1. Confirmatory Diagnostic Tests

Confirmatory Diagnostic Tests Table

| Test/Assay | \*Performed? | \*Date Performed (m (yyyy-mm-dd) | \*Abnormal/Normal | \*Result details  (including units) |
| --- | --- | --- | --- | --- |
| AChR Antibody Binding Assay | Yes  No | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |
| MuSK Antibody Assay | Yes  No | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |
| Repetitive Nerve Stimulation | Yes  No | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |
| Neuromuscular Jitter | Yes  No | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |
| Edrophonium Test | Yes  No | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |
| Ice Pack Test | Yes  No | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |
| Rest Test | Yes  No | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |
| Other antibody assay, specify: | Data to be filled out by site | Data to be filled out by site | Abnormal  Normal | Data to be filled out by site |

\*Element is classified as Core

## General Instructions

Confirmatory diagnostic tests data are collected to verify a Myasthenia Gravis diagnosis.

Important Note: The AChR antibody binding assay element on this CRF Module is classified as Core (i.e., strongly recommended for all Myasthenia Gravis clinical studies to collect). If the AChR antibody binding assay is negative, then the MuSK antibody assay is Core and must be performed. If both AChR and MuSK are negative, then the electrophysiology studies (repetitive nerve stimulation and neuromuscular jitter) are Core and must be performed. The remaining data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Confirmatory diagnosis test/ assay – Choose all that apply.
* Diagnostic test/assay performed - If Yes is answered for Edrophonium test, specify the dose used in milligrams (mg).
* Diagnostic test/assay performed date and time - Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ([ISO 8601](http://www.iso.org/iso/iso8601)). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
* Diagnostic test/assay result - Only answered if AChR Antibody Binding Assay, MuSK Antibody Assay, and Other antibody assay are performed. Also record the units. Do not answer for Repetitive Nerve Stimulation, Neuromuscular Jitter, Edrophonium Test, Ice Pack Test, or Rest Test.