

canvas Dx™

AND SUPPORTING SOFTWARE

User Guide

for Clinicians

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

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Product Description | Rx only

Canvas Dx is a prescription diagnostic device designed to support clinical diagnosis 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 video analysts, and clinicians (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.



Caregiver Input

~ 5 MINS

With smartphone caregiver answers questions about the child.



Video Input

~ 10 MINS

Caregiver uploads two videos of the child. Videos are securely transmitted to a portal for analysis.



Clinical Input

~ 10 MINS

A clinician answers a questionnaire about the child's behavior and development.

Algorithm analysis and classification for autism

Inputs are combined into a mathematical vector for machine learning analysis and classification

Positive | **Negative** | **Indeterminate**

+

Canvas Dx Detailed Report

Captures child's developmental strengths and challenges to help guide 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.

Clinical Workflow

[Introduction to Canvas Dx for Clinicians]
Watch video: click or scan QR code

1 Prescribe Canvas Dx for children meeting indications for use*

- ☑ Concern for developmental delay

– and –

- ☑ 18–72 months

2 Complete the clinical questionnaire

Once caregiver and video analyst inputs are also completed you will be notified that a result is available to view.

3 View and download the Canvas Dx Detailed Report**



A full sample report can be viewed on pages 19–26

*For the full list of Indications for Use see Indications for Use
**Clinicians will also have access to their questionnaire responses, caregiver questionnaire responses and uploaded videos, and device performance metrics, to inform their clinical judgment.

The Canvas Dx Portal



The Canvas Dx portal is where you:

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

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

Setup

1. Look for an email from support@cognoa.com with the subject line:
   Welcome to Canvas Dx by Cognoa!
   ➡ *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

   click link above 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

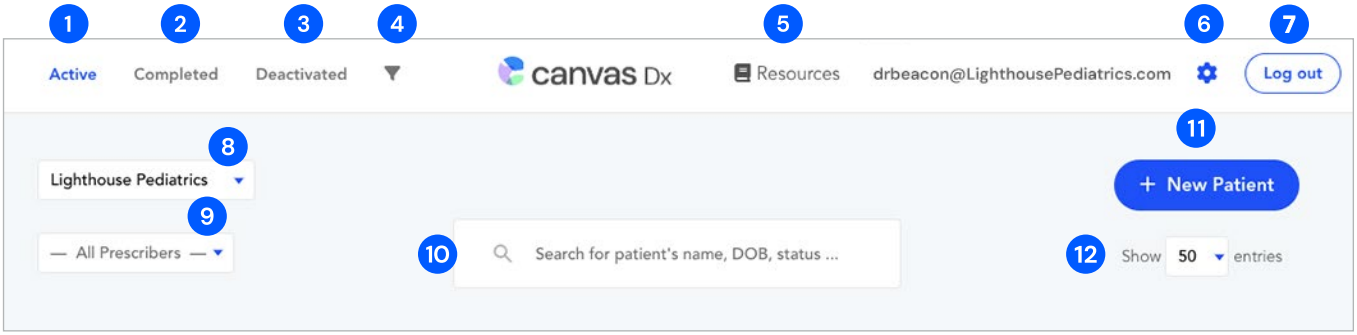
5. If your mobile number appears in the box, verify that is correct and click the acknowledgment box, then click Send Code. If your number does not appear, enter it manually.

6. Enter the 6-digit code you received via text message into the box labeled Verification Code

You are now logged into the Canvas Dx Portal

*For minimum technical requirements and cybersecurity considerations please refer to Appendix
**It is also possible to authenticate using Google Authenticator

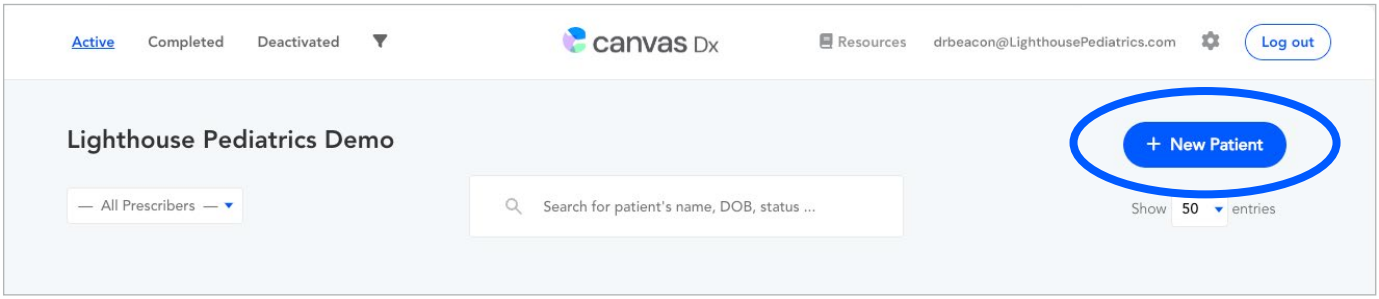
Portal Navigation



1. **Active:** Click here to view prescriptions that are in progress
2. **Completed:** Click here to view and download completed reports
3. **Deactivated:** Click here to view prescriptions that have been manually deactivated due to non-completion
4. **Filter:** Click here to filter prescriptions by Canvas Dx result, sex, age or ICD-10 codes
5. **Resources:** Click here to view user guide and training resources for clinicians and families
6. **My Profile:** Click through to access and edit your profile. Use this feature to customize how your signature and credentials appear on the Canvas Dx Detailed Report.
7. **Log out:** Click here to log out of the portal
8. **Toggle between practices:** This feature allows users working across multiple practice locations to switch dashboard views
9. **Toggle between prescribers:** This feature allows users to specify whose patients they wish to view
10. **Search bar:** Search by Caregiver name, Patient name, Patient Date of Birth, or Prescriber name
11. **+ New Patient:** Click here to add new patients
12. **Show (#) entries:** Adjust to show a different number of entries per screen

Depending on the configuration of your portal and practice, you may see more than one prescriber listed. 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



Dashboard

1. On the upper right-hand corner of the dashboard click the **+ New Patient** button
2. Fill in all required fields. If you are an office staff member, you will need to specify which doctor you're prescribing on behalf of.
3. Check the Terms of Use box
4. Click the Order and Dispense button (located lower left hand corner)

   Immediately upon ordering Canvas Dx the child's caregiver will receive an automated communication from Cognoa with instructions on how to complete their tasks.

