



# Cognitrax

Measure and Monitor Brain Performance

## Brief Interpretation Guide

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"Diseases of the brain commonly produce changes in behavior, including impairment of cognitive abilities and production of neuropsychiatric symptoms. Knowledge of the presence and characteristics of these changes can aid in the evaluation, management, and longitudinal care of patients with neurologic and psychiatric diseases." Adapted from: *Neurology* 1996;47:592-599.

A Product of CNS Vital Signs

# Contents

<b>Introduction</b> .....	<b>3</b>
<b>Interpretation Guide</b> .....	<b>4</b>
<b>Cognitrax Testing Report</b> .....	<b>5</b>
<b>Evaluate Effort - Test Validity Indicator</b> .....	<b>6</b>
<b>Evaluate Severity – Impairment Status</b> .....	<b>8</b>
<b>Evaluate Pattern – Suggestive Pathology</b> .....	<b>11</b>
<b>Formulas for Calculating the Neurocognitive Domain Scores</b> .....	<b>11</b>
<b>Cognitrax Normed Neurocognitive Tests</b> .....	<b>12</b>
<b>Cognitrax Clinical Domain Description</b> .....	<b>12</b>

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# Introduction

## About Neurocognitive Health

**“The defining characteristics of these disorders are that their core or primary deficits are in cognition and that these deficits represent a *decline from a previously attained level of cognitive functioning...*”** Source: DSM-5 Neurocognitive disorder working group.

Much like physical health, neurocognitive health can be viewed as a journey—from optimal, healthy functioning to mild cognitive impairment to severe dementia. Mental decline may not be an inevitable part of aging. Normal aging is a gradual process that comes with certain changes in mental function. ***It is important to measure and monitor the higher functions of the brain with a non-painful procedure called neurocognitive testing.***

Cognitrax is an optimized (ease of administration) objective assessment of a patient’s “BRIEF CORE” neurocognitive function. Using computerized neuropsychological tests can assist in the recognition and evaluation of ***Neurodegenerative Disorders*** (e.g., MS, MCI - Mild Cognitive Impairment, Early Dementia, Epilepsy, Parkinson’s, etc.), ***as well as aid in the monitoring of their progression and measuring the response of the treatment.*** Cognitrax helps clinicians detect and track even subtle neurological deficits and subtle cognitive variations.

The Cognitrax tests are intended to be used as a stand-alone battery for the ***baselining and characterization of neurocognitive deficits when the clinician wants an immediate assessment*** of their patient’s neurocognitive function ***when lengthier assessments are either impractical or inappropriate.***

Neuropsychological tests are designed to psychometrically measure a patient’s neurocognitive function that is compromised when the neural system that maintains that function is damaged or diseased. The domain scores are presented as Subject (raw) Scores, Standard Scores, and Percentile Ranks computed from calculations using the data values of individual subtests and are simply the number of correct responses, incorrect responses, and reaction times. Cognitrax grades ***severity of impairment*** based on an age-matched normative comparison database. These are based on standard values generated from a normative control population and patients with various neurological and psychiatric conditions. ***Cognitrax has lifespan norms from ages 8 to 90.***

All assessment results should be considered with other relevant clinical information such as history, physical examination, other psychological or neuropsychological tests, lab results, imaging studies, etc., in accordance with good clinical practice standards. Cognitrax is not a diagnostic. Diagnosis is a clinical exercise that relies on data from many different sources. Cognitrax generates objective, valid, and reliable assessment of neurocognitive clinical endpoints that can support the evaluation and management of a variety of clinical conditions associated with neurocognitive impairment.

