the child (made by trained video analysts who view home videos of the child that are uploaded by the parent/caregiver). Inputs are combined in a trained machine learning algorithm to produce an output of "Positive for autism", "Negative for autism" or "Indeterminate for autism".

The Canvas Dx output was: Positive for autism.

This detailed report was generated using Canvas Dx item-level inputs for this child.

**At a Glance**

Visual summary of the child's challenges across developmental domains:

This graph combines item-level data from the three Canvas Dx inputs. In cases where a behavior was recorded as "not observed" (rather than present or absent) the response was excluded from the count.

#### Strength Identification

**Healthcare provider reported:**

- Healthcare provider reports the child imitates actions of caregivers, e.g. vacuuming, household tasks and incorporates it into own play.
- Healthcare provider reports that the child does not engage in repetitive whole-body movements.

**Caregiver reported:**

- Caregiver reports that the child often tends to show concern or try to comfort others when they are upset, sick, or hurt. The child will use different ways to comfort others.
- Caregiver reports that the child often copies or imitates the way they do things around the house. The child will act out or copy a wide range of things that they see.
- Caregiver reports that the child usually uses a variety of expressions that are appropriate to the mood or situation.

#### Observed / reported behaviors and history of concern

##### SOCIAL COMMUNICATION AND SOCIAL INTERACTION

DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Social-emotional reciprocity	<p>Healthcare provider reports the child doesn't smile with people but might smile at other things.</p> <p>Healthcare provider reports the child sometimes offers comfort without prompting but only in certain situations.</p> <p>Videos show some deficits in developing, maintaining, and understanding of relationships.</p> <p>Caregiver reports that the child does not understand the words and phrases that the caregiver says to them. The child does not seem to understand any words.</p> <p>Caregiver reports that the child rarely looks people in the eye during conversations or other social interactions.</p> <p>Caregiver reports that the child rarely responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them.</p> <p>Caregiver reports that the child rarely shows things, like toys, to the caregiver or other people to share their interest and joy for getting help.</p> <p>Caregiver reports that, when smiled at, typically, the child only smiles back if told to, or with familiar people.</p> <p>Caregiver reports that the child rarely plays back-and-forth social games like "patty-cake" or "Simon Says." Caregiver reports that the child is not really interested in playing games with others.</p> <p>Caregiver reports that the child rarely or never tends to share their excitement or happiness with the caregiver and other people.</p>

Example of sections of a Detailed Report generated by Canvas Dx  
[A full sample report can be viewed on pages 17–24](#)

\*For the full list of Indications for Use see [Indications for Use](#)

\*\*HCPs will also have access to their questionnaire responses, caregiver questionnaire responses and uploaded videos, and device performance metrics, to inform their clinical judgment.

# The Healthcare Provider Portal

## Introduction to the Canvas Dx HCP portal



Video: click or scan QR code to the right  
[Canvas Dx HCP Portal: Setup](#)



### The HCP portal is where you:

- Add new patients
- Access and complete the HCP questionnaire
- Follow patient progress through the product
- View, customize and download the Canvas Dx result

The portal can be accessed using a web browser via computer\*



## Setup

1. Look for an email with the subject line: **New Cognoa HCP Portal Account**  
**This email contains the user name and password you will need to access the portal.**

2. Navigate to the portal webpage:

[https://app.cognoa.com/sign\\_in](https://app.cognoa.com/sign_in)

*or scan the QR code to the right*



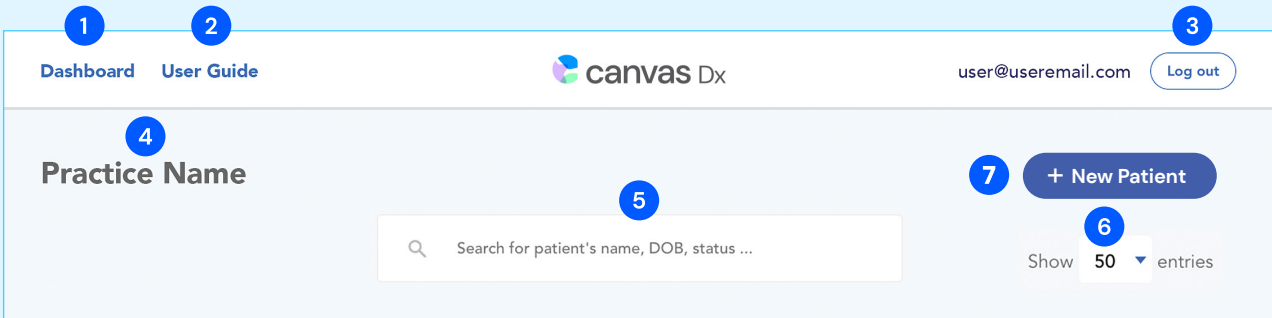
3. Enter the username and password supplied in the email.  
Remember to record and store your username and password in a secure location. **You will need these details each time you log in.**
4. For Two-Factor Authentication\*\*selection, select **Text Message**
5. If your mobile number appears in the box, verify that is correct and click the acknowledgment box, then click **Send Code**. If your number does not appear, enter it manually.
6. Enter the 6 digit code you received via text message into the box labeled **Verification Code**

**You are now logged into the HCP Portal**

\*For minimum technical requirements and cybersecurity considerations please refer to [Appendix](#)

\*\*It is also possible to authenticate using Google Authenticator

# The Healthcare Provider Portal



## 1 Dashboard

Click here to access the Dashboard

## 2 User Guide

Click here to access the full User Guide

## 3 Log out

Click here to log out of the portal

## 4 Practice Name

Customize to your practice

## 5 Search bar

Search by Caregiver name, Patient name, Patient Date of Birth, or Prescriber name

## 6 Show (#) entries

Adjust to show a different number of entries per screen

## 7 + New Patient

Click here to add new patients

# The Healthcare Provider Portal

## Dashboard

Patient Name & DOB ↕	Caregiver Name ↕	Next Step ↕	Prescriber ↕	Prescribed At ↕
Jane Doe Jan 01 2021	John Doe	<a href="#">Answer Questions</a>	Dr. Joseph Roe	2023-04-27 19:42 PST

### The dashboard is where you:

- View your Canvas Dx patients and check on their progress through the product
- Check for [Next Steps](#)
- Access and complete your portion of Canvas Dx (the HCP questionnaire)
- View, customize and download the Canvas Dx result and Detailed Report

Depending on the configuration of your portal and practice, you may see more than one provider listed (if you are a large practice with multiple Canvas Dx prescribers), or you may see only your name listed with the patients' names you specifically prescribed Canvas Dx for. You always have the search function located at the top of the screen as well as the ability to sort each column by clicking the header in ascending or descending order.

## Adding New Patients



Video: [click or scan QR code to the right](#)  
[Adding New Patients](#)



Practice Name

[+ New Patient](#)

Search for patient's name, DOB, status ...

Show 50 entries

1. On the upper right-hand corner of the dashboard click the [+ New Patient](#) button
2. Fill in all required fields
3. Check the [Terms of Use](#) box
4. Click the [Order and Dispense](#) button (located lower left hand corner)

### Tip: prepare in advance by gathering the following details

- ✓ Patient's full name
- ✓ Patient's date of birth
- ✓ Patients' biological sex
- ✓ Caregiver's full name
- ✓ Caregiver's email address
- ✓ Caregiver's mobile phone number

Once you have added the new patient you will be directed to their HCP questionnaire

- If you are ready, complete and submit the questionnaire right away
- If you are not yet ready to complete the questionnaire, navigate back to the main dashboard. The new patient will now be viewable on your dashboard. Click [Answer Questions](#) on the [Next Steps](#) tab to complete their questionnaire at your convenience.

# The Healthcare Provider Portal

## Understanding the 'Next Step' column



Video: click or scan QR code to the right  
[The Next Step column](#)

The **Next Step** column, located inside the dashboard, shows where each of your patients is on their Canvas Dx journey.

- ● **Colored buttons** indicate a next step for you
- **Buttons in gray** show where the patient is on their Canvas Dx journey, but do not require you to take action

Patient Name & DOB	Caregiver Name	Next Step ▾
First name Last name Sep 24 2019	First name Last name	Awaiting Caregiver Answers
First name Last name Sep 24 2019	First name Last name	Answer Questions
First name Last name Sep 24 2019	First name Last name	Positive: Report Saved >
First name Last name Sep 24 2019	First name Last name	Analysis Pending
First name Last name Sep 24 2019	First name Last name	View Result

### Items requiring healthcare provider action/s:

#### Answer Questions

- This item indicates that you have not yet completed your portion of Canvas Dx (the HCP questionnaire)
- *Click through to access and complete the HCP questionnaire*

#### View Result

- This item indicates your patient has completed their Canvas Dx journey
- *Click through to view and download the result and Detailed Report*

#### Positive: Report Saved >

- This item indicates that HCP has reviewed the result and completed the child's assessment

### Items not requiring healthcare provider action/s:

#### Awaiting Caregiver Answers

- Caregiver has not yet completed their questionnaire

#### Awaiting Video

- Caregiver has completed their questionnaire but has not yet uploaded the required videos

#### Analysis Pending

- Videos have been uploaded and are in the queue for video analysis

#### Age out of Range

- After prescription, but prior to beginning Canvas Dx input completion, the child aged out of product use (>72 months). Product can no longer be used.



