

What Are Antibodies?

What You Need to Know About NABs

What the Experts Say About NABs

Testing for NABs

Everything you need to know about neutralizing antibodies (NABs) and their impact on MS therapy.



What You Need To Know

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What the Experts Say

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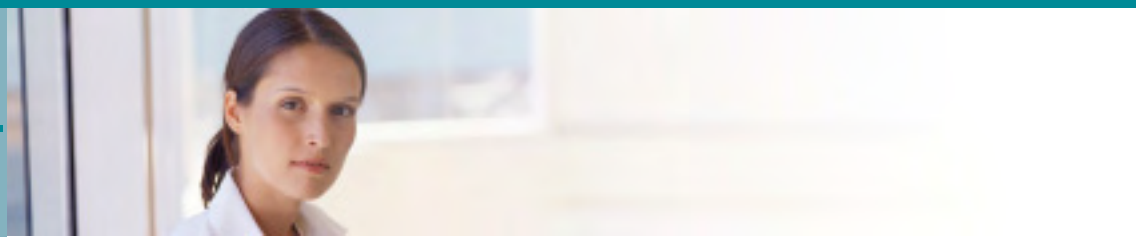
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What are Antibodies?

The human immune system is a complex assembly of defense and attack mechanisms that work together to keep the body free of infection. **Antibodies** are one part of this intricate system.

How do antibodies develop?

When the body is invaded by foreign or unrecognized material (eg, a common cold virus), the immune system responds by producing antibodies. Antibodies interact with the invaders, marking them for destruction by other players in the immune system. In this way, the body is able to recognize, target, and ultimately rid itself of unwanted intruders and prevent infection from occurring.

The creation of antibodies is a normal and necessary function of the human body. However, the antibody response can also cause unwanted effects. The body may manufacture antibodies in response to medical therapy, reducing the effectiveness of the treatment. In multiple sclerosis (MS), some patients treated with interferon (Avonex®, Betaseron®, Rebif®) develop antibodies to their medication, potentially reducing the overall benefits of the treatment.

How do antibodies work?

The immune system produces antibodies in response to the numerous invaders (eg, bacteria) encountered on a daily basis. Each antibody is designed to target a specific intruder, also called a **pathogen**. The primary function of the antibody is to inactivate the pathogen. Antibodies accomplish this goal in 3 ways:

1. **Neutralization:** Antibodies bind directly to their targets, forming large antibody/pathogen complexes. This formation inhibits the invader from communicating with other cells in the body, effectively neutralizing the pathogen.
2. **Opsonization:** Antibodies bind to and coat the invader so that it is recognized as a target by **phagocytic cells**. Phagocytic cells are also part of the immune system and are designed to digest and destroy recognized enemy cells.
3. **Complement activation:** Antibodies bind to the invader and initiate a series of events that increases opsonization (see number 2 above). These antibodies may also directly destroy some bacteria.

The method used to inactivate an invader is dependent on the type of antibody present.