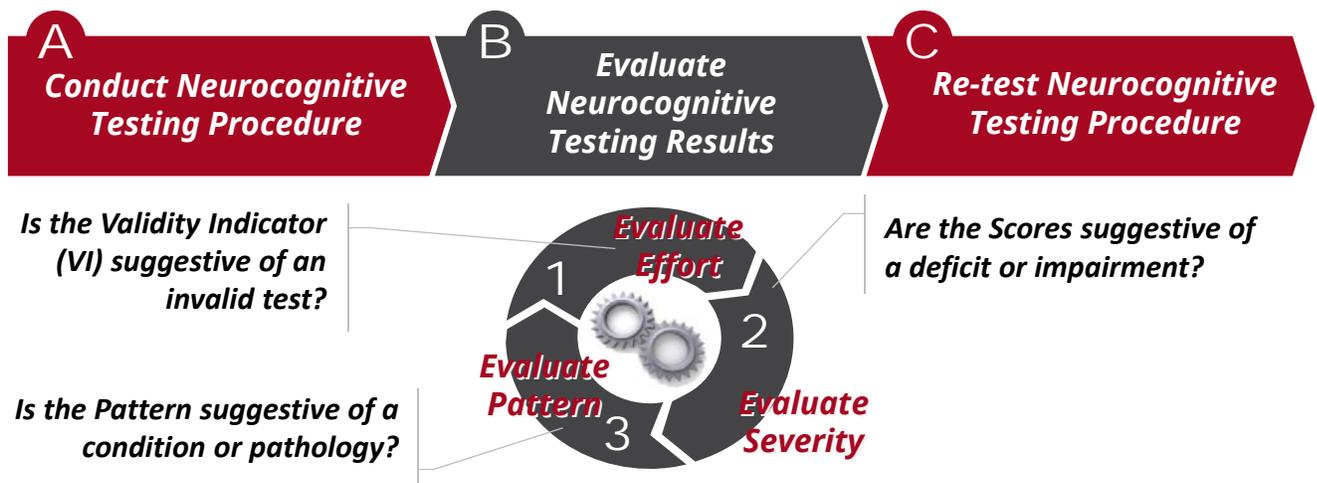
# Interpretation Guide

Assessing Brain Function Status:

Cognitrax is a clinical testing procedure used by clinicians to evaluate and manage the neurocognitive state of a patient. Across the lifetime, serial testing allows ongoing assessments of a patient's condition, disease progression, or clinical outcome.

Assessing Psychiatric Status:

Cognitrax uses a well known, evidence-based medical and health rating scale to help clinicians identify, assess, and track a patient's depressive status.



HOW? **Cognitrax begins with...**

**A:** Conducting a Valid Assessment (Refer to the Test Administration Guide.) To begin the staff should collect information about the CHIEF or PATIENT COMPLAINT. This will be a primary driver for the medical necessity of the procedure. For initial evaluations or in complex presentations, a broad spectrum battery is always an appropriate starting point.

**B:** Review the immediately auto-scored report to (1) validate testing effort, (2) evaluate the Domain Dashboard to quickly assess the level of impairment or grade the deficit, and (3) Evaluate the Domain Pattern to help rule-in, rule-out, or confirm clinical conditions. Feedback to the patient on the testing results may be presented at the clinical encounter or at a subsequent patient visit.

**C:** If invalid test results were noted then consider re-testing the patient to confirm clinical results. If the test results were valid, then, as part a continuum of care, reschedule testing to track disease progression and measure ongoing status or outcomes.

**NOTE:** The **Validity Indicator** denotes a guideline for representing the possibility of an invalid test or domain score. "No" means a clinician should evaluate whether or not the test subject understood the test, put forth their best effort, or has a clinical condition requiring further evaluation.

# Cognitrax Testing Report

<b>Cognitrax Report by CNS Vital Signs</b>	<b>Test Date: October 28, 2013 11:20:03</b>
Subject Reference/ID: Sample	Administrator: Technician
Age: 64	Language: English (United States)
Total Test Time: 18:38 (min:secs)	Cognitrax Online Version 0.0.1

Patient Profile:	Percentile Range				> 74	25 - 74	9 - 24	2 - 8	< 2
	Standard Score Range				> 109	90 - 109	80 - 89	70 - 79	< 70
Domain Scores	Subject Score	Standard Score	Percentile	VI**	Above	Average	Low Average	Low	Very Low
Verbal Memory	47	90	25	Yes		x			
Psychomotor Speed	138	91	27	Yes		x			
Processing Speed	39	94	34	Yes		x			
Simple Visual Attention	51	99	47	Yes		x			
Motor Speed	48	89	23	Yes			x		