# Completing the HCP Questionnaire



The questionnaire asks about the child's development, language and communication, sensory, repetitive and stereotypic behaviors and social skills. Answer questions based on your clinical observations, the child's developmental history and caregiver report of behaviors of concern, where relevant. Set aside about 10 minutes to complete the questionnaire. You may find it easiest to complete the questionnaire as part of an in-person or telehealth appointment with the caregiver and child.

## Be prepared!

- Login to the portal and open the questionnaire prior to beginning the appointment
- Review questions in advance if this is your first time using Canvas Dx

**Note:** two slightly different versions of the questionnaire are available:

**18–47 months (13 questions)** and **48–71 months (15 questions)**. The correct version will automatically appear in your portal based on the age of the child you are assessing.

See [Appendix](#) for additional information about completing the questionnaire



## Accessing the Questionnaire



Video: click or scan QR code to the right  
[Accessing the Questionnaire](#)



1. Login to the portal using your username and password
2. Navigate to the portal dashboard and search for the name of the child
3. From the **Next Step** column click **Answer Questions** to open and begin the questionnaire
4. You will be asked to confirm your responses prior to submitting the questionnaire, as answers cannot be changed once submitted. Once you click **Yes**, you will be returned to the dashboard where you can view the current status of the patient on their Canvas Dx journey.
  - a. If your questionnaire was the last outstanding item, your patient's **Next Step** will now show as **View Result**
  - b. Click through to immediately access the result and Detailed Report
  - c. If the caregiver has additional steps to complete, you will see the most current status listed

*In all cases, the HCP should follow the established guidelines when making a medical decision. For example, those of the American Academy of Pediatrics: Identification, Evaluation, and Management of Children with Autism Spectrum Disorder available at <https://doi.org/10.1542/peds.2019-3447>.*

# Device Result

## Accessing & Customizing



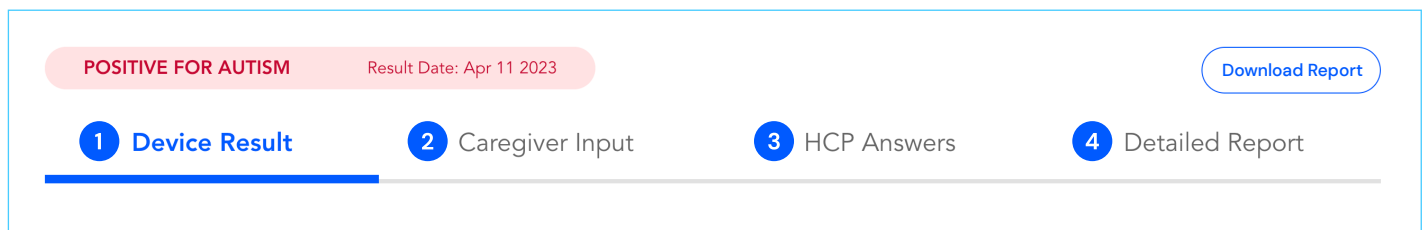
Video: click or scan QR code to the right

[Accessing & Customizing the Device Result](#)



You will receive an email notification when a result is available to view. The subject of the email will read: **Canvas Dx – Result Available**.

1. Navigate to dashboard
2. Locate the correct patient
3. Click **View Result**



The result page has four tabs you can toggle between:

- 1 Device Result**  
Displays the Canvas Dx output of positive, negative or indeterminate for autism
- 2 Caregiver Input**  
Displays the caregiver questionnaire responses and uploaded videos
- 3 HCP Answers**  
Displays the HCP questionnaire responses
- 4 Detailed Report**  
Displays the child's full report and customizable assessment summary

# Device Result

## Positive for autism

**A Positive for autism result from Canvas Dx indicates there is a high probability\* that the child has autism.**

Use this result, in conjunction with the clinical presentation of the child, to determine if DSM-5 diagnostic criteria for autism are met.

*\*Canvas Dx demonstrated a Positive Predictive Value (PPV) of 87.5% (95%CI, 82.5%–96.7%). The PPV is the probability that a child with a positive result from Canvas Dx has autism as determined by specialist clinicians. See [Appendix](#) for more information on the device performance metrics.*

## Negative for autism

**A Negative for autism result from Canvas Dx indicates there is a high probability\* that the child does NOT have autism.**

Use this result, in conjunction with the clinical presentation of the child, to determine that DSM-5 diagnostic criteria for autism are NOT met. Based on your clinical impression, continued monitoring or evaluation for non-autism conditions may be warranted.

*\*Canvas Dx demonstrated a Negative Predictive Value (NPV) of 96.1% (95%CI, 93.4%–98.6%). The NPV is the probability that a child with a negative result from Canvas Dx does not have autism as determined by specialist clinicians. See [Appendix](#) for more information on the device performance metrics.*

## Indeterminate for autism

**This result indicates there was insufficient information for Canvas Dx to render a highly predictive determination for autism.\* It does not mean the child does not have autism.**

**This result DOES NOT mean that Canvas Dx experienced a technical failure or that inputs are invalid or need to be re-entered.**

Based on your clinical impression, continued monitoring or additional evaluation for autism and/or non-autism conditions may be warranted.

*\*Canvas Dx demonstrated a determinate Positive or Negative output rate of 66.5% (95%, 95%CI, 62.5%–71%) and an Indeterminate rate of 33.5%. 96% of subjects who received an indeterminate for autism output had one or more neurodevelopmental conditions, according to blinded specialist assessment.*

# Detailed Report

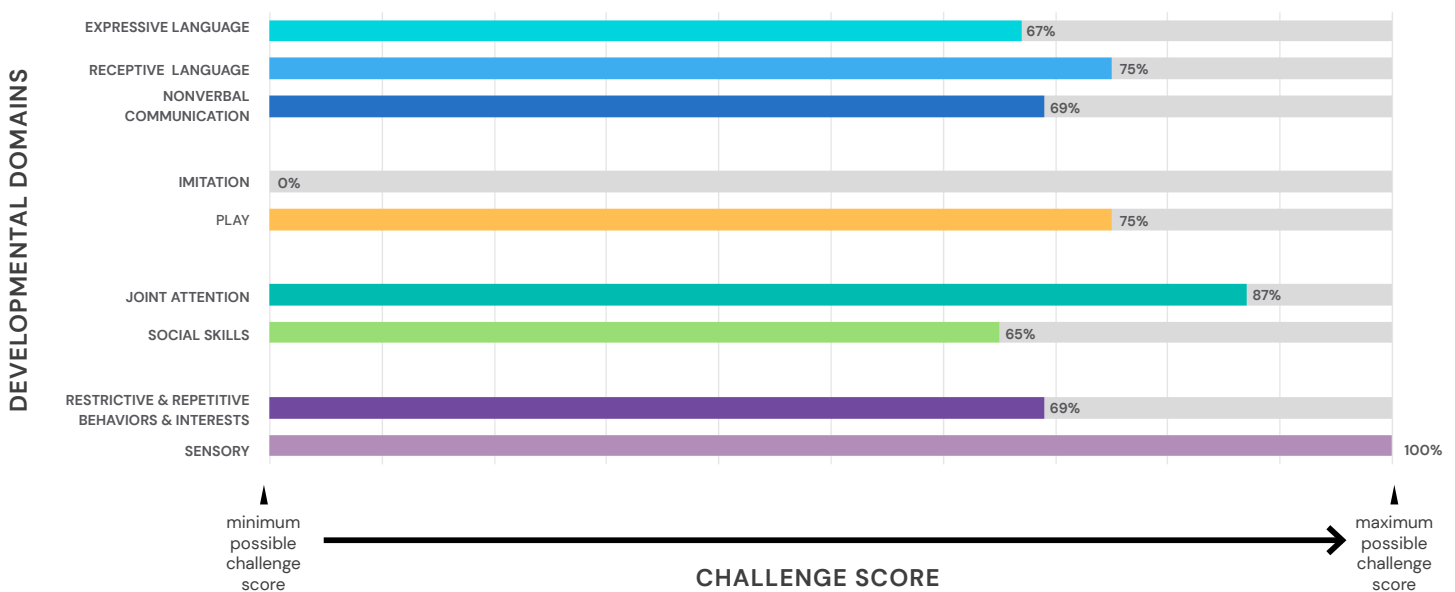
The **Detailed Report** provides a more in-depth look at the child's strengths and challenges across domains and is based on Canvas Dx input-level data. The report includes the following:

- A visual summary of the child's challenges across developmental domains
- A list of caregiver and HCP identified areas of strength for the child
- Caregiver, video analyst and HCP identified challenges mapped to DSM-5 compatible domains relevant to autism diagnosis
- A customizable assessment summary template where HCPs can select diagnostic codes (if relevant) based on their clinical judgment, record additional notes, and make treatment recommendations

## Downloading the Report

Once you have finished reviewing the result and making any desired report customizations, select **Download Report** (upper right-hand corner of the result page) to download the PDF. Please note that the PDF contains personal data and/or protected health information and use care to protect this data.

### Visual summary of the child's challenges across developmental domains:



*example challenge profile*

# Indications for Use

### Indications for Use

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.

# Minimum Technical Requirements

## Minimum Technical Requirements

### Caregiver-facing app

- Mobile Device Operating System: iOS 15 or 16 / Android 12 or 13 (excluding Android Go)
- Mobile Device Storage: 600 MB free
- Mobile Device Camera: Back facing
- Network: Wi-Fi access

The Canvas Dx App is compatible with the most recent and previous version of iOS and Android operating systems. It was running on iOS 12 and 13, as well as Android 9 and 10 operating systems during clinical studies.