Tip: prepare in advance by gathering the following details:

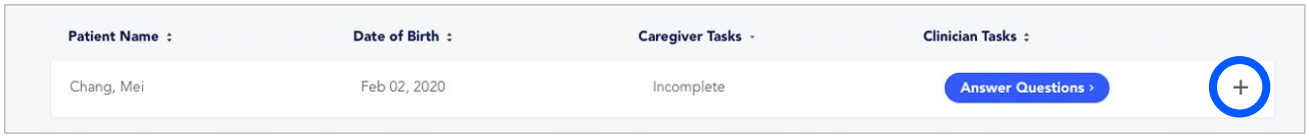
- ✓ Patient's full name
- ✓ Patient's date of birth
- ✓ Patients' biological sex
- ✓ Caregiver's full name
- ✓ Caregiver's email address
- ✓ Caregiver's mobile phone number

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

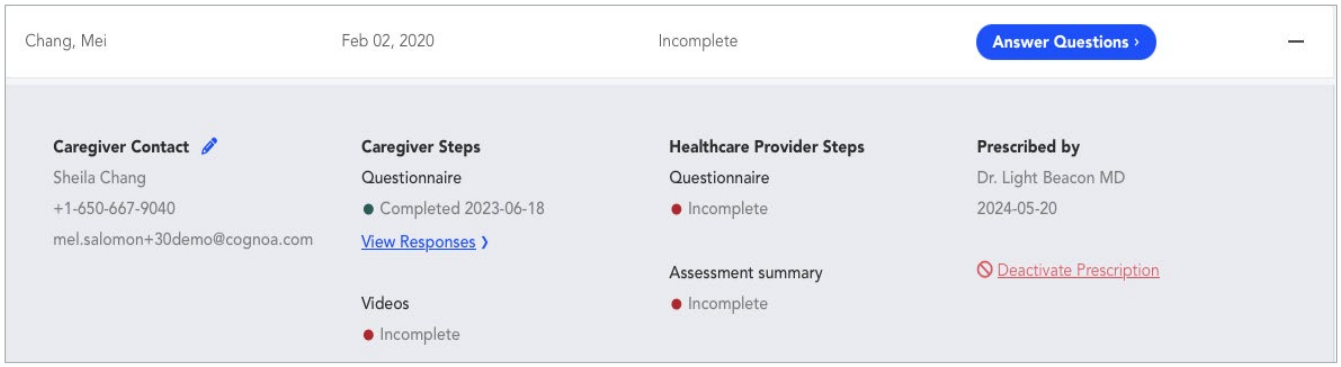
- If you are ready, complete and submit the questionnaire right away.
- If you are not yet ready to complete the questionnaire, navigate back to the Active dashboard. The new patient will now be viewable on your dashboard. Select **Answer Questions** on the Clinician Tasks column to complete their questionnaire at your convenience.

Checking Prescription Status

For additional details about each patient click the **+** icon to the right.



This will show you an expanded view that includes dates of task completion and any outstanding tasks. Once a task is **complete** you can click the hyperlink to view the recorded responses:



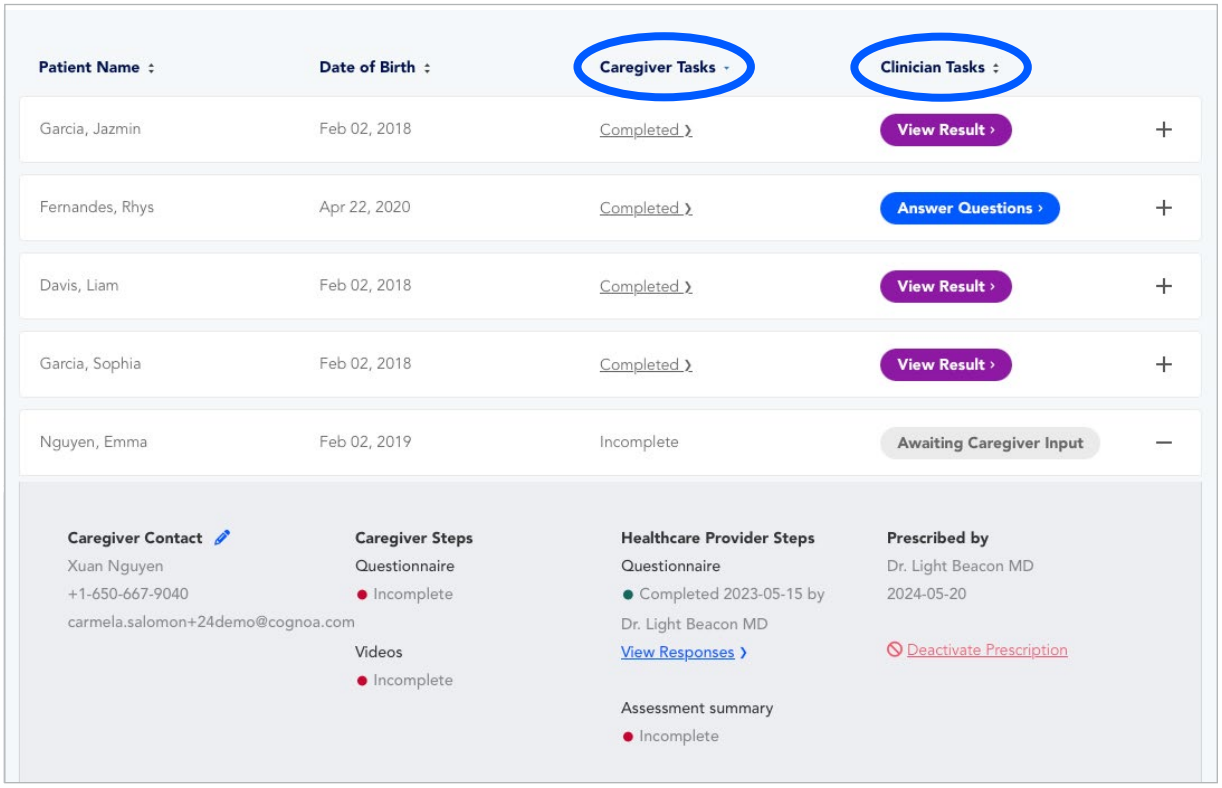
Expanded patient view

Pen icon
Select to edit caregiver contact details

Resend Access Code
Select If a caregiver reports they cannot find their product access code to re-forward it to them. Once the caregiver creates a password and username this option will no longer be available.

Deactivate Prescription
Select to deactivate a prescription

Understanding the Clinical & Caregiver Tasks column



Clinician Tasks

Answer Questions

➡ *Click through to access and complete the clinical questionnaire*

View Result

➡ *Click through to view results and complete the assessment summary*

Positive: Report Saved >

➡ *Click through to view and download the final report*

Caregiver Tasks

Incomplete

The Caregiver has not yet completed all of their tasks. Click **+** to view a detailed breakdown of which tasks are outstanding.

Completed >

All caregiver tasks are complete. Use the hyperlink to view the completed questionnaire and video inputs.