Domain Dashboard: Above average domain scores indicate a standard score (SS) greater than 109 or a Percentile Rank (PR) greater than 74, indicating a high functioning test subject. Average is a SS 90-109 or PR 25-74, indicating normal function. Low Average is a SS 80-89 or PR 9-24 indicating a slight deficit or impairment. Below Average is a SS 70-79 or PR 2-8, indicating a moderate level of deficit or impairment. Very Low is a SS less than 70 or a PR less than 2, indicating a deficit and impairment. Reaction times are in milliseconds. An \* denotes that "lower is better", otherwise higher scores are better. Subject Scores are raw scores calculations generated from data values of the individual subtests.

VI\*\* - Validity Indicator: Denotes a guideline for representing the possibility of an invalid test or domain score. "No" means a clinician should evaluate whether or not the test subject understood the test, put forth their best effort, or has a clinical condition requiring further evaluation.

Finger Tapping Test (FTT)	Score	Standard	Percentile	
Right Taps Average	51	94	34	The FTT is a test of tapping speed on each hand. The FTT scores indicate motor speed are faster with their dominant hand.
Left Taps Average	45	86	18	
Verbal Memory Test (VBM)	Score	Standard	Percentile	
Correct Hits - Immediate	14	115	84	Verbal Memory Test measures the ability to recognize, remember, and reproduce verbal information. The test includes distractors. The test subject must be able to recognize, remember, and reproduce "Correct Hits" reference words to indicate impairment.
Correct Passes - Immediate	12	74	4	
Correct Hits - Delay	10	103	47	
Correct Passes - Delay	11	74	4	
Continuous Performance Test (CPT)	Score	Standard	Percentile	
Correct Responses	40	103	58	The CPT measures sustained attention or vigilance and choice reaction time. Most normal subjects obtain near-perfect scores on this test. A long response time may suggest cognitive slowing and/or impairment. More than 2 errors (total) may be clinically significant. More than 4 errors (total) indicate attentional dysfunction.
Omission Errors*	0	103	58	
Commission Errors*	1	97	42	
Choice Reaction Time Correct*	514	72	3	
Symbol Digit Coding (SDC)	Score	Standard	Percentile	
Correct Responses	42	96	40	The SDC test measures speed of processing and draw upon several cognitive processes simultaneously, such as visual scanning, visual perception, visual memory, and motor functions. Errors may be due to impulsive responding, misperception, or confusion.
Errors*	3	81	10	

The Cognitrax Neurocognitive Assessment Report is designed to present the testing results in a **SUMMARY DASHBOARD** and a **DETAILED REPORT** format immediately following the testing session.

Longitudinal View	2012-11-15 11:20:38	2013-7-24 11:20:38	2013-10-28 11:20:38
Verbal Memory	88	91	90
Psychomotor Speed	95	95	91
Processing Speed	85	85	94
Simple Attention	109	109	99
Motor Speed	91	90	89

Cognitrax serial administered neurocognitive tests can also be presented in a **LONGITUDINAL REPORT** format to track disease progression, outcomes, or treatment effects.

The Cognitrax reports are logical and intuitive making the reports interpretation by a qualified health professional relatively straightforward. All assessment results should be considered with other relevant clinical information such as history, physical examination, other psychological or neuropsychological tests, lab results, imaging studies, etc., in accordance with good clinical practice standards.



# Evaluate Effort - Validity Indicator

Patient Profile:	Percentile Range				> 74	25 - 74	9 - 24	2 - 8	< 2
	Standard Score Range				> 109	90 - 109	80 - 89	70 - 79	< 70
Domain Scores	Subject Score	Standard Score	Percentile	VI**	Above	Average	Low Average	Low	Very Low
Verbal Memory	47	90	25	Yes		x			
Psychomotor Speed	138	91	27	Yes		x			
Processing Speed	39	94	34	Yes		x			
Simple Visual Attention	51	99	47	Yes		x			
Motor Speed	48	89	23	Yes			x		

WHY? When analyzing test data, either in research, or in clinical practice, it is important to know whether a test result is valid or not. Clinicians need to know if testing subjects are generating “dubious results” or a “non-credible response pattern.” Cognitrax/CNSVS has developed “validity indicators” for its tests and domains that indicate whether the patient gave poor effort or generated invalid results (feigning, malingering, etc.) Across the span of neurological and psychiatric disorders, it is important to have “valid” tests to get a true evaluation of a patient.