### HCP Portal

**Computer Operating system:** Mac (Monterey or Ventura) / Windows 10 or 11

**Browser version:** Chrome (109 or 110) / Safari (15 or 16)

The Canvas Dx HCP Portal supports the most recent and previous version of Chrome and Safari browsers running on the most recent and previous version of Mac and Windows operating systems. It was originally validated on a Mac operating system (Catalina and Mojave) using Chrome (84 or 85) and Safari (12 or 13) browsers. It has not been tested with other browsers such as Firefox or Microsoft Edge.

Please be sure the mobile device, computer and browsers are running an Operating System (OS) version matching those above. If not, please take time to update to the most recent versions.

## Cybersecurity

The measures below are recommended to manage cybersecurity-related risks when using the Device:

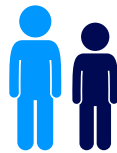
- It is recommended that you set a password on your computer. Do not share your password with others.
- The HCP Portal is password protected to reduce the risk of unauthorized access. We suggest using a unique combination of four words to create a password (“passphrase”). Minimum password requirement is eight (8) characters. For security reasons, please do not share your password with anyone.
- Please log out of the HCP portal anytime you need to step away from your computer. The HCP Portal will log you out automatically after more than 30 minutes of inactivity.
- Avoid using untrusted or unsecured Wi-Fi networks.
- It is recommended that you keep your computer and internet browsers updated to the most recent versions.
- It is also highly recommended that you install security software to protect against malware and viruses.

# When to Prescribe

Canvas Dx can be prescribed to children aged 18–72 months with concern for developmental delay

Developmental concerns could include:

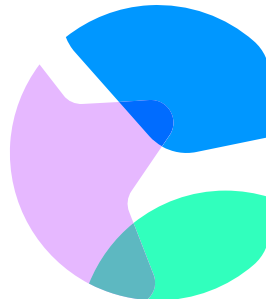
*Healthcare provider observation of developmental delay or atypical behaviors*



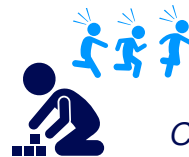
*Sibling with autism*



*Caregiver-reported developmental and/or behavioral concerns*



*Failed developmental screener*



*Child-care/school staff-reported concerns*

- To use Canvas Dx caregivers should have functional English or Spanish capability (8th grade reading level or above)
- The child's caregiver will require access to a [compatible smartphone](#) with internet connection

See the full list of [Indications for Use](#)

# Discussing Canvas Dx with Caregivers

## Caregiver Discussion

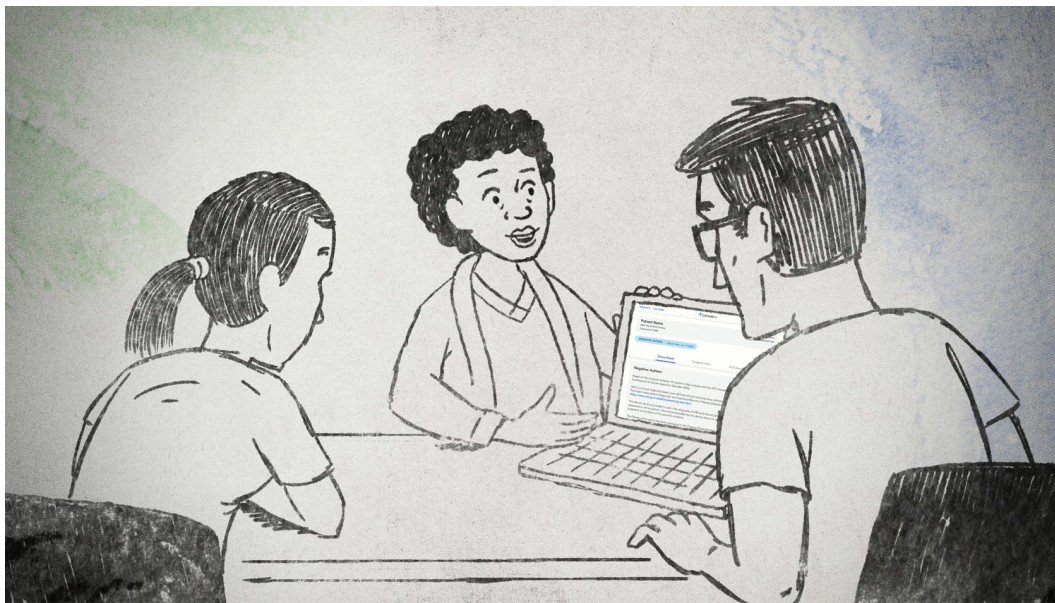


Video: click or scan QR code to the right

Example of an HCP discussing Canvas Dx with a caregiver



Remember to discuss Canvas Dx with the child's caregiver prior to prescribing



Learning that a child has a suspected developmental delay can be stressful for caregivers. It's important to provide the family with an opportunity to ask questions and express concerns.

### [Canvas Dx Overview for Caregivers](#)

contains information that will help caregivers successfully complete their portion of Canvas Dx.

Please share it with families before writing the prescription.



Click or scan the QR code to view and download

The screenshot shows the 'Overview for Caregivers' page for Canvas Dx. It includes a QR code to scan, a list of steps under 'Getting Started', and 'Video Tips'. The steps are: 1. Download the Canvas Dx app from the App Store or Google Play. 2. Complete a short questionnaire. 3. Record and upload two (2) videos of your child. The 'Video Tips' section provides detailed instructions on how to record the videos, such as ensuring the child is clearly visible and the video is at least 30 seconds long.



# Tips for Successful Completion

When answering the questions you can use a combination of sources of knowledge:

## Clinical observations



During a telehealth appointment you observe that JH responds to every question you and his mother ask with the phrase, “Hello superman hello hello.” He also interjects this phrase randomly at other times. **Based on your clinical observation you select the following answer:**

Language and Communication	
2. Uses odd phrases or repeats things over and over again?	
<input type="radio"/>	No.
<input type="radio"/>	Sometimes. Will repeat things but also uses productive language as well.
<input type="radio"/>	Often. Uses odd phrases mixed in with productive language.
<input checked="" type="radio"/>	Yes. Language is mostly repetitive or filled with odd phrases.
<input type="radio"/>	Not applicable. The child still doesn't communicate using phrases.
<input type="radio"/>	No opportunity to assess.

## Developmental history



During an in-person appointment with MS, her dad describes her development as “fairly normal”. However, as MS’s pediatrician since birth, you are aware that her speech was very delayed and she did not begin walking until 24 months. **Based on MS’s developmental history you select the following answer:**

Development	
1. Developmental challenges before age 3?	
<input type="radio"/>	No behavior indicating developmental delay.
<input type="radio"/>	Some uncertainty regarding behavior when compared with children the same age.
<input checked="" type="radio"/>	Developmentally delayed but not as obvious as autism.
<input type="radio"/>	Developmentally delayed and behaviors strongly indicative of autism.
<input type="radio"/>	No opportunity to assess.

## Caregiver report of behaviors and history



During a telehealth appointment VJ’s grandmother reports that he covers his ears, starts rocking and becomes very distressed whenever he hears a loud noise. He stays upset for a long time afterwards. This is only your second time seeing VJ who recently relocated from overseas and does not have any historical medical records available to review. During the appointment VJ has his back turned and keeps running off screen. **Based on the grandmother’s description and history, you select the following answer:**

Sensory, Repetitive & Stereotypic Behaviors	
5. Sensory issues? Upset, angered, or irritated by particular sounds, tastes, smells, sights or textures?	
<input type="radio"/>	No. Doesn't have any sensory issues.
<input type="radio"/>	Sometimes. But his or her reaction is mild.
<input type="radio"/>	Often. But it doesn't interfere too much with daily life.
<input checked="" type="radio"/>	Yes. And it interferes with daily life or prevents an activity.
<input type="radio"/>	No opportunity to assess.

**Note:** In cases where your historical knowledge or clinical observations or history conflict with caregiver report you should answer questions based on your clinical knowledge/observations.

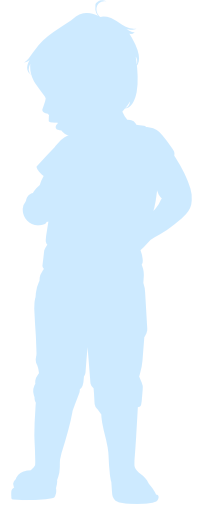
# Integrating Canvas Dx into practice

## Clinical Case Studies

*The following case studies are for illustrative purposes only and are not based on real patients or events. They are not intended to influence clinical decision-making or suggest any particular diagnosis or course of treatment for any particular set of symptoms. They are only intended to illustrate how Canvas Dx can be incorporated into your practice.*

### Case Study 1

JJ is a 2 year 3 month old boy being seen by his primary care pediatrician due to caregiver concerns regarding his development and behaviors. His mother reports that JJ was seen by an occupational therapist at 14 months because of his oral aversions. He has poor eye contact and rarely responds to others. He rarely points to things of interest and doesn't smile or use gestures to communicate. Mother reports he definitely had delays in speech and language. His first words were delayed at 2 years of age, and he currently speaks 1–2 word phrases. JJ currently has an expressive vocabulary of 50–60 words. The pediatrician notes that JJ failed his Ages & Stages questionnaire at his last well-check-up. During the consultation the pediatrician observes JJ avoids eye contact and is hyperfocused while he plays repetitively with the spinning the wheels of the train in the waiting room.