Completing the Clinical 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

1. Login to the portal using your username and password
2. Navigate to the Active dashboard and search for the name of the child
3. From the Clinician Tasks column select **Answer Questions** to open and begin the questionnaire
4. You will be asked to confirm your responses prior to submitting the questionnaire. Answers cannot be changed once submitted.

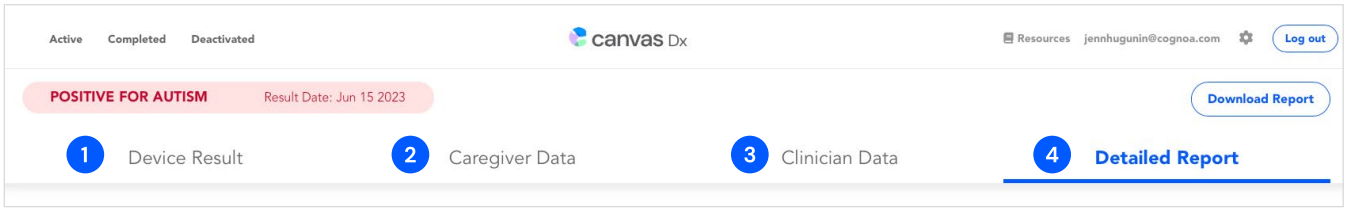
In all cases, the Clinician should follow the established guidelines when making a medical decision. For example, those of the American Academy of Pediatrics: Identification, Evaluation, and Management of Children with Autism Spectrum Disorder available at: https://doi.org/10.1542/peds.2019-3447.

Device Result

Accessing the Result

When the Canvas Dx result is available the Clinician Task status will change to **View Result** click through to view.

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



The result page has 4 tabs you can toggle between:

1 Device Result

Displays the Canvas Dx output of Positive, Negative or Indeterminate

2 Caregiver Input

Displays the caregiver questionnaire responses and uploaded videos

3 Clinician Answers

Displays the clinical questionnaire responses

4 Detailed Report

Displays the child's full report and customizable assessment summary

Device Result: Outputs

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.

**See Appendix for 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.

**See Appendix for information on the device performance metrics*

Indeterminate

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. ****See Indeterminate Range, next page***

Indeterminate Range Breakdown

Indeterminate results are grouped into Low, Moderate, and High categories. These groupings were based on blinded clinical specialist diagnosis of children in our data-sets† who received an Indeterminate Canvas Dx result. Data is provided for reference only and is not designed to replace the clinicians judgment and analysis of the patients condition.

† n=261, autism prevalence 26.8%, 34% female

Low Indeterminate

Low Indeterminates

- 5% received an autism diagnosis

Moderate Indeterminate

Moderate Indeterminates

- 25% received an autism diagnosis

High Indeterminate

High Indeterminates

- 35% received an autism diagnosis

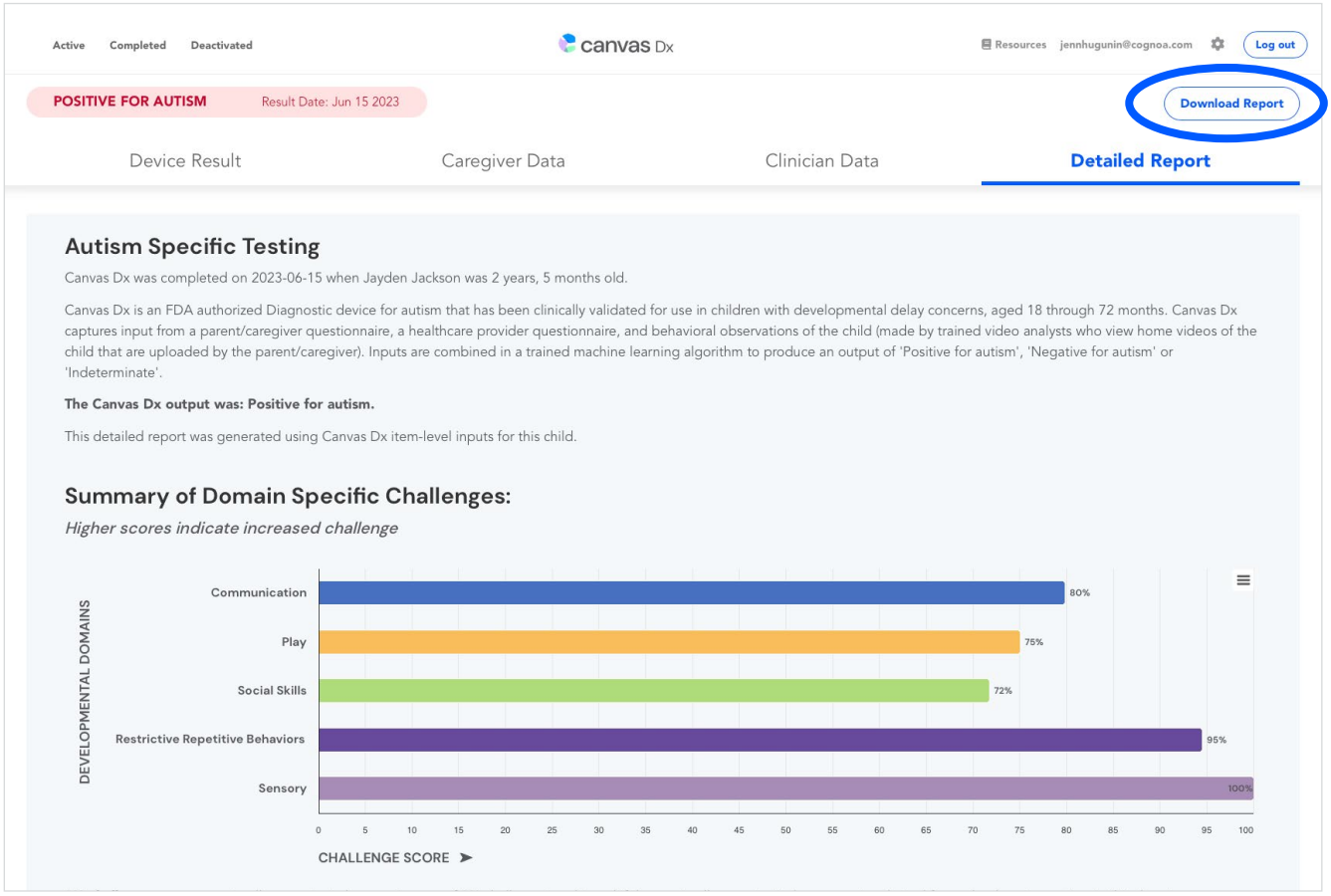
Detailed Report

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

Downloading the Report

Once you sign and save the report it will be available for download from the completed dashboard. 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.



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 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 (excluding Android Go). It was running on iOS 12 and 13, as well as Android 9 and 10 operating systems during clinical studies.

