

NeuroGage[®] 4.0 Radar Report

Patient: 000	Location of MRI: 000
Date of MRI: OOO	Date of report: OOO
Age at MRI: OOO years	Referring Physician: 000

Quality control

- *Summary*: The grayscale and segmented DICOM images were high quality and provided a valid basis for the NeuroQuant[®] results.
- Details:
 - MRI scanner:
 - Brand: Siemens, 3T
 - Model: OOO
 - Scanner software version: OOO
- Inspection of the MRI grayscale images showed:
 - The images were high quality and showed good differentiation between gray and white matter.
 - The ears, nose and vertex all were present.
- Visual inspection of the segmented DICOM images showed no segmentation errors.
- Manual comparison of the scanning parameters used versus those recommended by CorTechs Labs showed good compatibility.
- NeuroQuant 4.0 automated Compatibility Assessment (attached) showed good quality but noted the following problems:
 - EchoTime was 4.2 and expected value was 2.9 (not within 10% tolerance). This was a known technical issue that typically did not reduce the quality of the segmented images (Micki Maes, CorTechs Labs Clinical Operations Manager, email communication on 08/05/20).
 - SpecificCharacterSet was noted as "missing, ASCII will be assumed". But, in fact, it was included in the metadata under a different tag/label and therefore was not missing. More generally, the NeuroQuant[®] 3.0 software occasionally will not match DICOM parameter tags/labels with scanner tags/labels which could result in a blank parameter; this will not affect the scan quality as it is indicating the amount of noise and quality of contrast. Therefore, the results of the scan may still be reliable (Micki Maes, CorTechs Labs Clinical Operations Manager, email communication on 01/05/21).

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- More generally, per email communication on 05/12/23 with Micki Maes, CorTechs Labs Clinical Operations Manager:
 - The Compatibility Assessment report is a useful tool that can help point out problems with scanner parameters but is not always diagnostic of whether the results are accurate.
 - Visual inspection of the segmented DICOM images generally is a better way to determine whether the results are accurate.
 - Reviewing the Compatibility Assessment report and visually inspecting DICOMs is a better approach than either one alone.
- Regarding NQ 4.0 Brain Atrophy report, per email communication on 12/19/23 with Micki Maes, CorTechs Labs Clinical Operations Manager
 - For parenchymal values > 95% tile, they are still valid findings from the perspective of clinical interpretation or research, and the only difference from previous versions of NQ is that they are no longer associated with a blue flag (email communication with Micki Maes, Clinical Operations Manager, CorTechs AI, 12/19/23).

NeuroQuant Volumes	Left	Right	Total	Asym	NeuroGage Literature Review										
Region	No	ormative	Percentil	es	TBI mild mod	TBI mod sev	ALZ	мсі	SCI	Mold	PTSD	MDD	GAD	scz	СВ
Whole brain parenchyma	1	75	16	1	1	~	~							1	
Forebrain parenchyma	1	84	26	1						X					
Cerebral white matter	1	11	2	1	✓	✓								~	
Cortical gray matter	45	99	91	1	✓	X				1				X	
Ventricles	99	93	99	99	✓	✓								1	
Superior lateral ventricle	99	93	99	99	✓	✓								1	
Inferior lateral ventricle	99	99	99	99											
Subcortical structures						·					·				
Cerebellum	22	30	26	16											
Cerebellar white matter	62	91	81	1	~										
Cerebellar gray matter	15	13	14	60											
Brainstem	-	-	9	-											
Thalamus	44	64	55	13											
Ventral diencephalon	48	14	28	97	✓										
Basal ganglia	1	60	18	1	√	✓									
Putamen	2	72	27	1		✓	~								
Caudate	32	54	44	11											
Nucleus accumbens	1	35	3	1	X										X
Pallidum	3	22	9	1		1		~	~	X					
Cingulate	87	75	85	65											
Anterior cingulate	96	76	93	78	✓	X	х				X	х	X		
 Rostral anterior cingulate 	68	78	81	38										X	
Caudal anterior cingulate	99	60	96	92	✓								X		
Posterior cingulate	83	23	55	95											
Isthmus cingulate	19		62	1											
Cortical structures															
Frontal lobe	95	99	97	1		X	X							 ✓ 	
Superior frontal	2	86	73	7	X	✓						~	~	X	
Middle frontal	78	99	99	43	✓	X						X	X		
Anterior middle frontal	87	99	99	60	1						√	X			
Inferior frontal	85	99	98	1									X	X	
Pars opercularis	69	99	85	1											

<u>Comparison of NeuroQuant Volumetric Results (left table) with NeuroGage Literature-</u> <u>based Volume Patterns (right table)</u>