**Based on reported caregiver concerns, observed behavior and history of a failed Ages & Stages questionnaire, the pediatrician prescribes Canvas Dx.**

#### **Canvas Dx returns a “Positive for autism” output for JJ**

The pediatrician uses this output, in conjunction with her observations of JJ, and the family's report of JJ's behavioral difficulties and developmental delays to determine that JJ meets DSM-5 criteria for autism. The pediatrician discusses the findings and next steps with JJ's family.

Given the nature of his delays the pediatrician decides that JJ would benefit most from a combination of ABA, speech and language therapy and OT for his sensory sensitivities.

The pediatrician forwards the Canvas Dx result, together with the Detailed Report and an assessment summary he created within his portal, to relevant providers to access needed therapies.

The pediatrician schedules a future meeting with JJ and his caregivers in 6 weeks time to discuss progress and any arising concerns.

# JJ's Canvas Dx Detailed Report

<b>NAME</b> JJ	<b>SEX</b> Male	<b>DOB</b> 2021-01-01
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## Testing

Canvas Dx was completed on 2023-03-14 when JJ was 2 years 3 months old.

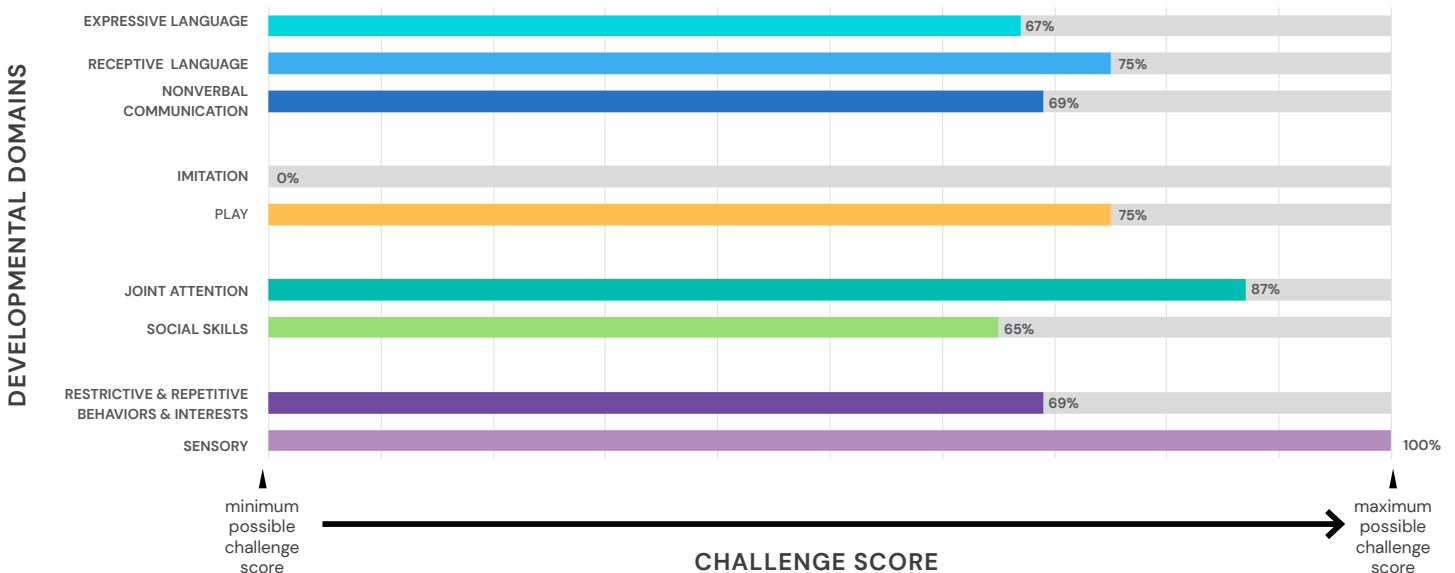
Canvas Dx is an FDA authorized Diagnostic device for autism that has been clinically validated for use in children with developmental delay concerns, aged 18 through 72 months. Canvas Dx captures input from a parent/caregiver questionnaire, a healthcare provider questionnaire, and behavioral observations of the child (made by trained video analysts who view home videos of the child that are uploaded by the parent/caregiver). Inputs are combined in a trained machine learning algorithm to produce an output of 'Positive for autism', 'Negative for autism' or 'Indeterminate for autism'.

The Canvas Dx output was: **Positive for autism**

This detailed report was generated using Canvas Dx item-level inputs for this child.

## At a Glance

Visual summary of the child's challenges across developmental domains:



This graph combines item-level data from the three Canvas Dx inputs. In cases where a behavior was recorded as "not observed" (rather than present or absent) the response was excluded from the count.

# Developmental Domains Overview

DOMAIN	DESCRIPTION	EVIDENCE BASED THERAPIES <sup>1</sup>
Expressive Language	Language that is produced or used to communicate (e.g. the child using words to ask for something)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> </ul>
Receptive Language	The ability to understand and comprehend spoken language (e.g. the child understanding a conversation or request)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> </ul>
Nonverbal Communication	Communication that occurs through ways other than words, such as body language or gestures (e.g. the child using appropriate eye contact during a social interaction)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Social Skills	Ability to use tools to communicate, interact, and build healthy relationships (e.g. the child's ability to engage in group play)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Joint Attention	Ability to share focus on an object or area with another person (e.g. a parent points to a plane in the sky and says "look, a plane" and child looks at parents and then sky to share the experience)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Imitation	Action of copying words, facial expressions or actions of another person (e.g. a child imitates vacuuming after seeing a parent vacuum)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Play	Enjoyable activity when the child is actively engaged (e.g. a child throws a ball back and forth with his friend)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Sensory	Related to processing information from the senses, like sight, smell and sound (e.g. a child has hypersensitivity to the tags in clothing)	Occupational therapy*
Restricted & Repetitive Behaviors and Interests	Highly restrictive or repetitive behaviors fixated on an interest (e.g. a child spends a lot of time lining up his toys)	Behavioral intervention

1. Hyman, S. L., Levy, S. E., & Myers, S. M. (2020). Identification, evaluation, and management of children with autism spectrum disorder. *Pediatrics*, 145(1).

\*Emerging literature/evidence base for sensory integration treatments.

# Strength Identification

## Healthcare provider reported:

- Healthcare provider reports the child imitates actions of caregivers, e.g. vacuuming, household tasks and incorporates it into their own play.
- Healthcare provider reports that the child does not engage in repetitive whole-body movements

## Caregiver reported:

- Caregiver reports that the child often tends to show concern or try to comfort others when they are upset, sick, or hurt. The child will use different ways to comfort others.
- Caregiver reports that the child often copies or imitates the way they do things around the house. The child will act out or copy a wide range of things that they see.
- Caregiver reports that the child usually uses a variety of expressions that are appropriate to the mood or situation.

# Observed / reported behaviors and history of concern

SOCIAL COMMUNICATION AND SOCIAL INTERACTION	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Social-emotional reciprocity	<p><b>Healthcare provider</b> reports the child doesn't smile with people but might smile at other things.</p> <p>Healthcare provider reports the child sometimes offers comfort without prompting but only in certain situations.</p>
	<p><b>Videos</b> show some deficits in developing, maintaining, and understanding of relationships.</p>
	<p><b>Caregiver</b> reports that the child does not understand the words and phrases that the caregiver says to them. The child does not seem to understand any words.</p> <p>Caregiver reports that the child rarely looks people in the eye during conversations or other social interactions.</p> <p>Caregiver reports that the child rarely responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them.</p> <p>Caregiver reports that the child rarely shows things, like toys, to the caregiver or other people to share their interest and not just for getting help.</p> <p>Caregiver reports that, when smiled at, typically, the child only smiles back if told to, or with familiar people.</p> <p>Caregiver reports that the child rarely plays back-and-forth social games like "patty-cake" or "Simon Says." Caregiver reports that the child is not really interested in playing games with others.</p> <p>Caregiver reports that the child rarely or never tends to share their excitement or happiness with the caregiver and other people.</p>

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Detailed Report: 3 of 8

## Observed / reported behaviors and history of concern (cont.)

SOCIAL COMMUNICATION AND SOCIAL INTERACTION (CONT.)	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Nonverbal communication	<p><b>Healthcare provider</b> reports that the child rarely uses hands or gestures to communicate; imitates others only.</p> <p>Healthcare provider reports that the child has little or no eye contact for social interactions.</p> <p>Healthcare provider reports the child rarely socially picks up or shows objects to connect with others. The child brings objects to get help but not to share interest.</p> <p>Healthcare provider reports the child doesn't smile with people but might smile at other things.</p> <p>Healthcare provider reports the child sometimes offers comfort without prompting but only in certain situations.</p> <p>Healthcare provider reports that child sometimes shakes head "no" when asked a question or a request is made but not always.</p> <p>Healthcare provider reports that the child does not point to communicate things or objects of interest from a distance.</p>
	<p><b>Videos</b> show some deficits in nonverbal communication.</p> <p><b>Caregiver</b> reports that, when communicating, the child never uses gestures such as waving "hello" or "good bye," clapping, giving a thumbs-up, or other similar hand signals: The child does not use any gestures or hand signals.</p> <p>Caregiver reports that the child rarely looks people in the eye during conversations or other social interactions.</p> <p>Caregiver reports that the child rarely responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them.</p> <p>Caregiver reports that, when smiled at, typically, the child only smiles back if told to, or with familiar people.</p> <p>Caregiver reports that, when communicating, the child rarely or never naturally shakes their head to mean "No" and nods their head to mean "Yes" without being told to.</p> <p>Caregiver reports that the child rarely or never points to show something the child is interested in that is far away, such as an airplane in the sky, or a toy across the room.</p>
Developing, maintaining, and understanding relationships	<p><b>Healthcare provider</b> reports the child rarely socially picks up or shows objects to connect with others. The child brings objects to get help but not to share interest.</p> <p>Healthcare provider reports the child doesn't smile with people but might smile at other things.</p> <p>Healthcare provider reports the child sometimes offers comfort without prompting and only in certain situations.</p> <p>Healthcare provider reports that the child does not point to communicate things or objects of interest from a distance.</p>