Canvas Dx Portal

The Canvas Dx Clinician 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 a supported Operating System (OS) version. 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 Canvas Dx 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 Canvas Dx portal anytime you need to step away from your computer. The Canvas Dx Portal will log you out automatically after more than 60 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.

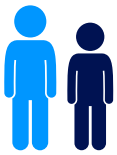
When to Prescribe

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

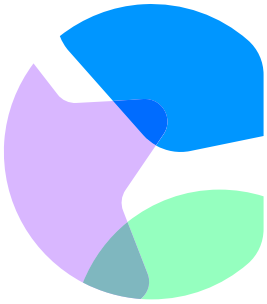
Developmental concerns could include:

Clinician observation of developmental delay or atypical behaviors





Risks such as a sibling with autism or prematurity





Caregiver-reported developmental and/or behavioral concerns



Failed developmental screener



Childcare/school staff-reported concerns

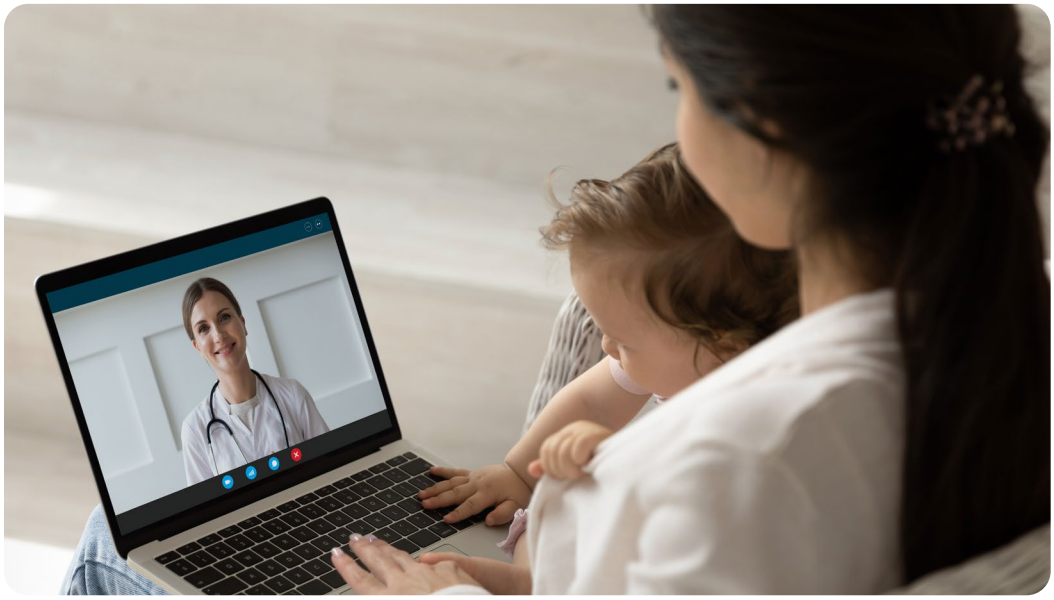
- ☑ To use Canvas Dx caregivers should have functional English or Spanish capability (8th grade reading level or above)
- ☑ The child's caregiver will require access to a compatible smartphone with internet connection

See the full list of Indications for Use

Discussing Canvas Dx with Caregivers

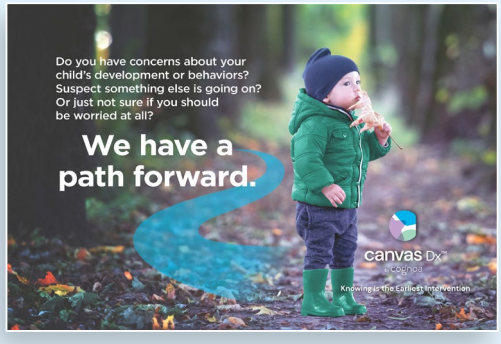
[Example of a clinician discussing Canvas Dx with a caregiver]

Watch video: click or scan QR code



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 Guide For Families] contains information that will help caregivers successfully complete their portion of Canvas Dx.

Please share it with families before writing the prescription.

Available in English & Spanish

Click or scan the QR code to view and download

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?	
○	No.
○	Sometimes. Will repeat things but also uses productive language as well.
○	Often. Uses odd phrases mixed in with productive language.
●	Yes. Language is mostly repetitive or filled with odd phrases.
○	Not applicable. The child still doesn't communicate using phrases.
○	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?	
○	No behavior indicating developmental delay.
○	Some uncertainty regarding behavior when compared with children the same age.
●	Developmentally delayed but not as obvious as autism.
○	Developmentally delayed and behaviors strongly indicative of autism.
○	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?	
○	No. Doesn't have any sensory issues.
○	Sometimes. But his or her reaction is mild.
○	Often. But it doesn't interfere too much with daily life.
●	Yes. And it interferes with daily life or prevents an activity.
○	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

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.



Clinical Case Study 1: JJ

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 delays in speech and language.
- His first words were delayed at 2 years of age, and he currently speaks 1–2 word phrases with a expressive vocabulary of 50–60 words.
- 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.

Read JJ's Detailed Report on the next page

Detailed Report

NAME	DATE OF ASSESSMENT	SEX	DOB
Jayden Jackson	2023-07-28	Male	2021-01-01

Autism Specific Testing

Canvas Dx was completed on 2023-06-15 when Jayden Jackson was 2 years, 5 months old.