WHAT? The Cognitrax **Validity Indicator (VI)** is a guideline identifying the possibility of an invalid test or domain score. When reviewing a report, a “No” in the VI column suggests the clinician should evaluate whether or not the test subject understood the test, put forth their best effort, or has a clinical condition requiring further evaluation. The CLINICAL DOMAIN validity indicators are based on summary data from multiple tests. **NOTE:** The Cognitrax test can be successfully completed, without assistance, by a normal child with a 4<sup>th</sup> grade reading level. Likewise, elderly with MMSE scores above 22 can complete the battery. Keep in mind, it is not uncommon for patients to generate an invalid result on one test in the battery due to misreading the instructions or giving-up on the test. ***Proper pretest instruction leads to a better testing experience.***

HOW? The Validity Indicator alerts the clinician to the possibility of an invalid test allowing the clinician, examiner or testing technician to question the testing subject: Do the testing results reflect an understanding of the test and the instructions? Did the testing subject put forth their best effort? Did they get a good night’s sleep? Does the subject have poor vision and need their glasses? Do the results suggest willful exaggeration, e.g., malingering?

Should a subject test abnormally low triggering an “invalid” test (NO as displayed in the Validity Indicator section of the report) then that would be a reason for retesting the individual, unless your clinical judgment makes you believe that is the best score the patient can achieve. Like any suspicious lab, the test should be re-administered, and it can be done with Cognitrax through the RETEST function.



# Evaluate Effort - Validity Indicator

Before Retesting, the test examiner or technician should reinforce the need for the subject to give a good testing effort and use the “Validity Indicator” as a tool to help with the reinforcement. To RETEST a subject go to MENU > RETEST SUBJECT > and select the appropriate subject and retest the subject. Upon retest, should a subject test abnormally low again triggering yet another “invalid” test (NO as displayed in the Validity Indicator section of the report) and the clinician believes it was the patient’s best effort further evaluation or referrals should be considered.

The “Validity Indicator” scoring algorithm is based on research presented (Detecting Invalidity In Neurocognitive Tests) at International Society for CNS Clinical Trials and Methodology (ISCTM) in 2009. The poster is available on the CNS Vital Signs website.

## Cognitrax Embedded Indicators of Valid Effort

Clinical Domains	TEST VALIDITY INDICATORS
<b>Verbal Memory</b>	Verbal Memory raw score > 30.
<b>Psychomotor Speed</b>	Both FTT and SDC are Valid
<b>Processing Speed</b>	SDC: Correct Responses >= 20 AND Correct Responses > Errors
<b>Simple Attention</b>	CPT: Correct Responses >= 30 AND Correct Responses > Commission Errors
<b>Motor Speed</b>	FTT: total taps >= 40

FTT - Finger Tapping Test; SDC – Symbol Digit Coding Test; CPT – Continuous Performance Test

“ Cognitrax helps assess a patients neurocognitive status...



Cognitrax helps assess a patients neuropsychiatric symptoms...”