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Detailed Report: 4 of 8

## Observed / reported behaviors and history of concern (cont.)

SOCIAL COMMUNICATION AND SOCIAL INTERACTION (CONT.)	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Developing, maintaining, and understanding relationships	Videos show some deficits in developing, maintaining, and understanding of relationships.
	Videos show some deficits in the quality of the child's play.
	<b>Caregiver</b> reports that the child rarely shows things, like toys, to the caregiver or other people to share their interest and not just for getting help.
	Caregiver reports that the child rarely plays back-and-forth social games like "patty-cake" or "Simon Says." The caregiver reports that the child is not really interested in playing games with others.
	Caregiver reports that the child rarely or never points to show something the child is interested in that is far away, such as an airplane in the sky, or a toy across the room.
Caregiver reports that the child rarely or never tends to share their excitement or happiness with the caregiver and other people.	
Caregiver reports that the child rarely starts playing on their own with toys, crafts, games, or other activities without the caregiver's help.	

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## Observed / reported behaviors and history of concern (cont.)

RESTRICTIVE OR REPETITIVE BEHAVIORS AND INTERESTS	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Stereotypic or repetitive behaviors	<b>Healthcare provider</b> reports abnormal playing with toys or objects with some repetitive use of objects but doesn't interfere with other activities.
	<b>Videos</b> show some examples of restricted, repetitive behavior.
	Videos show some examples of unusual sensory and/or repetitive interests.
Ritualized or inflexible behaviors	<b>Caregiver</b> reports that the child usually seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening: The child has a lot of very intense sensory interests, and it is difficult to get them to stop or to do something else.
Highly restricted, fixated interests	<b>Healthcare provider</b> reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time.
	<b>Caregiver</b> reports that the child usually seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening: The child has a lot of very intense sensory interests, and it is difficult to get them to stop or to do something else.
	Caregiver reports that, when playing alone or with toys, the child never pretends or makes up stories and characters.
Hyper- or hyporeactivity or unusual interest in sensory input	<b>Healthcare provider</b> reports the child often has sensory issues, that is, upset, angered, or irritated by particular sounds, tastes, smells, sights or textures, and it interferes with daily life or prevents an activity.
	Healthcare provider reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time.
	<b>Videos</b> show some examples of unusual sensory and/or repetitive interests.
	<b>Caregiver</b> reports that the child usually predictably gets upset by certain common noises, smells, sights, textures, flavors, or movements: This interferes with a lot of their daily activities.
	Caregiver reports that the child usually seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening: The child has a lot of very intense sensory interests, and it is difficult to get them to stop or to do something else.



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**Developmental history:**

- In relation to the child's development, the caregiver reports that the child has had definite delays in development, such as a speech delay, but no difficulties socially interacting and no unusual behaviors
- Healthcare provider reports the child is developmentally delayed before age 3 but not obvious as autism.

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**Clinically significant impairment in social, occupational, or other important areas of current functioning:**

- Caregiver reports that the child does not understand the words and phrases that the caregiver says to them. The child does not seem to understand any words.
- Caregiver reports that the child usually predictably gets upset by certain common noises, smells, sights, textures, flavors, or movements: This interferes with a lot of their daily activities.
- Caregiver reports that the child usually seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening: The child has a lot of very intense sensory interests, and it is difficult to get them to stop or to do something else.
- Healthcare provider reports the child often has sensory issues, that is, upset, angered, or irritated by particular sounds, tastes, smells, sights or textures, and it interferes with daily life or prevents an activity.
- Healthcare provider reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time

# Assessment Summary prepared by Dr. Light Beacon, MD

JJ is a 2 year 3 months old who presents with symptoms of challenge in the following domains: social-emotional reciprocity; nonverbal communication; developing, maintaining, and understanding relationships; stereotypic or repetitive behaviors; ritualized or inflexible behaviors; highly restricted, fixated interests; hyper- or hyporeactivity or unusual interest in sensory input; expressive language; receptive language; social skills; play; joint attention

Dr. Light Beacon, MD findings:

- F84.0 Autistic disorder: Based on testing (results above), caregiver input, clinician and objective findings, DSM-5 criteria and evidence of impairment this child meets criteria for Autism Spectrum Disorder.

## Restricted, repetitive behaviors domain severity rating

- (3) Very Substantial Support

## Social communication domain severity rating

- (3) Very Substantial Support

## Intellectual disability present

- No intellectual disability present

- Disturbances are not better explained by intellectual disability or global developmental delay
- Symptoms cause clinically significant impairment in social, occupational, or other important areas of current functioning


## RECOMMENDATIONS

Early intensive behavioral intervention

- Applied Behavior Analysis (ABA) Services
- Speech & Language Therapy
- Occupational Therapy
- Early Intervention (0-3 years old)

## Notes:

Parent to provide update in 6 weeks as to access of services recommended and given local parental resources. Follow-up appointment for JJ recommended in 2 months.

<b>PROVIDER NAME</b> Dr. Light Beacon	<b>PROVIDER CREDENTIALS</b> MD
<b>SIGNATURE</b> 	<b>DATE</b> 03/14/2023

# Integrating Canvas Dx into practice: Clinical Case Studies

## Case Study 2

RM is a 2 year, 3 month old boy being seen by his primary care pediatrician due to caregiver concerns regarding his development and behaviors. His mother reports that at age 15 months, RM started having increased temper tantrums because he could not express his needs. Mother reports using time-out and redirection for these tantrums, but states that the tantrums can last up to an hour. Mother reports early motor developmental milestones were on time (fine, gross motor). His first words were delayed at 18 mo and he currently speaks some sentences. He interacts well with his parents, has good eye contact and at times can be very pleasant and cooperative. His diet is somewhat restricted, and he won't eat any vegetables and a few fruits. This has resulted in constipation and delayed toilet training; he is trained for urine but will not have a bowel movement on the toilet. He has very few items of clothing that he can wear; clothing that "feels bad" will set off his tantrums. When RM is constipated his behavior is much worse, and he has many more tantrums. His behavior has resulted in being expelled from one preschool, and parents are concerned about enrolling him in another preschool.

**Based on caregiver report and observed behavior the pediatrician prescribes Canvas Dx.**

### **Canvas Dx returns an "Indeterminate for autism" result for RM**

The pediatrician uses this result, in conjunction with his observations of RM, and the family's report of RM's behavioral difficulties to evaluate if RM meets DSM-5 criteria for autism. Because of his complex behaviors, in combination with the "Indeterminate for autism" result, the pediatrician decides RM would benefit from a specialty evaluation to help determine a specific diagnosis. Based on findings in the detailed report, the pediatrician also determines that RM has a mixed receptive-expressive language disorder and suspected sensory integration disorder and risk for ADHD.

The pediatrician forwards the Canvas Dx result, together with the detailed report and an assessment summary he created within his portal, to the specialist to streamline future investigations.

While waiting for the specialist evaluation results, provides referrals for Speech and Language Therapy and Occupational Therapy to begin addressing RM's noted challenges as soon as possible.

The pediatrician discusses the findings and next steps with RM's family and schedules a future meeting with RM and his caregivers in 6 weeks time to discuss progress and any arising concerns.

# RM's Canvas Dx Detailed Report

<b>NAME</b> RM	<b>SEX</b> Male	<b>DOB</b> 2021-01-01
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## Testing

Canvas Dx was completed on 2023-03-14 when RM was 2 years 3 months old.