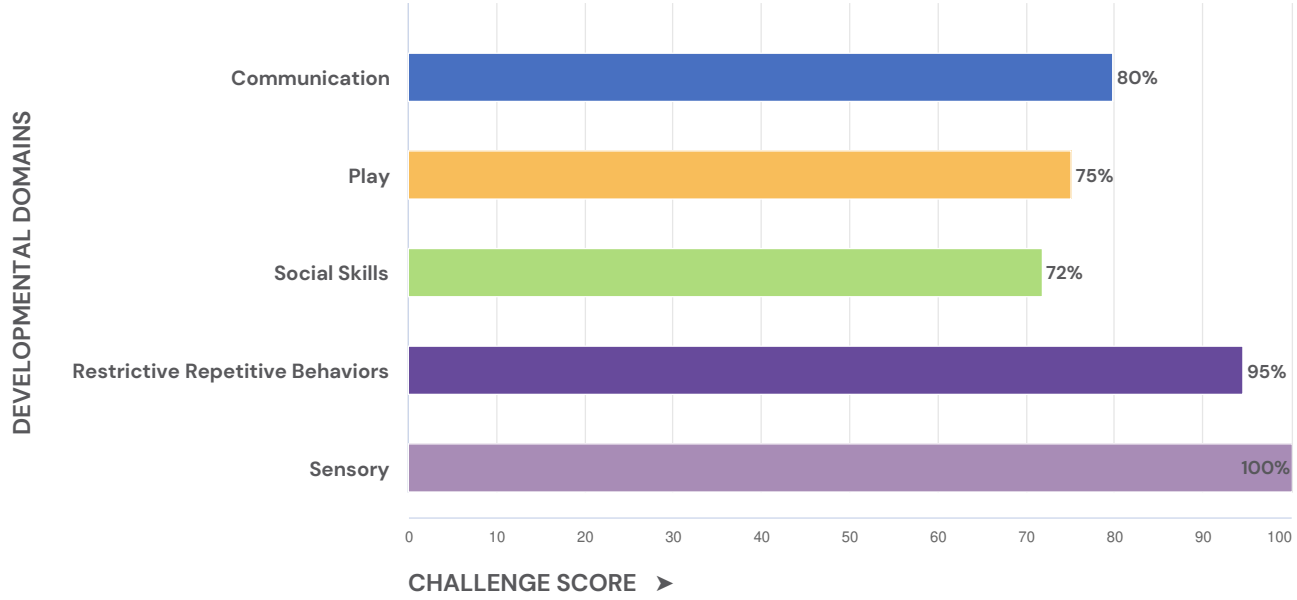
Canvas Dx is an FDA authorized Diagnostic device for autism that has been clinically validated for use in children with developmental delay concerns, aged 18 through 72 months. Canvas Dx captures input from a parent/caregiver questionnaire, a healthcare provider questionnaire, and behavioral observations 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'.

The Canvas Dx output was: Positive for autism.

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

Summary of Domain Specific Challenges:

Higher scores indicate increased challenge



0% challenge score = maximally neurotypical score. *A score of 0% challenge is achieved if the maximally neurotypical response is selected for each relevant question in this domain.*
100% challenge score = maximally atypical score. *A score of 100% challenge is achieved if the maximally atypical response is selected for each relevant question in this domain.*

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 [1]
Communication	Includes aspects of nonverbal communication, receptive and expressive language as they relate to autism. For example, gestures, ability to understand spoken language or to communicate needs.	• Speech/language therapy • Social skills training • Early intensive behavioral intervention (e.g. ABA, NDBI) • Developmental therapy
Play	Includes aspects of play such as imaginative play, imitation, interest and engagement with other people.	• Social skills training • Early Intensive Behavioral Intervention (e.g. ABA, NDBI) • Developmental therapy
Social skills	Ability to use tools to communicate, interact, and build healthy relationships (e.g. the child's ability to engage in group play)	• Speech/language therapy • Social skills training • Early Intensive Behavioral Intervention (e.g. ABA, NDBI) • Developmental 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
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*

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.

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	• The healthcare provider reports the child doesn't smile with people but might smile at other things. • The 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.
	• The caregiver reports that the child only understands only a little of the words and phrases that the caregiver says to them: The child only understands a few words. • The caregiver reports that the child never looks people in the eye during conversations or other social interactions, or that the child has unusual eye contact. • The caregiver reports that the child never responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them. • The 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. • The caregiver reports that the child rarely copies or imitates the way they do things around the house. Even if the child copies what they see in the moment they do not use it in play. • The 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. • The caregiver reports that, when smiled at, typically, the child only smiles back if told to, or with familiar people. • The caregiver reports that the child only sometimes tends to show concern or try to comfort others when they are upset, sick, or hurt. • The caregiver reports that the child only sometimes tends to share their excitement or happiness with the caregiver and other people: The child's sharing of joy is limited to certain activities, people or situations.
	• Videos show some deficits with social emotional reciprocity.

Nonverbal communication	• The healthcare provider reports the child does not socially pick up or bring objects to share interest or to get help. • The healthcare provider reports the child doesn't smile with people but might smile at other things. • The 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. • The healthcare provider reports that child never shakes head "no" when asked a question or a request is made and never shakes head spontaneously to mean "no". • The healthcare provider reports that the child does not point to communicate things or objects of interest from a distance. • The healthcare provider reports that the child rarely use hands or gestures to communicate; imitates others only. • The healthcare provider reports that the child occasionally uses eye contact and is rarely used in social interactions.
	• The caregiver reports that the child never looks people in the eye during conversations or other social interactions, or that the child has unusual eye contact. • The caregiver reports that the child never responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them. • The caregiver reports that the child rarely shows a variety of emotional facial expressions that match the mood or situation. The child tends to use only one facial expression for most situations. • The 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. • The caregiver reports that, when communicating, the child rarely uses gestures such as waving "hello" or "good bye", clapping, giving a thumbs-up, or other similar hand signals: The child only uses gestures when told to. • The caregiver reports that, when smiled at, typically, the child only smiles back if told to, or with familiar people. • The caregiver reports that the child sometimes 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, but generally, the child doesn't check back to make sure you are paying attention.
	• Videos show some deficits in nonverbal communication.

Developing, maintaining, and understanding relationships	• The healthcare provider reports the child does not socially pick up or bring objects to share interest or to get help. • The healthcare provider reports the child doesn't smile with people but might smile at other things. • The 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. • The healthcare provider reports that the child does not point to communicate things or objects of interest from a distance. • The healthcare provider reports the child rarely imitates actions of caregivers, e.g. vacuuming which is limited to a few routines that were learned.
	• The caregiver reports that the child never starts playing on their own with toys, crafts, games, or other activities without the caregiver's help: The child needs help to find something to do or to start playing. • The 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. • The caregiver reports that the child rarely copies or imitates the way they do things around the house. Even if the child copies what they see in the moment they do not use it in play. • The 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. • The caregiver reports that the child only sometimes tends to show concern or try to comfort others when they are upset, sick, or hurt. • The caregiver reports that the child sometimes 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, but generally, the child doesn't check back to make sure you are paying attention. • The caregiver reports that the child only sometimes tends to share their excitement or happiness with the caregiver and other people: The child's sharing of joy is limited to certain activities, people or situations.
	• Videos show some deficits in the quality of the child's play. • Videos show some deficits in developing, maintaining, and understanding of relationships.

RESTRICTIVE OR REPETITIVE BEHAVIORS	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Stereotypic or repetitive behaviors	• The healthcare provider reports abnormal playing with toys or objects with definite repetitive use of objects that seriously interferes with other activities. • The healthcare provider reports that the child engages in repetitive whole-body movements all the time and this causes distress when interrupted.
	• Videos show some examples of restricted, repetitive behavior. • Videos show some examples of unusual sensory and/or repetitive interests.
Ritualized or inflexible behaviors	• The 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.
Highly restricted, fixated interests	• The healthcare provider reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time.
	• The 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. • The caregiver reports that, when playing alone or with toys, the child doesn't really pretend or make up stories and characters: The child may occasionally repeat a certain made-up story, but rarely plays pretend.
Hyper- or hyporeactivity or unusual interest in sensory input	• The 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. • The healthcare provider reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time.
	• The 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. • The 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.
	• Videos show some examples of unusual sensory and/or repetitive interests.