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<u>Comparison of NeuroQuant Volumetric Results (left table) with NeuroGage Literature-</u> <u>based Volume Patterns (right table)</u> (continued)

NeuroQuant Region	Left	Right	Total	Asym	NeuroGage Literature Review										
Frontal lobe (continued)	No	ormative I	Percentile	es	TBI mild mod	TBI mod sev	ALZ	мсі	SCI	Mold	PTSD	MDD	GAD	scz	СВ
 Pars triangularis 	68	99	99	1	X	X									
 Pars orbitalis 	52	88	77	11											
Frontal pole	95	96	98	51											
Lateral orbitofrontal	2	57	20	1	√	√						1	✓		
Medial orbitofrontal	78	82	84	53											
Paracentral	87	74	86	67											
Primary motor	85	85	87	46											
Premotor	69	85	81	26											
Parietal lobe	95	99	99	1	√		X								
Primary sensory	99	90	97	74	√	X									
Medial parietal	99	99	99	90	√		X						1		
Superior parietal	99	99	99	5	√										
Inferior parietal	31	91	72	4	√										
Supramarginal	2	99	60	1	√										
Occipital lobe	80	69	76	72											
Medial occipital	76	93	87	13											
 Cuneus 	76	99	98	1			X								
 Lingual gyrus 	57	69	64	38											
 Pericalcarine 	89	89	85	82											
Lateral occipital	77	23	49	98	√										
Temporal lobe	1	91	9	1		1	~							1	
Superior temporal	14	97	60	1		X								X	
Transverse temporal	20	58	30	20											
Posterior superior temporal sulcus	60	96	87	18	~										
Middle temporal	65	65	14	1	√	✓									
Inferior temporal	1	65	2	1	1	1								1	
Fusiform	1	53	2	1	X									1	
Parahippocampal	3	54	14	1		1	~	1						1	~
Entorhinal cortex	1	81	22	1			~	~	✓						
Temporal pole	39	99	93	1	√			X							 ✓
Amygdala	1	22	3	1	1	✓	~	~	~	X	1	1	X	✓	
Hippocampus	11	74	40	1	✓										1

Key for NeuroQuant Volumetric Results table:

--- (strikethrough) indicates that the data were unreliable.

Bold font indicates a normative percentile that was statistically significantly abnormal, defined as $\leq 5^{\text{th}}$ or $\geq 95^{\text{th}}$ normative percentile.

Pink background indicates an abnormally small parenchymal volume, or similarly, abnormally large ventricular volume.

Green background indicates an abnormally large parenchymal volume, or similarly, abnormally small ventricular volume.

Asymmetries $\leq 5^{\text{th}}$ %ile are associated with L<R volumes, and asymmetries $\geq 95^{\text{th}}$ %ile are associated with R<L volumes.

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☐ Yellow background indicates abnormal asymmetry with L<R for parenchymal regions, or similarly, L>R for ventricular regions.

Purple background indicates abnormal asymmetry with R<L for parenchymal regions, or similarly, R>L for ventricular regions.

Key for NeuroGage Differential Diagnoses table:

 \checkmark A green checkmark indicates that an abnormal brain volume finding was consistent with the peer-reviewed literature for a specific diagnosis.

X A red X indicates that an abnormal brain volume finding was opposite the peerreviewed literature for a specific diagnosis.

A white, blank field indicates that peer-reviewed literature was available for the given brain volume, but the brain volume finding was "neutral" because either the volume finding was normal or the literature did not report any volume abnormalities for that region.

A grayed-out field indicates that there were no literature findings available for that brain volume region vis-à-vis a specific diagnosis.

Abbreviations:

ALZ = Alzheimer's disease.

CB = cannabis use disorder.

GAD = generalized anxiety disorder.

MCI = mild cognitive impairment.

MDD = major depressive disorder (also called major depression).

Mold = mold-related illness (also called chronic inflammatory response syndrome [CIRS]).

PTSD = posttraumatic stress disorder.

SCI = subjective cognitive impairment.

SCZ = schizophrenia.

TBI mild mod = mild or moderate traumatic brain injury.

TBI mod sev = moderate or severe traumatic brain injury.