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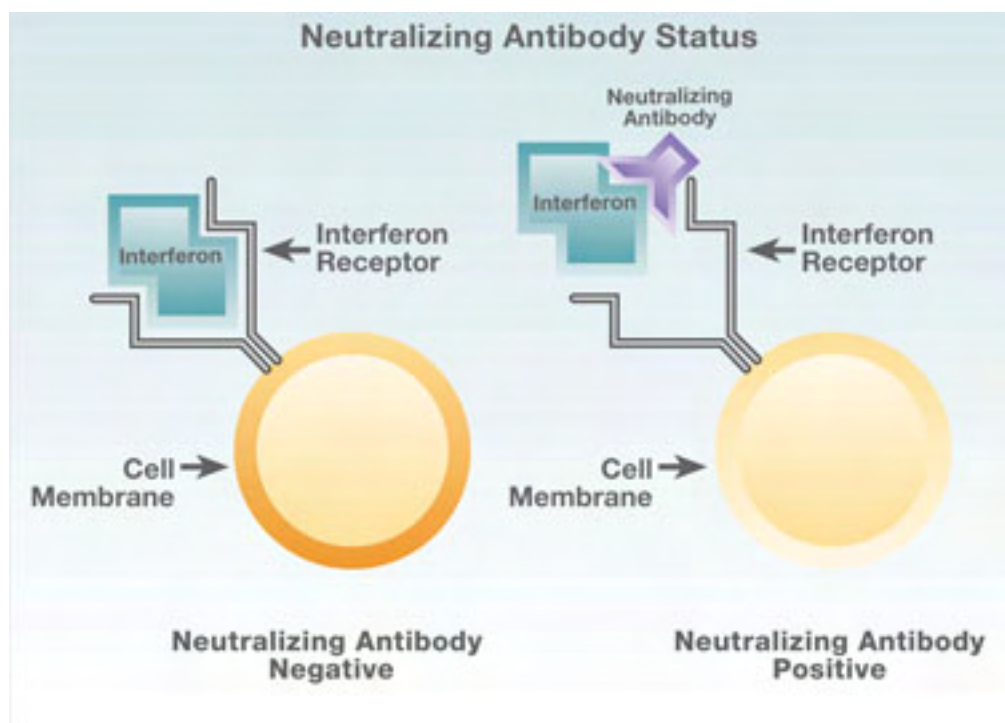
Some multiple sclerosis patients treated with interferon develop antibodies to the therapy. This discussion will focus on two types of antibodies found in these patients: neutralizing antibodies (NABs) and binding antibodies.

What are neutralizing antibodies?

In some patients with MS undergoing interferon therapy, antibodies bind to the drug, but still allow it to communicate with cells in the body and help control the disease. These antibodies are known as binding antibodies. Other antibodies bind to interferon and inhibit or reduce its ability to help control disease. These antibodies are known as neutralizing antibodies (NABs).

How do neutralizing antibodies impact therapy?

MS patients can develop NABs to each of the interferon products currently available in the marketplace (Avonex®, Betaseron®, Rebif®). However, not all patients receiving interferon therapy will develop NABs. According to their respective prescribing information profiles, 45% of patients receiving Betaseron®, 24% of patients receiving Rebif®, and 5% of patients receiving Avonex® will develop NABs. The time it takes to develop NABs is usually between 12 to 18 months after initial treatment with interferon.



Label claims of each Interferon therapy currently on the market:

- Avonex: [Download PDF](#)
- Betaseron: [Download PDF](#)
- Rebif: [Download PDF](#)

To find the specific section on neutralizing antibodies in each of the documents below, press CONTROL+F and then search for "neutralizing".

Studies have shown that patients with MS who develop NABs in response to interferon treatment may begin to lose some of the benefits of their therapy. The resulting disease progression may effect an increase in MRI (brain scan) activity, an increased risk of disease relapse, or an increase in disease-related disability as measured by the Expanded Disability Status Scale. Recent studies suggest that MS progresses faster in patients who develop NABs versus patients who do not develop NABs. Patients who develop NABs are more likely to see little to no benefit from future interferon therapy than patients who do not develop NABs.

What are binding antibodies?

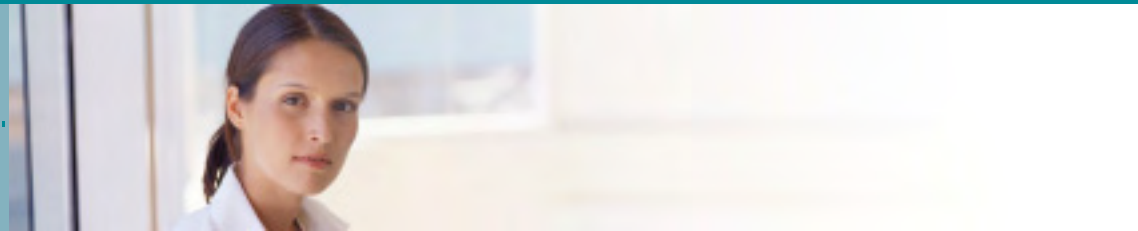
Binding antibodies are another type of antibody found in some patients on interferon treatment. Binding antibodies develop with greater frequency than NABs, but do not decrease the efficacy of interferon treatment. The function of binding antibodies is not known at this time.