To meet DSM-5 diagnostic criteria for autism a child must have persistent deficits in each of the three social communication and interaction domains PLUS at least two of the four restricted, repetitive behavior domains

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.
- The healthcare provider reports the child is developmentally delayed before age 3 and behavior is strongly indicative of autism.

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

- The 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.
- The 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.
- The 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.
- The healthcare provider reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time.
- The healthcare provider reports abnormal playing with toys or objects with definite repetitive use of objects that seriously interferes with other activities.
- The healthcare provider reports that the child engages in repetitive whole-body movements all the time and this causes distress when interrupted.

Assessment summary prepared by Dr. Light Beacon MD

Jayden Jackson is a 2 years, 5 months old who was assessed due to developmental concern.

ICD-10 CODES

☒ 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. 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.

Restricted, repetitive behaviors domain severity rating:

◉ (3) Very Substantial Support

Social communication domain severity rating:

◉ (3) Very Substantial Support

◉ No intellectual disability present

RECOMMENDATIONS

☒ Early intensive behavioral intervention (i.e. ABA or other)

☒ Speech & Language Therapy

PROVIDER NAME	
Dr. Light Beacon MD	
SIGNATURE	**DATE**
Dr. Light Beacon MD	2023-07-28 08:13PM UTC

Signature Line

Electronically Signed by Dr. Light Beacon MD at 2023-07-28 08:13PM UTC. This note is a complete document once electronically signed.

Practice Name: Lighthouse Pediatrics

Practice Address: 100 Main Street, Suite 240, Scranton, PA 18510



Clinical Case Study 2: RM

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, he won't eat any vegetables and only eats 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. When RM is constipated his behavior is much worse, and he has many more tantrums.
- He has very few items of clothing that he can wear; clothing that "feels bad" will set off his 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 a Low INDETERMINATE output 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** 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.

Read RM's Detailed Report on the next page

Detailed Report

NAME	DATE OF ASSESSMENT	SEX	DOB
Rowan Martinez	2023-10-26	Male	2021-01-01

Autism Specific Testing

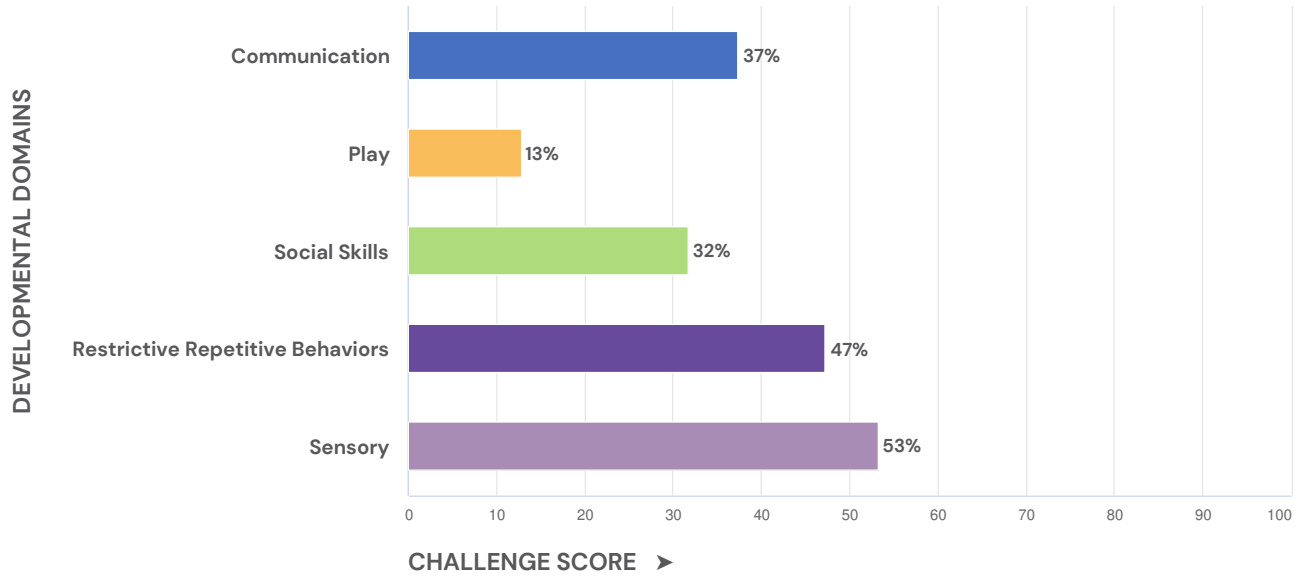
Canvas Dx was completed on 2023-05-15 when Rowan Martinez was 2 years, 4 months old.

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).

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

Summary of Domain Specific Challenges:

Higher scores indicate increased challenge



0% challenge score = maximally neurotypical score. *A score of 0% challenge is achieved if the maximally neurotypical response is selected for each relevant question in this domain.*
100% challenge score = maximally atypical score. *A score of 100% challenge is achieved if the maximally atypical response is selected for each relevant question in this domain.*

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 [1]
Communication	Includes aspects of nonverbal communication, receptive and expressive language as they relate to autism. For example, gestures, ability to understand spoken language or to communicate needs.	• Speech/language therapy • Social skills training • Early intensive behavioral intervention (e.g. ABA, NDBI) • Developmental therapy
Play	Includes aspects of play such as imaginative play, imitation, interest and engagement with other people.	• Social skills training • Early Intensive Behavioral Intervention (e.g. ABA, NDBI) • Developmental therapy
Social skills	Ability to use tools to communicate, interact, and build healthy relationships (e.g. the child's ability to engage in group play)	• Speech/language therapy • Social skills training • Early Intensive Behavioral Intervention (e.g. ABA, NDBI) • Developmental 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
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*

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:

- The 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.
- The healthcare provider reports that the child consistently looks back and forth during conversations.
- The 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.
- The healthcare provider reports the child imitates actions of caregivers, e.g. vacuuming, household tasks and incorporates it into own play.
- The healthcare provider reports that the child does not engage in repetitive whole-body movements.

Caregiver reported:

- The caregiver reports that the child usually starts playing on their own with toys, crafts, games, or other activities without the caregiver's help.
- The caregiver reports that the child understands the words and phrases that the caregiver says to them well: The child is able to understand more than 50 words but not if used in a new or unusual way.
- The caregiver reports that the child usually responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them.
- The 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.
- The caregiver reports that the child usually plays back-and-forth social games like "patty-cake" or "Simon says". The caregiver reports that the child enjoys social games like this.
- The 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.
- The caregiver reports that the child usually uses a variety of expressions that are appropriate to the mood or situation.
- The caregiver reports that, when playing alone or with toys, the child usually pretends or makes up stories and characters.