### Cognitrax Advantages

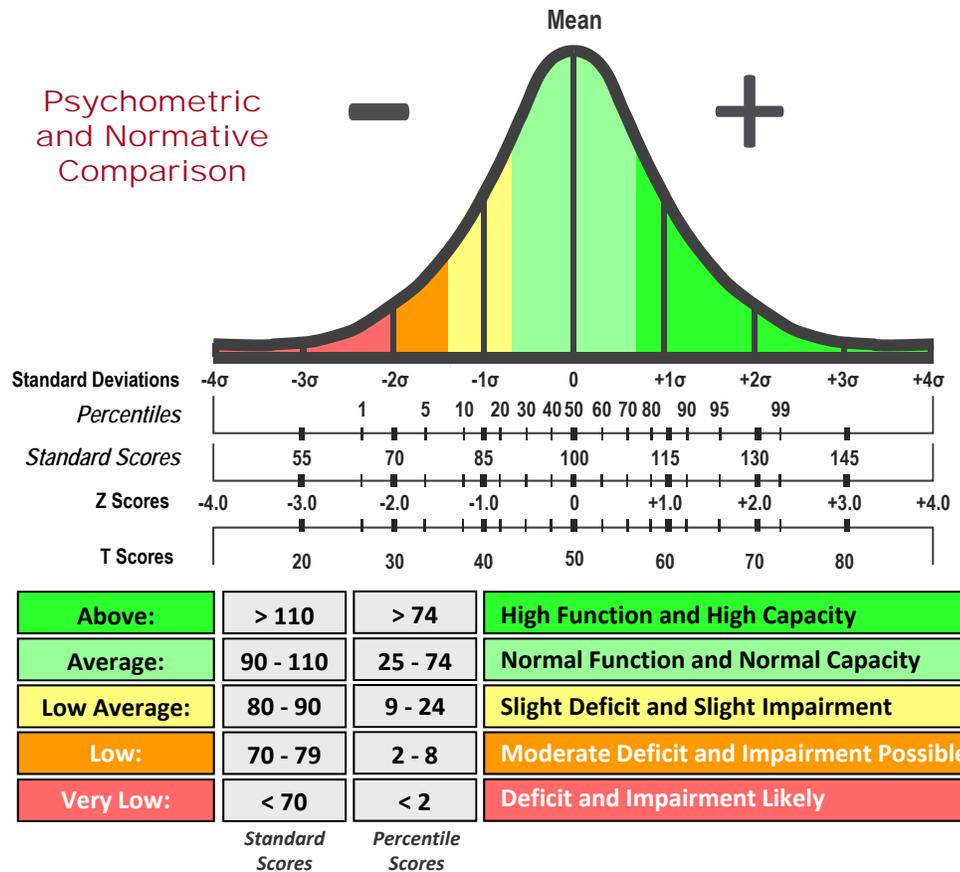
Cognitrax yields millisecond precision stimulus response timing allowing for consistent and accurate measurement of minute cognitive changes, such as those associated with drug effects and mild cognitive impairments. Cognitrax is optimized for serial testing with a unique auto-randomized algorithm which provides the ability to generate an almost unlimited number of alternative forms suitable for repeated or longitudinal testing. Computerized testing enables better standardization in administration and automated scoring, precise stimulus control, increased cost efficiency in testing, and the ability to develop large and accurate databases providing a clinical robustness to clinicians interested in following groups of patients in registries for outcomes, research, and surveillance purposes.



# Evaluate Severity - Impairment Status

Cognitrax grades **severity of impairment** based on an age-matched normative comparison database. Most neuropsychiatric and neurodegenerative conditions are multifactorial in nature. Effective evaluation of neurocognitive and behavioral issues can provide a standardized and efficient method of collecting valid and important neuropsychiatric clinical endpoints. These neuropsychiatric clinical endpoints can systematically document a patient's clinical course. Altogether, Cognitrax computerized testing can facilitate a more complete assessment and provide a basis for patient and family feedback.

The Cognitrax STANDARD SCORES and PERCENTILE RANKS are auto-scored using an algorithm based on a normative data set of 1600+ subjects, ranging from Ages 8 – 90. In the age-matched normative sample subjects were: (1) in good health, (2) had no past or present psychiatric or neurological disorders, head injury, or learning disabilities, and the (3) Sample subjects were free of any centrally acting medications.