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What the experts say about NABs

In the July 12, 2005 issue of Neurology, the journal published by the American Academy of Neurology, three research papers discussed the importance of NABs to patients on Interferon treatment. According to these studies:

- Neutralizing antibody development is correlated with reduced efficacy and is a potential cause for renewed disease activity
- In patients with MS, NABs reduce the therapeutic benefit of interferon on both MRI activity and relapse rate
- The results of the neutralizing antibody test should be viewed as predictive, since NAB-positive patients are more likely to fail interferon therapy in the future compared with Nab-negative patients

The studies conclude that NABs reduce the biologic and clinical efficacy of interferon treatment.

Abstract of the above-mentioned studies

- Appearance and disappearance of neutralizing antibodies during interferon-beta therapy
- Neutralizing antibodies and efficacy of interferon β -1a A 4-year controlled study
- Interferon β -1a in MS

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Testing for NABs

What antibodies should be tested for?

There is only one test commercially available for measuring NAb levels. The NAbFeron® (IFNβ) Antibody Testing Service offered by Athena Diagnostics directly measures the amount of NABs in a blood sample. This is the only method recommended by the World Health Organization.

Who should be tested?

Knowing your NAb status is an important consideration in the management of your disease. Experts recommend the following schedule of testing:

1. All patients on interferon should be tested at 12 months and 24 months after initiating therapy. In addition, patients who have been on interferon for more than 24 months and have never been tested should be tested to verify that they do not have NABs.
2. Patients should be tested at the time of a relapse
3. Patients should be tested before switching therapy
4. Patients should be tested before adding adjunct therapy

Patients who remain NAb-free after two years of continuous therapy are unlikely to develop NABs in the future. Therefore, it is not necessary to routinely monitor these patients.

How can I get tested?

Talk to your doctor about NAb testing. If you are an MS patient and your interferon therapy does not appear to be effective, talk with your physician about scheduling a NAbFeron® Neutralizing Antibody Test.

Your physician is the only person that can order the NAbFeron test, and once the order is placed, either your physician's office or Athena Diagnostics will schedule a blood draw for you. This may happen either at a local lab or at a location convenient to you if your physician chooses to use Athena's home draw program. Once drawn, your blood is sent to Athena Diagnostics for the NAbFeron test. This test takes anywhere between one to two weeks to complete depending on the current demand. The results of the test are then sent back to your physician. Depending on the test results, you and your physician can decide how to modify your therapy.

[Click here](#) to download and print information and an order form to take to your physician.

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Glossary

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Antibody - Part of the human immune system. Identifies and marks invaders (eg, bacteria) for destruction.

Complement activation - 1 of 3 types of antibody response. Includes the binding of antibodies to a pathogen and the triggering of the complement cascade (see neutralization and opsonization).

Connective tissue - Supporting, binding, and protective tissue of the human body. Includes collagen, ligaments, and tendons, among others.

MRI - Magnetic resonance image. An imaging technique used to view internal soft tissues of the body (eg, brain).

Neutralization - 1 of 3 types of antibody response. Includes the formation of large antibody/pathogen complexes (see opsonization and complement activation).

Opsonization - 1 of 3 types of antibody response. Includes the coating of the pathogen with antibodies and the triggering of phagocytic cells (see neutralization and complement activation).

Pathogen - any disease-producing invader.

Phagocytic cells - Includes macrophages, monocytes, and neutrophils. These cells are capable of eating and destroying both pathogens and cellular "garbage."

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