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	• The healthcare provider reports the child mostly smiles but not with a lot of people. • The healthcare provider reports the child sometimes offers comfort without prompting and only in certain situations.

	• The caregiver reports that the child rarely looks people in the eye during conversations or other social interactions. • The 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. • The caregiver reports that, when smiled at, typically, the child only smiles back if told to, or with familiar people. • The caregiver reports that the child only sometimes tends to share their excitement or happiness with the caregiver and other people: The child's sharing of joy is limited to certain activities, people or situations.
	• Videos show some deficits with social emotional reciprocity.
Nonverbal communication	• The healthcare provider reports the child mostly smiles but not with a lot of people. • The healthcare provider reports the child sometimes offers comfort without prompting and only in certain situations. • The healthcare provider reports that child sometimes shakes head "no" when asked a question or a request is made but not always. • The healthcare provider reports that the child sometimes points to communicate things of interest from a distance. The child both points at things and looks at others to get their attention but doesn't always make eye contact.
	• The caregiver reports that the child rarely looks people in the eye during conversations or other social interactions. • The caregiver reports that, when communicating, the child sometimes uses gestures such as waving "hello" or "good bye", clapping, giving a thumbs-up, or other similar hand signals: The child uses a few gestures. • The caregiver reports that, when smiled at, typically, the child only smiles back if told to, or with familiar people. • The 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. • The caregiver reports that the child sometimes 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, but generally, the child doesn't check back to make sure you are paying attention.
	• Videos show some deficits in nonverbal communication.

Developing, maintaining, and understanding relationships	• The healthcare provider reports the child mostly smiles but not with a lot of people. • The healthcare provider reports the child sometimes offers comfort without prompting and only in certain situations. • The healthcare provider reports that the child sometimes points to communicate things of interest from a distance. The child both points at things and looks at others to get their attention but doesn't always make eye contact.
	• The 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. • The caregiver reports that the child sometimes 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, but generally, the child doesn't check back to make sure you are paying attention. • The caregiver reports that the child only sometimes tends to share their excitement or happiness with the caregiver and other people: The child's sharing of joy is limited to certain activities, people or situations.
	• Videos show some deficits in developing, maintaining, and understanding of relationships.

RESTRICTIVE OR REPETITIVE BEHAVIORS	
DSM-5 COMPATIBLE DOMAINS	IDENTIFIED DOMAIN SPECIFIC CHALLENGES FOR THIS CHILD
Stereotypic or repetitive behaviors	• The healthcare provider reports abnormal playing with toys or objects with some repetitive use of objects but doesn't interfere with other activities.
	• Videos show some examples of restricted, repetitive behavior.
Ritualized or inflexible behaviors	• The 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	• The healthcare provider reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time.

	• The 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	• The healthcare provider reports the child exhibits unusual sensory interests, and these behaviors take up a lot of time. • The healthcare provider reports the child sometimes has sensory issues, that is, upset, angered, or irritated by particular sounds, tastes, smells, sights or textures, But his or her reaction is mild.
	• The caregiver reports that the child sometimes predictably gets upset by certain common noises, smells, sights, textures, flavors, or movements, however, they do not get very upset. • The 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.

To meet DSM-5 diagnostic criteria for autism a child must have persistent deficits in each of the three social communication and interaction domains PLUS at least two of the four restricted, repetitive behavior domains

Developmental history:

- In relation to the child's development, the caregiver reports that the child met all milestones, but with a few concerns.
- The healthcare provider reports some uncertainty regarding developmental challenges/behavior before age 3 when compared with children the same age.

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

- The 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

Rowan Martinez is a 2 years, 4 months old who was assessed due to developmental concern.

ICD-10 CODES

- [x] F80.9 Developmental disorder of speech and language, unspecified

RECOMMENDATIONS

- [x] Occupational Therapy
- [x] Referral to specialist for additional assessment
- [x] Speech & Language Therapy

NOTES

Suspect sensory integration disorder and risk for ADHD

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.

PROVIDER NAME	
Dr. Light Beacon MD	
SIGNATURE	**DATE**
Dr. Light Beacon MD	2023-10-26 09:53PM UTC

Signature Line

Electronically Signed by Dr. Light Beacon MD at 2023-10-26 09:53PM UTC. This note is a complete document once electronically signed.

Practice Name: Lighthouse Pediatrics

Practice Address: 100 Main Street, Suite 240, Scranton, PA 18510



Clinical Case Study 3: LS

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 to 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 half 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 output 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.

Read LS's Detailed Report on the next page

Detailed Report

NAME	DATE OF ASSESSMENT	SEX	DOB
Lea Singh	2023-10-03	Female	2021-01-01

Autism Specific Testing

Canvas Dx was completed on 2023-05-14 when Lea Singh was 2 years, 4 months old.

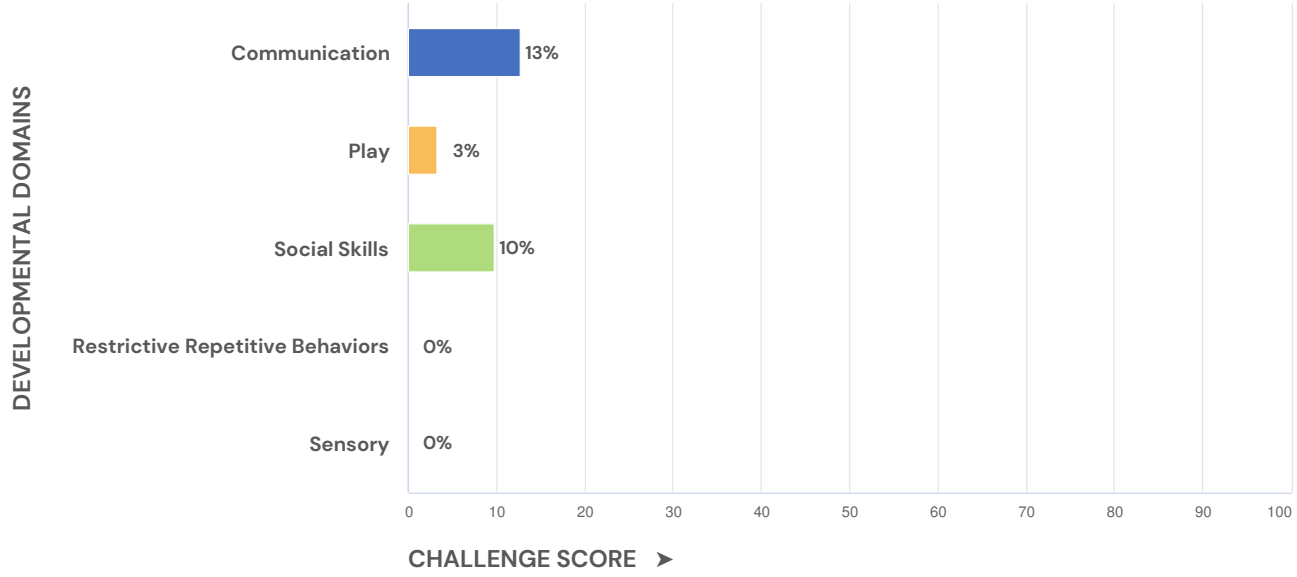
Canvas Dx is an FDA authorized Diagnostic device for autism that has been clinically validated for use in children with developmental delay concerns, aged 18 through 72 months. Canvas Dx captures input from a parent/caregiver questionnaire, a healthcare provider questionnaire, and behavioral observations 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'.