NeuroGage brain volume analyses showed the following:

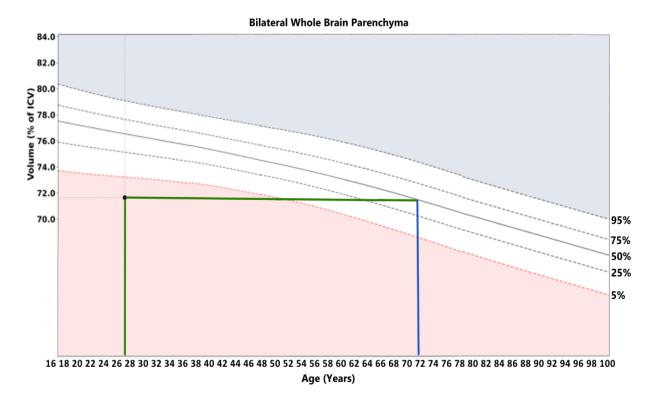
- The TBI Biomarker test:
 - o TBI ✓
 - Normal Ø
- The TBI Biomarker test (a test based on artificial intelligence algorithms) showed that their overall pattern of brain volumes matched that of patients with chronic mild or moderate TBI better than that of normal controls.

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<u>Figure 1:</u> The volume of the patient's bilateral whole brain parenchyma was as small as that of the average 72-year-old person based on NeuroQuant's normal control data.

Methods

MRI brain segmentation and analyses of volumetry and asymmetry were performed using NeuroQuant 4.0, developed by Cortechs.ai. Tables summarizing brain volume and asymmetry results were generated using NeuroQuant 4.0 additional data output provided by Cortechs.ai. The NeuroQuant csv file provides additional data through Cortechs.ai on a given MRI sequence. It includes 71 regions and subregions, absolute brain volumes, percent of intracranial volume, and 5th and 95 normative percentile references. This additional information expands on the information provided by the NeuroQuant reports which may be utilized for further comparisons and potential research.

The differential diagnoses table was created through an extensive review of brain volume findings of specific diagnoses based on the peer-reviewed literature. The NeuroGage software automatically fills in the differential diagnoses table based on a comparison of the subject's volume results to the data obtained from the literature.

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The TBI Biomarker test was based on NeuroQuant[®] 3.0 volume data and NeuroGage 3.0 asymmetry data. 61 patients with chronic mild or moderate TBI, selected using our previously published criteria, were compared to the NeuroQuant normal controls and the NeuroGage normal controls (N=80). Neural network analyses using JMP 16.2 software were used to predict whether each subject belonged to the group of normal controls or patients. Each neural network model was developed using a K-fold method for validation of the results and then a leave-one-out method for testing the results. (The leave-one-out method is a conservative method that minimizes overfitting of the models.) The final method consisted of the average of 3 neural networks for each subject, yielding the following results:

		Diagnosis						
		Normal	TBI					
Test	Normal	76	0					
result	TBI	4	61					
	Sensitivity:	100.0%						
	Specificity:	95.0%						

Since the development of the TBI Biomarker test, we have tested its validity in an additional sample of patients with chronic mild or moderate TBI, many of whom had brain disorders other than TBI. Of that sample (N=47), 93.6% tested positive for a diagnosis of TBI, confirming very good sensitivity of the test. For a subgroup of that sample that included patients with mild TBI but not moderate TBI (N=34), 97.1% tested positive for a diagnosis of TBI, again confirming excellent sensitivity of the test.

TBI BM test results:

NeuroGage 3.0 TBI Biomarker test:

Result: 100% (TBI)

Comparison ranges:

- Normal: 0-50%
- Chronic mild or moderate TBI: >50%

Key: TBI = traumatic brain injury.

Note: The TBI Biomarker test was developed in order to predict whether a given participant is a healthy normal control or a patient with chronic mild or moderate TBI.

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For patients with other disorders, the results may or may not be valid and should be interpreted accordingly.

Disclaimer

This NeuroGage Radar software is owned by NeuroGage LLC and the Virginia Institute of Neuropsychiatry and falls under the FDA Clinical Decision Support (CDS) guidelines. As such, it is intended to provide information to healthcare professionals to support their clinical decision-making. It is not intended to replace the healthcare professional's clinical judgment or to be used as a diagnostic tool. The healthcare professional is responsible for independently reviewing the basis of the recommendations and applying their own expertise to the individual patient's needs and circumstances. NeuroGage Radar does not acquire, process, or analyze medical images, signals, or patterns; instead, it relies on the imaging and volumetric results of NeuroQuant, which is FDA-cleared medical software owned by CorTechs.ai. NeuroGage Radar software does not provide specific diagnoses or treatments. The information presented is based on established medical knowledge and clinical guidelines, but it may not be entirely inclusive or exclusive of all reasonable courses of care. Deviations from the recommendations may be justified by individual patient factors. Users should seek the advice of a gualified healthcare professional for the application of NeuroGage Radar software to specific patient cases.

David E. Ross, M.D. Neuropsychiatrist Board-certified in:

- General psychiatry
- Neuropsychiatry
- Brain injury medicine

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