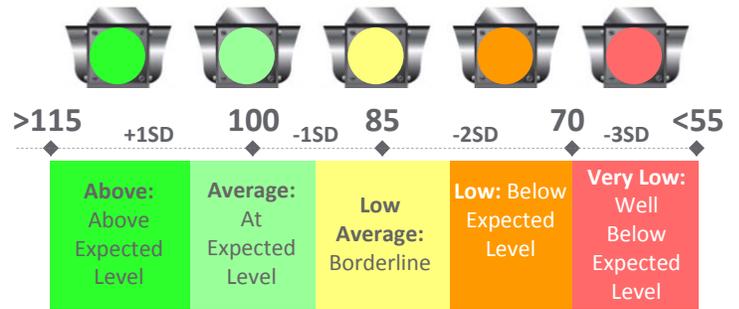


The Cognitrax/CNSVS normative data is presented in ten age groups: less than 10 years old, 10–14, 15–19; in deciles to 79, and finally, 80 years or older. The standard scores are normalized with a mean of 100 and standard deviation of 15. Percentile Ranks is a mathematical transformation of the standard score and an index of how the subject scored compared to other subjects of the same age on a scale of 1 to 99. NORMAL AGING affects performance on all Cognitrax tests. A patient's standard scores are based on data from normal controls that are the same age. EDUCATION and SPECIAL SKILLS may also affect test performance; therefore, concern should be taken for patients that are very intelligent or well educated yet their scores are below average. Like any laboratory test, an abnormal result should be the occasion for further evaluation. As with any neuropsychological tests, results can be affected by motivation or effort level and the Validity Indicator will help identify those patients.



# Evaluate Severity - Impairment Status

## Neurocognitive Domain Dashboard



Patient Profile:	Percentile Range				> 74	25 - 74	9 - 24	2 - 8	< 2
	Standard Score Range				> 109	90 - 109	80 - 89	70 - 79	< 70
Domain Scores	Subject Score	Standard Score	Percentile	VI**	Above	Average	Low Average	Low	Very Low
Verbal Memory	47	90	25	Yes		x			
Psychomotor Speed	138	91	27	Yes		x	4		
Processing Speed	39	94	34	Yes		x			
Simple Attention	51	99	47	Yes		x			
Motor Speed	48	89	23	Yes			x		



SD = Standard Deviation from the MEAN

Cognitrax presents testing results in Subject (raw), Standard Scores, and Percentile Ranks. Results obtained from a Cognitrax assessment can be used to evaluate or monitor a patient's condition and the subsequent treatment and management of that patient. Below, is a description of each domain category:

- Subject Scores** are computed from raw score calculations using the data values of individual subtests and are simply the number of correct responses, incorrect responses, and reaction times. Reaction times are in milliseconds. An ASTERISK (\*) denotes that "lower score is better" e.g., timing, otherwise higher scores are better.
- Standard Scores** are normalized from raw scores and present an age matched score relative to other people in a normative sample. Cognitrax standardized have a mean of 100 and a standard deviation is 15. Higher scores are always better. The schema where the mean is 100 and the standard deviation is 15 is similar to the presentation of IQ scores where the mean for normal is 100.
- Percentile Scores** is a mathematical transformation of the standard score and an index of how the subject scored compared to other subjects of the same age on a scale of 1 to 99. If an individual obtained a score at the 52<sup>nd</sup> percentile (50th percentile is average), this would mean that their performance would be equal to 52% of his same-aged peers in the general population. Higher scores are always better.

## Severity Classification Grade:

Above:	> 110	> 74	High Function and High Capacity
Average:	90 - 110	25 - 74	Normal Function and Normal Capacity
Low Average:	80 - 90	9 - 24	Slight Deficit and Slight Impairment
Low:	70 - 79	2 - 8	Moderate Deficit and Impairment Possible
Very Low:	< 70	< 2	Deficit and Impairment Likely

Standard Scores    Percentile Scores

Quick View Age-Matched Normative Scores





# Evaluate Severity - Impairment Status

## Evaluating Patient Reported Outcome

Assessing neurocognitive tests should be made in context of behavioral observations and other clinical variables and endpoints (Lezak et al., 2004). The Cognitrax MULTI-MODAL assessment platform enables the collection and autoscoring of important clinical data that can improve care management, support guidelines and document practice outcomes measures e.g., PQRS. **The PRO scale is auto-scored according to scale developers guideline** and is used to supplement clinical evaluation and management activities by helping make sure the right questions have been asked and by rating the severity of the illness or impairment. The use of Patient Reported Outcomes can help formalize the assessment approach, help ensure thoroughness, may clarify the presence or absence of disorders, generally helps provide an index of severity, and helps facilitate the determination of response to treatment and disease course over time.