The Canvas Dx output was: Negative for autism.

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

Summary of Domain Specific Challenges:

Higher scores indicate increased challenge



0% challenge score = maximally neurotypical score. *A score of 0% challenge is achieved if the maximally neurotypical response is selected for each relevant question in this domain.*
100% challenge score = maximally atypical score. *A score of 100% challenge is achieved if the maximally atypical response is selected for each relevant question in this domain.*

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 [1]
Communication	Includes aspects of nonverbal communication, receptive and expressive language as they relate to autism. For example, gestures, ability to understand spoken language or to communicate needs.	• Speech/language therapy • Social skills training • Early intensive behavioral intervention (e.g. ABA, NDBI) • Developmental therapy
Play	Includes aspects of play such as imaginative play, imitation, interest and engagement with other people.	• Social skills training • Early Intensive Behavioral Intervention (e.g. ABA, NDBI) • Developmental therapy
Social skills	Ability to use tools to communicate, interact, and build healthy relationships (e.g. the child's ability to engage in group play)	• Speech/language therapy • Social skills training • Early Intensive Behavioral Intervention (e.g. ABA, NDBI) • Developmental 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
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*

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:

- The 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.
- The healthcare provider reports that the child consistently looks back and forth during conversations.
- The healthcare provider reports the child smiles often with a variety of people.
- The healthcare provider reports the child does not have any sensory issues.
- The healthcare provider reports the child imitates actions of caregivers, e.g. vacuuming, household tasks and incorporates it into own play.
- The healthcare provider reports the child has no sensory interests.
- The healthcare provider reports that child consistently shakes head "no" when asked a question or a request is made. The child consistently shakes head "no" when he or she means "no".
- The 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.
- The healthcare provider reports no abnormal playing with toys or objects. The child shows little or no repetitive use of objects.
- The healthcare provider reports that the child does not engage in repetitive whole-body movements.

Caregiver reported:

- The caregiver reports that the child usually starts playing on their own with toys, crafts, games, or other activities without the caregiver's help.
- The 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".
- The caregiver reports that the child usually looks people in the eye during conversations or other social interactions: The child uses appropriate eye contact.
- The caregiver reports that the child usually responds, looks up, or pays attention to the caregiver when the caregiver starts talking to them.
- The 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.
- The caregiver reports that, when smiled at, typically, the child usually smiles back.
- The caregiver reports that the child usually plays back-and-forth social games like "patty-cake" or "Simon says". The caregiver reports that the child enjoys social games like this.
- The caregiver reports that the child rarely or never predictably gets upset by certain common noises, smells, sights, textures, flavors, or movements.
- The 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.
- The caregiver reports that the child usually uses a variety of expressions that are appropriate to the mood or situation.
- The caregiver reports that the child rarely or never seeks out, or becomes distracted with, sensations like touching, smelling, looking at, or listening.

- The caregiver reports that, when playing alone or with toys, the child usually pretends or makes up stories and characters.
- The 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.
- The 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.
- The 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	• The healthcare provider reports the child sometimes offers comfort without prompting and only in certain situations.
	• The caregiver reports that the child only sometimes tends to show concern or try to comfort others when they are upset, sick, or hurt.
Nonverbal communication	• The healthcare provider reports the child will sometimes socially pick up or show objects to connect with others but is limited in frequency. • The healthcare provider reports the child sometimes offers comfort without prompting and only in certain situations.
	• The caregiver reports that, when communicating, the child sometimes uses gestures such as waving "hello" or "good bye", clapping, giving a thumbs-up, or other similar hand signals: The child uses a few gestures.
Developing, maintaining, and understanding relationships	• The healthcare provider reports the child will sometimes socially pick up or show objects to connect with others but is limited in frequency. • The healthcare provider reports the child sometimes offers comfort without prompting and only in certain situations.
	• The caregiver reports that the child only sometimes tends to show concern or try to comfort others when they are upset, sick, or hurt.

RESTRICTIVE OR REPETITIVE BEHAVIORS	
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	

To meet DSM-5 diagnostic criteria for autism a child must have persistent deficits in each of the three social communication and interaction domains PLUS at least two of the four restricted, repetitive behavior domains

Developmental history:

- In relation to the child's development, the caregiver reports that the child has had a few mild delays in development.
- The healthcare provider reports some developmental delay is suspected before age 3.

Assessment summary prepared by Dr. Light Beacon MD

Lea Singh is a 2 years, 4 months old who was assessed due to developmental concern.

ICD-10 CODES

☒ F80.89 Other developmental disorders of speech and language

RECOMMENDATIONS

☒ Speech & Language Therapy

PROVIDER NAME	
Dr. Light Beacon MD	
SIGNATURE Dr. Light Beacon MD	**DATE** 2023-10-03 04:34PM UTC

Signature Line

Electronically Signed by Dr. Light Beacon MD at 2023-10-03 04:34PM UTC. This note is a complete document once electronically signed.

Practice Name: Lighthouse Pediatrics

Practice Address: 100 Main Street, Suite 240, Scranton, PA 18510

Performance Metrics

Current Device Performance

As measured in a representative testing population of patients with concern for developmental delay (n=148, autism prevalence 46%, 30% female) the Device performs as follows:

Negative Predictive Value (NPV)	Positive Predictive Value (PPV)	Sensitivity*	Specificity*
96.55% (CI 91.86-100.0%)	94.83% (CI 89.13-100.0%)	94.83% (CI 89.13-100.0%)	94.92% (CI 89.31-100.0%)

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

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 Clinician 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.

Contact & Support

canvas Dx™ by cognoa

For help contact the Cognoa Care Team

Email*

support@cognoa.com

Emails will be answered by the following business day

**please ensure emails containing protected health information are encrypted*

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

- Logging into the Canvas Dx Portal
- Password resets
- Technical support for Mac, PC, iOS, and Android devices
- Questions about your patients' prescriptions
- Creating additional portal accounts for your non-prescribing office staff

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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