

## NINDS Multiple Sclerosis Common Data Elements (CDE)

### Laboratory Tests and Non-Imaging Diagnostics Subgroup Recommendations

The following are the Non-Imaging Diagnostics recommendations of the MS CDE Laboratory Tests and Non-Imaging Diagnostics Subgroup. The CDE recommendations have been divided into separate categories and are presented in different tables as shown below:

- Table 1 – **ECG/EKG**
- Table 2 – **Pulmonary Function Test**
- Table 3 – **Scalp Electroencephalogram**
- Table 4 – **Immune Cell Subsets**
- Table 5 – **Electrophysiology**
- Table 6 – **Nerve Conduction Studies**

**Table 1. EKG/ECG**

<b>CDE</b>	<b>General Comments</b>	<b>Purpose</b>	<b>Classification</b>
ECG/EKG	If results are abnormal, use the following permissible values: Abnormal, Not Clinically Significant; Abnormal, Clinically Significant ; Other, specify	Safety	Supplemental

**Table 2. Pulmonary Function Tests**

<b>CDE</b>	<b>General Comments</b>	<b>Purpose</b>	<b>Classification</b>
Pulmonary Function Tests	Interpreted as predicted value based on age and size	Safety	Supplemental

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**Table 3. Scalp Electroencephalogram**

<b>CDE</b>	<b>General Comments</b>	<b>Purpose</b>	<b>Classification</b>
Activating procedures used	Permissible values: Sleep; Hyperventilation; Photic stimulation; Unknown; Other, specify	Diagnosis/ Safety	Supplemental
Behavioral states recorded	Permissible values: Awake; Asleep; Unresponsive state; Indeterminate; Other, specify	Diagnosis/ Safety	Supplemental
Date EEG recorded	mm/dd/yyyy	Diagnosis/ Safety	Supplemental
Duration, if prolonged	Permissible values: Less than 24 hours; Greater than or equal to 24 hours; N/A; Other, specify	Diagnosis/ Safety	Supplemental
Frequency of the posterior dominant rhythm during relaxed wakefulness	Round to the nearest 0.5 Hz	Diagnosis/ Safety	Supplemental
Location	Permissible values: Outpatient EEG Lab; Inpatient Monitoring Unit; Intensive Care Unit; Ambulatory; Other, specify	Diagnosis/ Safety	Supplemental
Number of seizures with EEG only		Diagnosis/ Safety	Supplemental
Number of seizures with Video and EEG		Diagnosis/ Safety	Supplemental
Number of seizures with video only		Diagnosis/ Safety	Supplemental
Original purpose of EEG	Permissible values: Research purposes - prospective; Research purposes - retrospective; Clinical purposes; Other, specify	Diagnosis/ Safety	Supplemental
Posterior dominant rhythm present?	Permissible values: Yes; No	Diagnosis/ Safety	Supplemental
Total number of seizures recorded		Diagnosis/ Safety	Supplemental
Type	Permissible values: Routine; Prolonged	Diagnosis/ Safety	Supplemental
Video?	Permissible values: Yes; No; Unknown; Other, specify	Diagnosis/ Safety	Supplemental

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**Table 4. Immune Cell Subsets**

<b>CDE</b>	<b>General Comments</b>	<b>Purpose</b>	<b>Classification</b>
CD2+	T cell % and number	Other/ Safety	Exploratory
CD2+DR	T cell % and number	Other/ Safety	Exploratory
CD3+/CD4+	T cell % and number	Other/ Safety	Exploratory
CD3+/CD8+	T cell % and number	Other/ Safety	Exploratory
CD3-/CD56+ (NK cells)		Other/ Safety	Exploratory
CD3-/CD56+ bright	Absolute number or proportional NK cells	Outcome/ Safety	Exploratory
CD3+ (T cells)	T cell % and number	Other/ Safety	Exploratory
CD4/CD8 ratio		Other/ Safety	Exploratory
CD4+DR	T cell % and number	Other/ Safety	Exploratory
CD8+DR	T cell % and number	Other/ Safety	Exploratory
CD14+ (monocytes)		Other/ Safety	Exploratory
CD19+ (B cells)	B cell % and number	Other/ Safety	Exploratory
Other mononuclear subsets		Other/ Safety	Exploratory

**Table 5. Electrophysiology**

<b>CDE</b>	<b>General Comments</b>	<b>Purpose</b>	<b>Classification</b>
Motor EP: Arm, right and left cortex - APB	Results should include: latency, amp, CMCT, threshold	Diagnosis/ Outcome	Supplemental
Motor EP: Leg, right and left cortex - EDB	Results should include: latency, amp, CMCT, threshold	Diagnosis/ Outcome	Supplemental
Motor EP: Leg, right and left cortex - TA	Results should include: latency, amp, CMCT, threshold	Diagnosis/ Outcome	Supplemental
VEP checkerboard size 16	N75 latency; P100 latency; N145 latency	Diagnosis/ Outcome	Supplemental
VEP checkerboard size 32	N75 latency; P100 latency; N145 latency	Diagnosis/ Outcome	Supplemental

**Table 6. Nerve Conduction Studies**

<b>CDE</b>	<b>General Comments</b>	<b>Purpose</b>	<b>Classification</b>
Fwave studies (right and left; M-latency, F-latency)	Permissible values: Peroneal (EDB); Peroneal (TA); Median	Diagnosis/ Outcome	Supplemental
Median Right and Left (amp, latency, CV, temp)	Segment: abductor pollicis brevis (wrist right and left)	Diagnosis/ Outcome	Supplemental
Peroneal (amp, latency, CV, temp)	Segment: extensor digitorum brevis (ankle right and left); TA (ankle right and left)	Diagnosis/ Outcome	Supplemental