## Patient Health Questionnaire (PHQ-9)

**Major Depressive Syndrome:** If 5 more responses are shaded ("More than half the days" or "Nearly every day") and at least one the shaded questions is #1 or #2.

**Other Depressive Syndrome:** If 2 to 4 responses are shaded ("More than half the days" or "Nearly every day") and at least one the shaded questions is #1 or #2.

**Note:** the diagnoses of Major Depressive Disorder and Other Depressive Disorder requires ruling out normal bereavement (mild symptoms, duration less than 2 months), a history of a manic episode (Bipolar Disorder) and a physical disorder, medication or other drug as the biological cause of the depressive symptoms.

**PHQ-9 Depression Severity:** This is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of "Not at all", "Several days", "More than half the days", and "Nearly every day" respectively. PHQ-9 total score for the nine items ranges from 0 to 27.

### Interpretation of Total Score:

1-4 Minimal depression	15-19 Moderately severe depression
5-9 Mild depression	20-27 Severe depression
10-14 Moderate depression	

1	Little interest or pleasure in doing things	3 - Nearly every day
2	Feeling down, depressed, or hopeless	2 - More than half the days
3	Trouble falling or staying asleep, or sleeping too much	2 - More than half the days
4	Feeling tired or having little energy	3 - Nearly every day
5	Poor appetite or overeating	3 - Nearly every day
6	Feeling bad about yourself - or that you are a failure or have let yourself or your family down	2 - More than half the days
7	Trouble concentrating on things, such as reading the newspaper or watching television	3 - Nearly every day
8	Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	2 - More than half the days
9	Thoughts that you would be better off dead, or of hurting yourself in some way	1 - Several days
<b>PHQ-9 Score</b>		<b>21</b>

10. How difficult have the problems you reported made it for you to do your work, take care of things at home, or get along with other people?

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.



# Evaluate Pattern - Suggestive Pathology

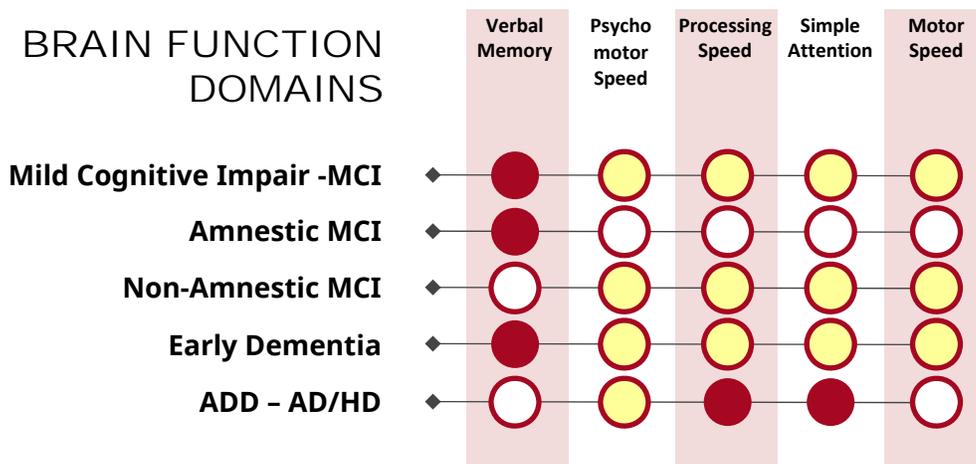
Like most neuropsychological or psychological tests, clinicians will recognize, over time, which domains reveal the clinical conditions of their patients. The profiles below may help clinicians evaluate test results. The profiles are based on thousands of well-characterized patients, as well as a review of published literature and data.

Variation in neurocognitive scores can be multifactorial in nature.