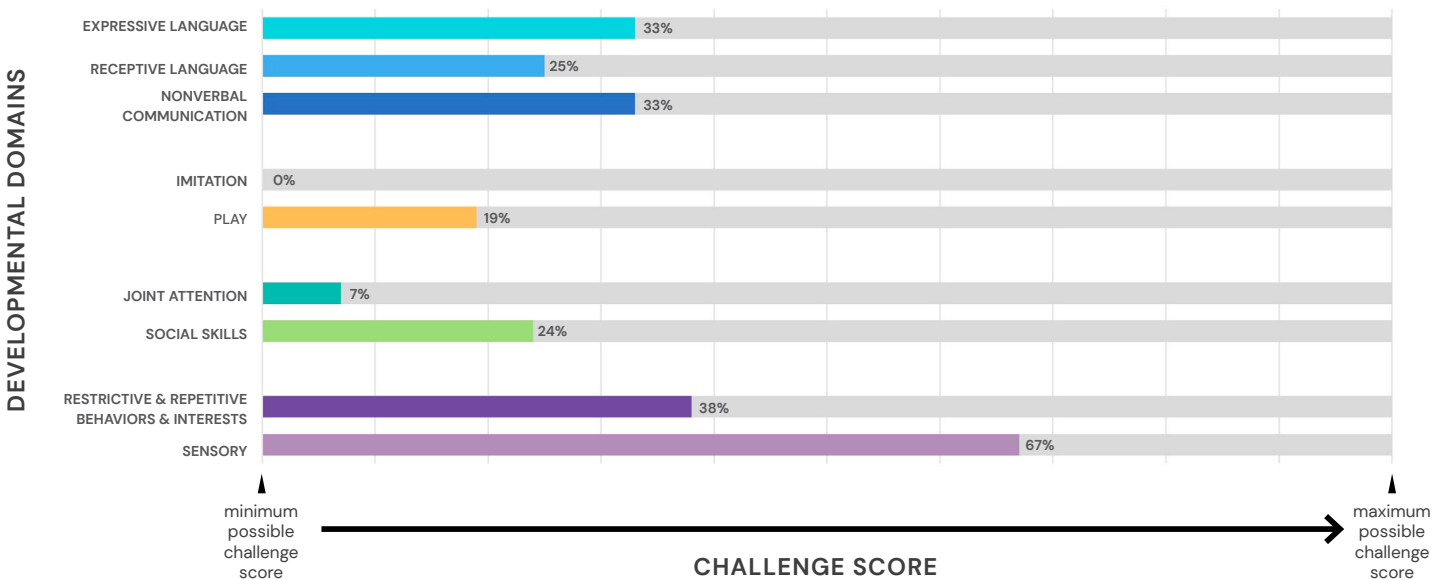
Canvas Dx is an FDA authorized Diagnostic device for autism that has been clinically validated for use in children with developmental delay concerns, aged 18 through 72 months. Canvas Dx captures input from a parent/caregiver questionnaire, a healthcare provider questionnaire, and behavioral observations of the child (made by trained video analysts who view home videos of the child that are uploaded by the parent/caregiver). Inputs are combined in a trained machine learning algorithm to produce an output of 'Positive for autism', 'Negative for autism' or 'Indeterminate for autism'.

The Canvas Dx output was: **Indeterminate for autism**

This detailed report was generated using Canvas Dx item-level inputs for this child.

## At a Glance

Visual summary of the child's challenges across developmental domains:



This graph combines item-level data from the three Canvas Dx inputs. In cases where a behavior was recorded as "not observed" (rather than present or absent) the response was excluded from the count.

# Developmental Domains Overview

DOMAIN	DESCRIPTION	EVIDENCE BASED THERAPIES <sup>1</sup>
Expressive Language	Language that is produced or used to communicate (e.g. the child using words to ask for something)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> </ul>
Receptive Language	The ability to understand and comprehend spoken language (e.g. the child understanding a conversation or request)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> </ul>
Nonverbal Communication	Communication that occurs through ways other than words, such as body language or gestures (e.g. the child using appropriate eye contact during a social interaction)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Social Skills	Ability to use tools to communicate, interact, and build healthy relationships (e.g. the child's ability to engage in group play)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Joint Attention	Ability to share focus on an object or area with another person (e.g. a parent points to a plane in the sky and says "look, a plane" and child looks at parents and then sky to share the experience)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Imitation	Action of copying words, facial expressions or actions of another person (e.g. a child imitates vacuuming after seeing a parent vacuum)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Play	Enjoyable activity when the child is actively engaged (e.g. a child throws a ball back and forth with his friend)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Sensory	Related to processing information from the senses, like sight, smell and sound (e.g. a child has hypersensitivity to the tags in clothing)	Occupational therapy*
Restricted & Repetitive Behaviors and Interests	Highly restrictive or repetitive behaviors fixated on an interest (e.g. a child spends a lot of time lining up his toys)	Behavioral intervention

1. Hyman, S. L., Levy, S. E., & Myers, S. M. (2020). Identification, evaluation, and management of children with autism spectrum disorder. *Pediatrics*, 145(1).

\*Emerging literature/evidence base for sensory integration treatments.

# Strength Identification

## Healthcare provider reported:

- Healthcare provider reports the child socially picks up or shows objects to connect with others. The child will regularly bring objects to show others to share interest.
- Healthcare provider reports the child smiles often with a variety of people.
- Healthcare provider reports the child imitates actions of caregivers, e.g. vacuuming, household tasks and incorporates it into their own play.
- Healthcare provider reports that the child points to communicate things of interest from a distance. The child both points at things and looks at others to get their attention.

## Caregiver reported:

- Caregiver reports that the child understands the words and phrases that the caregiver says to them very well: The child is able to understand more than 50 words even when said in a new way, like "put your socks on your hands."
- Caregiver reports that the child usually responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them.
- Caregiver reports that the child often copies or imitates the way they do things around the house. The child will act out or copy a wide range of things that they see.
- Caregiver reports that the child usually uses a variety of expressions that are appropriate to the mood or situation.
- Caregiver reports that, when playing alone or with toys, the child usually pretends or makes up stories and characters.
- Caregiver reports that the child usually points to show something the child is interested in that is far away, such as an airplane in the sky, or a toy across the room and checks back to make sure you are paying attention.
- Caregiver reports that the child usually tends to share their excitement or happiness with the caregiver and other people: The child shares their enjoyment in different ways, and with multiple people

# Observed / reported behaviors and history of concern

SOCIAL COMMUNICATION AND SOCIAL INTERACTION	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Social-emotional reciprocity	<p><b>Caregiver</b> reports that the child sometimes looks people in the eye during conversations or other social interactions but the child only makes brief or inconsistent eye contact.</p> <p>Caregiver reports that the child sometimes shows things, like toys, to the caregiver or other people to share their interest and not just for getting help.</p> <p>Caregiver reports that, when smiled at, typically, the child only sometimes smiles back.</p> <p>Caregiver reports that the child only sometimes tends to show concern or try to comfort others when they are upset, sick, or hurt.</p> <p>Caregiver reports that the child only sometimes plays back-and-forth social games like "patty-cake" or "Simon Says."</p>
	<p><b>Healthcare provider</b> reports the child rarely offers comfort without prompting. The child tries to do so in odd ways such as laughing when someone is crying.</p>

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Detailed Report: 3 of 7

## Observed / reported behaviors and history of concern (cont.)

SOCIAL COMMUNICATION AND SOCIAL INTERACTION (CONT.)	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Nonverbal communication	<p><b>Caregiver</b> reports that, when communicating, the child sometimes uses gestures such as waving "hello" or "goodbye," clapping, giving a thumbs-up, or other similar hand signals. The child uses a few gestures.</p> <p>Caregiver reports that the child sometimes looks people in the eye during conversations or other social interactions but the child only makes brief or inconsistent eye contact.</p> <p>Caregiver reports that, when smiled at, typically, the child only sometimes smiles back.</p> <p>Caregiver reports that, when communicating, the child only sometimes naturally shakes their head to mean "No" and nods their head to mean "Yes" without being told to.</p>
	<p><b>Videos</b> show some deficits in nonverbal communication.</p>
	<p><b>Healthcare provider</b> reports that the child sometimes uses a few hand signals or gestures, but not everywhere or with everyone.</p> <p>Healthcare provider reports that the child uses some eye contact, which is brief or inconsistent during social interactions.</p> <p>Healthcare provider reports the child rarely offers comfort without prompting. The child tries to do so in odd ways such as laughing when someone is crying.</p> <p>Healthcare provider reports that child sometimes shakes head "No" when asked a question or a request is made but not always.</p>
	<p><b>Healthcare provider</b> reports the child rarely offers comfort without prompting. The child, tries to do so in odd ways such as laughing when someone is crying.</p>
Developing, maintaining, and understanding relationships	<p><b>Caregiver</b> reports that the child rarely starts playing on their own with toys, crafts, games, or other activities without the caregiver's help.</p> <p>Caregiver reports that the child sometimes shows things, like toys, to the caregiver or other people to share their interest and not just for getting help.</p> <p>Caregiver reports that the child only sometimes tends to show concern or try to comfort others when they are upset, sick, or hurt.</p> <p>Caregiver reports that the child only sometimes plays back-and-forth social games like "patty-cake" or "Simon Says."</p>
	<p><b>Healthcare provider</b> reports the child rarely offers comfort without prompting. The child, tries to do so in odd ways such as laughing when someone is crying.</p>
	<p><b>Healthcare provider</b> reports the child rarely offers comfort without prompting. The child, tries to do so in odd ways such as laughing when someone is crying.</p>
	<p><b>Healthcare provider</b> reports the child rarely offers comfort without prompting. The child, tries to do so in odd ways such as laughing when someone is crying.</p>

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## Observed / reported behaviors and history of concern (cont.)

RESTRICTIVE OR REPETITIVE BEHAVIORS AND INTERESTS	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Stereotypic or repetitive behaviors	Healthcare provider reports that the child occasionally engage in repetitive whole-body movements.
	Videos show some examples of unusual sensory and/or repetitive interests.
Ritualized or inflexible behaviors	Caregiver reports that the child sometimes seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening. The child has a few sensory interests, but this does not interfere with playing, or with other activities.
Highly restricted, fixated interests	Caregiver reports that the child sometimes seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening. The child has a few sensory interests, but this does not interfere with playing, or with other activities.
Hyper- or hyporeactivity or unusual interest in sensory input	Caregiver reports that the child often predictably gets upset by certain common noises, smells, sights, textures, flavors, or movements, however, this does not interfere much with daily activities.
	Caregiver reports that the child sometimes seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening. The child has a few sensory interests, but this does not interfere with playing, or with other activities.
	Healthcare provider reports the child often has sensory issues, that is, upset, angered, or irritated by particular sounds, tastes, smells, sights or textures, and it interferes with daily life or prevents an activity.
	Healthcare provider reports the child sometimes has unusual sensory interests. The child tends to seek out or focus on one or two interests routinely.



