

Multiple Sclerosis Treatment Testing

An estimated 400,000 Americans have Multiple Sclerosis (MS), an incurable and sometimes debilitating autoimmune disease that damages the central nervous system. Treatment with interferon-beta (Avonex®, Rebif®, or Betaseron®) and Tysabri® (natalizumab) can help manage symptoms, but some patients produce antibodies to the drug, making it ineffective for continued treatment. Quest Diagnostics in conjunction with Focus Diagnostics now offers assays to detect antibodies to Interferon-beta and Tysabri that can help monitor therapy in MS patients.

INTERFERON-BETA ANTIBODIES

For interferon-beta (IFNβ) an ELISA screening method is performed to detect IgG antibodies capable of binding to IFNβ. However, only the neutralizing antibodies correlate with loss of bioactivity. The interferon-beta neutralizing antibody (NAb) assay is a follow-up test after a positive ELISA test has been reported. The NAb assay will be performed as a reflex to the ELISA screening assay or as a monitoring test for patients who have been previously shown to have neutralizing antibody to a specific interferon-beta. This viral neutralization bioassay method yields semi-quantitative results at clinically relevant serum antibody titers of 1:20 and 1:100. Currently, formulations for MS interferon-beta are available from different manufacturers, and the specific drug being used to treat the patient must be provided with the patient requisition. The test for neutralizing antibodies will *not* be performed without a previous positive test report (either positive Interferon-Beta IgG, ELISA or previous positive Neutralizing Antibody assay) for the specific interferon-beta drug being administered.

TYSABRI ANTIBODIES

Tysabri is a new monoclonal antibody drug that is used to treat patients with relapsing forms of multiple sclerosis. Patients may develop drug-specific antibodies that interfere with its therapeutic effect. Tysabri binds to proteins called alpha-4-integrins, which are found primarily on the surface of white blood cells, and play a role in immune system activity. This assay detects antibodies that bind to Tysabri *in vitro*; a positive result should not be interpreted as definitive evidence of *in vivo* blocking activity.

Test Code	19509X
Test Name	Interferon-beta IgG, ELISA w/Reflex to Neutralization
Specimen Requirements	1.5 mL serum, refrigerated If interferon-beta is ≥ 4 , neutralizing antibodies will be performed at an additional charge.
Test Code	19510X
Test Name	Interferon-beta Neutralizing Antibodies
Specimen Requirements	1 mL serum, refrigerated
Test Code	19215X
Test Name	Tysabri Antibodies, ELISA
Specimen Requirements	1 mL serum, refrigerated

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