Genetic, maternal health issues, environmental, developmental, other disease processes e.g., diabetes or comorbidities can affect neurocognition. Patients may experience global deficits or domain specific deficits across a variety of neurological and psychiatric disease states which may differ from what is displayed below. Cognitrax is sensitive to medication effects. Attention should be paid to the nature and response pattern as well as errors. Patient's scoring well below average in one domain or below average in two domain areas, might well be impaired and should be evaluated further. The first step in evaluating such a patient is to repeat the test under more favorable circumstances. Like any laboratory test, repetitive results outside of normal should be investigated. If the scores are low the second time, a targeted work-up may be necessary.

Nature of Pattern     ● = Most Sensitive     ◐ = Moderate Sensitivity     ○ = Less Sensitivity

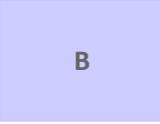
## BRAIN FUNCTION DOMAINS



BRIEF-CORE Clinical Domains	Domain Score Calculations: 1600+ Norms, Ages 8 to 90
<b>Verbal Memory</b>	VBM Correct Hits Immediate + VBM Correct Passes Immediate + VBM Correct Hits Delay + VBM Correct Passes Delay
<b>Psychomotor Speed</b>	FTT Right Taps Average + FTT Left Taps Average + SDC Correct Responses
<b>Processing Speed</b>	SDC Correct Responses - SDC Errors
<b>Simple Attention</b>	Continuous Performance (CPT) Correct Responses minus CPT Commission Errors
<b>Motor Speed</b>	Finger Tapping Test Right Taps Average + Finger Tapping Test Left Taps Average

**Abbreviations Defined:** VBM - Verbal Memory Test; SDC - Symbol Digit Coding Test; FTT - Finger Tapping Test; CPT - Continuous Performance Test.

# Cognitrax Neurocognitive Tests

<p><b>Verbal Memory (VBM)</b> <i>Approx. 3 Minutes</i></p>		<ul style="list-style-type: none"> <li>■ Verbal Learning</li> <li>■ Memory for Words</li> <li>■ Word Recognition</li> <li>■ Immediate and Delayed Recall</li> </ul>
<p><b>Finger Tapping (FTT)</b> <i>Approx. 2 Minutes</i></p>		<ul style="list-style-type: none"> <li>■ Motor Speed</li> <li>■ Fine Motor Control</li> </ul>
<p><b>Symbol Digit Coding (SDC)</b> <i>Approx. 4 Minutes</i></p>		<ul style="list-style-type: none"> <li>■ Information Processing Speed</li> <li>■ Complex Attention</li> <li>■ Visual-Perceptual Speed</li> <li>■ Information Processing Speed</li> </ul>
<p><b>Continuous Performance (CPT)</b> <i>Approx. 5 Minutes</i></p>		<ul style="list-style-type: none"> <li>■ Sustained Visual Attention</li> <li>■ Choice Reaction Time</li> <li>■ Impulsivity</li> </ul>

## Clinical Domain Description

<b>Verbal Memory</b>	<b>Measure:</b> How well subject can recognize, remember, and retrieve words. <b>Relevance:</b> Remembering a scheduled test, recalling an appointment, taking medications, and attending class.
<b>Psychomotor Speed</b>	<b>Measure:</b> How well a subject perceives, attends, responds to visual-perceptual information, and performs motor speed and fine motor coordination. <b>Relevance:</b> Ability perform simple motor skills and dexterity through cognitive functions i.e., use of precision instruments or tools, performing mental and physical coordination i.e., driving a car, playing a musical instrument.
<b>Processing Speed</b>	<b>Measure:</b> How well a subject recognizes and processes information i.e., perceiving, attending/responding to incoming information, motor speed, fine motor coordination, and visual-perceptual ability. <b>Relevance:</b> Ability to recognize and respond/react i.e., fitness-to-drive, occupation issues, possible danger/risk signs or issues with accuracy and detail.
<b>Simple Visual Attention</b>	<b>Measure:</b> Ability to track and respond to a single defined stimulus over lengthy periods of time while performing vigilance and response inhibition quickly and accurately. <b>Relevance:</b> Self-regulation and simple attention control.
<b>Motor Speed</b>	<b>Measure:</b> Ability to perform movements to produce and satisfy an intention towards a manual action and goal. <b>Relevance:</b> Preparation and production of simple manual dexterity actions e.g. manipulate and maneuver objects