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**Developmental history:**

- In relation to the child's development, the caregiver reports that the child met all milestones, but with a few concerns.
- Healthcare provider reports some developmental delay is suspected before age 3.

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**Clinically significant impairment in social, occupational, or other important areas of current functioning:**

- Healthcare provider reports the child often has sensory issues, that is, upset, angered, or irritated by particular sounds, tastes, smells, sights or textures, and it interferes with daily life or prevents an activity.

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## Assessment Summary prepared by Dr. Light Beacon, MD

RM is a 2 year 3 months old who presents with symptoms of challenge in the following domains: social-emotional reciprocity; developing, maintaining, and understanding relationships; nonverbal communication, stereotypic or repetitive behaviors; ritualized or inflexible behaviors; highly restricted, fixated interests; hyper- or hyporeactivity or unusual interest in sensory input; expressive language; receptive language; play; joint attention; social skills

Dr. Light Beacon, MD findings:

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- F80.2 Mixed receptive-expressive language disorder
  - Other Suspect sensory integration disorder and risk for ADHD
- 

### RECOMMENDATIONS

- Speech & Language Therapy
- Occupational Therapy
- Referral to specialist for additional assessment: Neuropsychological testing

### Notes:

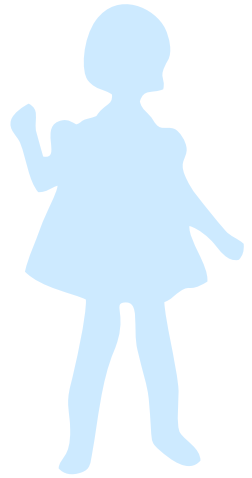
Parents to provide update in 6 weeks as to access of services recommended. Referral sent to specialist for neuropsych testing and determination of definitive diagnosis.

<b>PROVIDER NAME</b> Dr. Light Beacon	<b>PROVIDER CREDENTIALS</b> MD
<b>SIGNATURE</b> 	<b>DATE</b> 03/14/2023

# Integrating Canvas Dx output into practice: Clinical Case Studies

## Case Study 3

LS is a 2 year 3 month old girl being seen by her primary care pediatrician due to caregiver concerns regarding her development. Her father reports that she was 4 weeks premature and early motor developmental milestones were somewhat delayed. LS didn't sit independently until she was 9 months old and didn't walk until she was 20 months old. She was referred to Early Intervention for her physical delays and is now walking, running, and jumping appropriately. Her fine motor milestones are intact. Her speech is also delayed; her first words were at 2 yr and she currently speaks 1–2–word phrases. LS makes eye contact, points to objects to show her parents, and understands most commands. LS currently has an expressive vocabulary of 50–60 words, and strangers understand about ½ of these words. She is cooperative and is already toilet trained. LS has an older brother with autism and parents are concerned that she may have autism as well.



Based on reported caregiver concerns, observed behavior and history of a brother with autism the pediatrician prescribes Canvas Dx.

### Canvas Dx returns a “Negative for autism” result for LS

The pediatrician uses this output, in conjunction with her observations of LS, and the family's report of LS's developmental delays to determine that LS **does not** meet DSM–5 criteria for autism. She discusses the findings and next steps with LS's family.

Given the nature of her delays the pediatrician decides that LS would benefit from speech and language therapy. She would also benefit from an early childhood special education program and will need an Individualized Education Plan (IEP) once she is three years old.

The pediatrician schedules a future meeting with LS and her caregivers in 6 weeks time to discuss progress and any arising concerns.

# LS's Canvas Dx Detailed Report

<b>CHILDS NAME</b> LS	<b>SEX</b> Male	<b>DOB</b> 2021-01-01
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## Testing

Canvas Dx was completed on 2023-03-14 when LS was 2 years 3 months old.

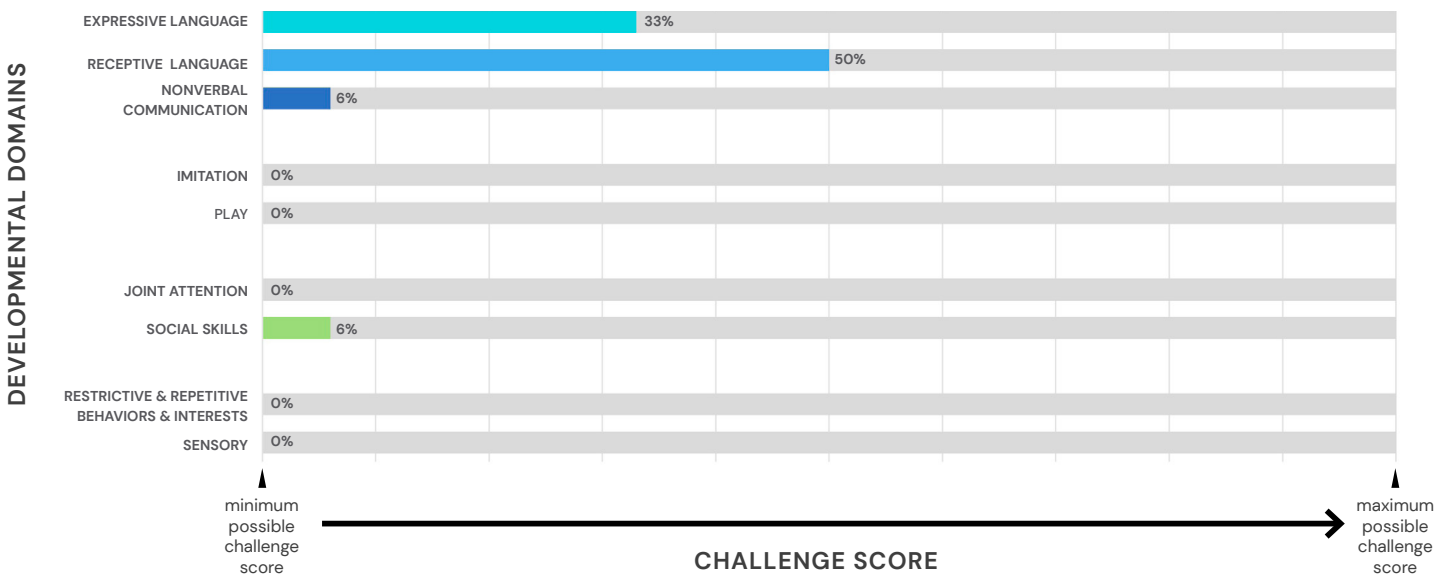
Canvas Dx is an FDA authorized Diagnostic device for autism that has been clinically validated for use in children with developmental delay concerns, aged 18 through 72 months. Canvas Dx captures input from a parent/caregiver questionnaire, a healthcare provider questionnaire, and behavioral observations of the child (made by trained video analysts who view home videos of the child that are uploaded by the parent/caregiver). Inputs are combined in a trained machine learning algorithm to produce an output of 'Positive for autism', 'Negative for autism' or 'Indeterminate for autism'.

The Canvas Dx output was: **Negative for autism**

This detailed report was generated using Canvas Dx item-level inputs for this child.

## At a Glance

Visual summary of the child's challenges across developmental domains:



This graph combines item-level data from the three Canvas Dx inputs. In cases where a behavior was recorded as "not observed" (rather than present or absent) the response was excluded from the count.

# Developmental Domains Overview

DOMAIN	DESCRIPTION	EVIDENCE BASED THERAPIES <sup>1</sup>
Expressive Language	Language that is produced or used to communicate (e.g. the child using words to ask for something)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> </ul>
Receptive Language	The ability to understand and comprehend spoken language (e.g. the child understanding a conversation or request)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> </ul>
Nonverbal Communication	Communication that occurs through ways other than words, such as body language or gestures (e.g. the child using appropriate eye contact during a social interaction)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Social Skills	Ability to use tools to communicate, interact, and build healthy relationships (e.g. the child's ability to engage in group play)	<ul style="list-style-type: none"> <li>• Speech/language therapy</li> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Joint Attention	Ability to share focus on an object or area with another person (e.g. a parent points to a plane in the sky and says "look, a plane" and child looks at parents and then sky to share the experience)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Imitation	Action of copying words, facial expressions or actions of another person (e.g. a child imitates vacuuming after seeing a parent vacuum)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Play	Enjoyable activity when the child is actively engaged (e.g. a child throws a ball back and forth with his friend)	<ul style="list-style-type: none"> <li>• Social skills training</li> <li>• Early Intensive Behavioral Intervention (e.g. ABA, NDBI)</li> <li>• Developmental therapy (e.g. DIRFloortime<sup>®*</sup>)</li> </ul>
Sensory	Related to processing information from the senses, like sight, smell and sound (e.g. a child has hypersensitivity to the tags in clothing)	Occupational therapy*
Restricted & Repetitive Behaviors and Interests	Highly restrictive or repetitive behaviors fixated on an interest (e.g. a child spends a lot of time lining up his toys)	Behavioral intervention

1. Hyman, S. L., Levy, S. E., & Myers, S. M. (2020). Identification, evaluation, and management of children with autism spectrum disorder. *Pediatrics*, 145(1).

\*Emerging literature/evidence base for sensory integration treatments.

