

# anti-IFN-beta BAB ELISA

For an Efficient Patient and  
Cost Management

Antibody induced  
Reduction of  
IFN-beta  
Efficacy?



The only commercial ELISA assay  
for anti-IFN-beta antibody  
screening

Best correlation with overall NAB  
titers

Simple and reliable test procedure

Supports cost efficient therapy  
management for Multiple Sclerosis

# Monitoring the Efficacy of IFN-beta Therapies

## IFN-beta in Multiple Sclerosis, an Overview

Multiple Sclerosis (MS) affects over 2.5 mio individuals worldwide and is the most common disease of the CNS that causes prolonged and severe disability. IFN-beta is the most commonly used treatment in Relapsing/Remitting Multiple Sclerosis (RRMS). The widely used disease modifying agents with annual global sales of \$ 3 billion are Interferon-beta 1a and -1b. Various studies have proven the value of these biologicals in the treatment of RRMS by reducing the relapse rates by 30% and increasing the remittance time span. These therapies are very expensive (15 - 17 k€ per year/patient).

## IFN-beta Antibodies

Caused by the appearance of anti IFN-beta Antibodies, a substantial number of patients fail to respond to IFN-beta therapies. Antibody mediated decrease in bioactivity, will lead to decreased clinical effect of injected IFN-beta.

Commercial name	Betaferon® Betaseron®	Rebif®	Avonex®
Cell origin	E. coli IFN-beta 1b	mammalian IFN-beta 1a	mammalian IFN-beta 1a
Market share [in Mio US\$]	1200	1375	1000
Immunogenicity of IFN-beta Therapies	45%	24%	5%

Binding Antibodies (BABs) to IFN-beta develop as early as 3 months during therapy in up to 80% of treated patients and Neutralizing antibodies (NABs) prevent the binding of the Interferon to its receptor on the target cells, neutralizing the biological effects of IFN-beta.

NABs have clearly been shown to be a subset of BABs.

## Should routine screens for anti-IFN-beta antibodies be performed?

It is highly important to control the antibody status early on during therapy as BABs/NABs appear after 3 - 6 months and are highly predictive indicators for therapy success, as the clinical effects of NABs only appear around 18 months after therapy starts!

**The Bühlmann BAB Assay is suggested as first step screening tool. It is simple, quick and inexpensive!**

In a second step NAB Assays can be performed with the positive samples from the previous BAB screening. NAB tests are activity assays. They are time consuming and more difficult to perform.

**Generally, only samples that are positive for BAB are assayed for NABs.**

## The Guidelines of the EFNS (European Federation of Neurological Societies) on IFN-beta Antibodies are very clear:

BAB assays: BAB assays can be reliably used for IFN-beta antibody screening before performing a NAB assay (level A recommendation)

BAB & NAB assays: measurements of BABs and NABs against IFN-beta should be performed in specialized laboratories (level A recommendation).

Tests for the presence of NABs should be performed at 12 and 24 months of therapy (level A recommendation).

Therapy with IFN-beta should be discontinued in patients with high titers of NABs sustained at repeated measurements with 3 – 6 month intervals (level A recommendation).

The anti-IFN-beta BAB ELISA from BÜHLMANN fits these requirements completely.

- a simple ELISA assay yielding results in 4.5 hours.
- Can be run semi-automated.
- Cheap compared to any NAB test and other BAB products.
- CE-marked, intra- and inter-laboratory correspondance.

A recent study by an IFN-beta expert group acknowledged the BÜHLMANN-BAB ELISA to be a valuable tool for the IFN-beta antibody screening test: In comparison with other methods, the EIA (BÜHLMANN BAB Assay) had the best overall correlation to NAB titers (from Gneiss et al,ECTRIMS 2005).

## Literature

### Sørensen, PS et al.

Guidelines on use of anti-IFN-β antibody measurements in multiple sclerosis: report of EFNS Task Force on IFN-β antibodies in multiple sclerosis; Europ J Neurol, 12, 817-27 (2005)

### Hesse, D and Sørensen, PS

Using measurements of neutralizing antibodies: the challenge on IFN-beta therapy; Europ J Neurol, 14(8), 850-9 (2007)

### Hartung, HP et al.

Neutralising antibodies to interferon beta in multiple sclerosis: Expert panel report; J Neurol, 254(7), 827-37 (2007)

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BÜHLMANN Laboratories AG  
Baselstrasse 55  
CH-4124 Schönenbuch/Basel  
Switzerland

Phone +41 61 487 12 12  
Fax orders +41 61 487 12 99  
info@buhlmannlabs.ch  
www.buhlmannlabs.ch



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