# Strength Identification

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## Healthcare provider reported:

- Healthcare provider reports that the child often uses hand signals to convey a message: The child spontaneously uses a variety of hand signals or gestures to get what they want.
  - Healthcare provider reports that the child consistently looks back and forth during conversations.
  - Healthcare provider reports the child socially picks up or shows objects to connect with others. The child will regularly bring objects to show others to share interest.
  - Healthcare provider reports the child smiles often with a variety of people.
  - Healthcare reports the child offers comfort without prompting in a variety of ways using appropriate facial expressions.
  - Healthcare provider reports the child does not have any sensory issues.
  - Healthcare provider reports the child imitates actions of caregivers, e.g. vacuuming, household tasks and incorporates it into their own play.
  - Healthcare provider reports the child has no unusual sensory interests.
  - Healthcare provider reports that the child points to communicate things of interest from a distance. The child both points at things and looks at others to get their attention.
  - Healthcare provider reports no abnormal playing with toys or objects. The child shows little or no repetitive use of objects.
  - Healthcare provider reports that the child does not engage in repetitive whole-body movements.
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## Caregiver reported:

- Caregiver reports that the child usually starts playing on their own with toys, crafts, games, or other activities without the caregiver's help.
- Caregiver reports that, when communicating, the child usually uses gestures such as waving "hello" or "goodbye," clapping, giving a thumbs-up, or other similar hand signals: The child frequently uses many different gestures appropriate to the situation.
- Caregiver reports that the child usually looks people in the eye during conversations or other social interactions: The child uses appropriate eye contact.
- Caregiver reports that the child usually responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them.
- Caregiver reports that the child usually shows things, like toys, to the caregiver or other people to share their interest and not just for getting help.
- Caregiver reports that, when smiled at, typically, the child usually smiles back.
- Caregiver reports that the child often tends to show concern or try to comfort others when they are upset, sick, or hurt. The child will use different ways to comfort others.
- Caregiver reports that the child usually plays back-and-forth social games like "patty-cake" or "Simon says." Caregiver reports that the child enjoys social games like this.
- Caregiver reports that the child rarely or never predictably gets upset by certain common noises, smells, sights, textures, flavors, or movements.
- Caregiver reports that the child often copies or imitates the way they do things around the house. The child will act out or copy a wide range of things that they see.
- Caregiver reports that the child usually uses a variety of expressions that are appropriate to the mood or situation.
- Caregiver reports that the child rarely or never seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening.

Detailed Report: 3 of 6

- Caregiver reports that, when playing alone or with toys, the child usually pretends or makes up stories and characters.
- Caregiver reports that, when communicating, the child usually naturally shakes their head to mean "No" and nods their head to mean "Yes" without being told to.
- Caregiver reports that the child usually points to show something the child is interested in that is far away, such as an airplane in the sky, or a toy across the room and checks back to make sure you are paying attention.
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## Observed / reported behaviors and history of concern

SOCIAL COMMUNICATION AND SOCIAL INTERACTION	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Social-emotional reciprocity	Caregiver reports that the child only somewhat understands the words and phrases that the caregiver says to them: The child is able to understand more than 50 words but not when put together into phrases.
Nonverbal communication	Healthcare provider reports that child sometimes shakes head "No" when asked a question or a request is made but not always.
Developing, maintaining, and understanding relationships	

RESTRICTIVE OR REPETITIVE BEHAVIORS AND INTERESTS	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Stereotypic or repetitive behaviors	
Ritualized or inflexible behaviors	
Highly restricted, fixated interests	
Hyper- or hyporeactivity or unusual interest in sensory input	

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**Developmental history:**

- Healthcare provider reports some uncertainty regarding developmental challenges/behavior before age 3 when compared with children the same age.



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## Assessment Summary prepared by Dr. Light Beacon, MD

LS is a 2 year 3 month old who presents with symptoms of challenge in the following domains: social-emotional reciprocity; nonverbal communication.

Dr. Light Beacon, MD findings:

F80.1 Expressive language disorder

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### RECOMMENDATIONS

Speech & Language Therapy

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### Notes:

Parent to provide update in 6 weeks as to access of services recommended and given local parental resources.

<b>PROVIDER NAME</b> Dr. Light Beacon	<b>PROVIDER CREDENTIALS</b> MD
<b>SIGNATURE</b> 	<b>DATE</b> 03/14/2023

# Performance Metrics

## Current Device Performance

As measured in a population of patients with concern for developmental delay (28% with autism, 50% with one or more non-autism developmental delays, and 22% with neurotypical development) the Device performs as follows:

Negative Predictive Value (NPV)	Positive Predictive Value (PPV)	Sensitivity*	Specificity*	Indeterminate for autism Rate
95.6% (93.8–98.4%)	87.5% (81.7–96.7%)	84.8% (75.5–94.3%)	96.4% (94.4–99.0%)	33.5% (29.5–38.5%)

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

In the 33.5% of patients for whom the device abstained from providing a determinate result for autism (also referred to as Indeterminate for autism), specialists determined that 95.9% had one or more neurodevelopmental conditions (39.7% were positive for autism, 56.2% had one or more non-autism neurodevelopmental conditions, and 4.1% were neurotypical).

# 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: Probability 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.

# Device Algorithm Performance Modification Process

An authorized predetermined change control plan was followed to modify the Device Algorithm performance with no change to the intended use or new input type. The Algorithm was updated and evaluated using two datasets comprised of 722 subjects balanced for age, sex, and specialist diagnosis. 70% were randomly selected for threshold optimization (“training set”) and 30% for evaluation (“test set”), resulting in 504 samples (mean age 3.6 +/- 1.2 years; 39.1% female) used for training and 218 (mean age 3.7 +/- 1.2 years; 39.0% female) samples used for testing.

The Algorithm Modification Dataset contained a percentage of children that is representative of the intended use population for the device with 28% autism, 50% with one or more non-autism developmental delays, and 22% with neurotypical development as determined by a specialist clinician.

The pivotal clinical study evaluated the Device with Algorithm version 1 (“Algorithm V1”). FDA Good Machine Learning Practices were followed. No data used in training the updated Algorithm (“Algorithm V2”) were used to test the model. Model optimization focused only on optimizing/increasing the determinate rate while maintaining accuracies with equivalence or superiority for each of the performance measures as assessed by overlapping 95% confidence intervals (95% CI) and empirical p-value using null hypothesis of “V2 is within the confidence bars of V1” for 1,000 bootstraps of the V1 Pivotal confusion matrix to compare to the accuracies found in the evaluation of the Device in the pivotal clinical study.

As shown in Table 5, the Device with Algorithm V2 has a 66.5% determinate rate.

		Clinical Reference Standard		
		Autism Positive	Autism Negative	Total Subjects
Cognoa Device	Autism Positive	28	4	32
	Autism Negative	5	108	113
	Indeterminate	29	44	73
	Total Subjects	62	156	218

Table 4. Algorithm V2 results comparing number of subjects in each category of Device output to clinical reference standard (specialist diagnosis).

Measures	Value	95% Confidence Interval
PPV	87.5% (28/32)	81.7%, 96.7%
NPV	95.6% (108/113)	93.8%, 98.4%
Indeterminate for autism Rate	33.5% (73/218)	29.5%, 38.5%

Table 5. Outcomes measures with the Device with Algorithm V2.

The Device with Algorithm V2 abstained from providing a Positive or Negative for autism result (provided an Indeterminate output) on 33.5% of children, 96% of which had been identified by a specialist clinician to have one or more neurodevelopmental conditions. For the remaining 66.5% for which the Device with Algorithm V2 provided a determinate result, the NPV, PPV, sensitivity and specificity were 95.6%, 87.5%, 84.8%, and 96.4%, respectively.

# Algorithm Update

## Summary of Device Update:

The Device with Algorithm V2 maintains high accuracy metrics with a higher determinate rate (reduced No Result Rate) summarized in Table 6.

	Device with Algorithm V2 (95% CI)	Device with Algorithm V1 (95% CI)	Equivalence
<b>Negative Predictive Value (NPV)</b>	95.6% (93.8–98.4%)	98.3% (90.6–100%)	Equivalent by overlapping 95% CIs and $p > 0.05$
<b>Positive Predictive Value (PPV)</b>	87.5% (81.7–96.7%)	80.8% (70.3–88.8%)	Equivalent by overlapping 95% CIs and $p > 0.05$
<b>Sensitivity*</b>	84.8% (75.5–94.3%)	98.4% (91.6–100%)	Equivalent by overlapping 95% CIs and $p > 0.05$
<b>Specificity*</b>	96.4% (94.4–99.0%)	78.9% (67.6–87.7%)	Equivalent $p > 0.05$ . Note, non- overlapping 95% CIs with $V2 > V1$
<b>Indeterminate for autism Rate</b>	33.5% (29.5–38.5%)	68.2% (63.6–72.6%)	V2 Superior to V1 by non-overlapping 95% CIs with $V2 > V1$ and $p < 0.01$

Table 6. Comparison summary and evaluation of equivalence to predicate Algorithm. (\*Sensitivity and Specificity measured in the determinate group)

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We can support you or your office staff with questions related to:

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- Password resets
- Technical support for Mac, PC, iOS, and Android devices
- Questions about your patients' prescriptions
- Creating additional portal accounts for your non-prescribing clinical staff



### Phone

**1-866-426-4662 (4COGNOA)**

Messages left after hours are secure and will be answered the following business day



### Email\*

**support@cognoa.com**

Emails will be answered by the following business day

## 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.

### Name and Place of Business of Manufacturer

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LBL-001 - HCP Portal Instructions for Use, version 3 (2023-05-25)

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