Introducing the MONATOR Laboratory Developed Test: Dose Monitoring for Natalizumab

MONATOR is the first dose-monitoring laboratory test that that provides you with data that may aid in making clinical decisions when using Natalizumab (Tysabri).

MONATOR Test Benefits

With a simple blood draw, you can measure natalizumab levels in your patients at regular intervals to inform treatment decisions.

Help identify an optimal dosing interval for each patient

Help to monitor patients for possible efficacy or safety risks

Potentially reduce excessive costs to payers and patients

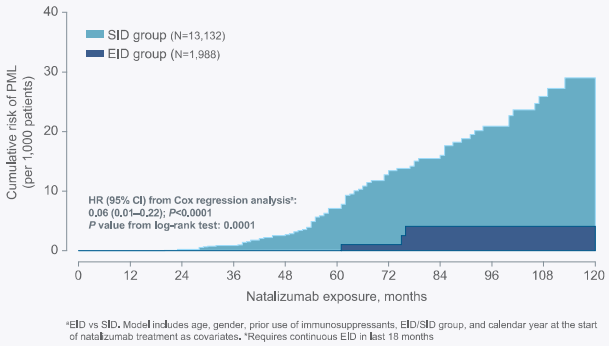
Precision Dosing

The standard dosing regimen for natalizumab is 300 mg by intravenous infusion every four weeks. A 2011 study reported that patients with MS who were receiving standard dosing of natalizumab exhibited significant variability in their serum natalizumab levels.[1]

Research also indicates that patients receiving natalizumab are at risk for progressive multifocal leukoencephalopathy (PML).

Extending infusion intervals has been suggested as one way to maintain the efficacy of natalizumab, while reducing exposure to the drug and thereby potentially reducing the risk for PML.[2,3]

Risk of PML for Patients on Standard Interval Dosing (SID) vs Extended Interval Dosing (EID) Patients[4]



*EID vs SID. Model includes age, gender, prior use of immunosuppressants, EID/SID group, and calendar year at the start of natalizumab treatment as covariates. †Requires continuous EID in last 18 months

94%↓*

reduction in PML risk for EID vs. SID

"Extended infusion intervals in combination with personalized monitoring may dramatically change the risk profile for patients on natalizumab."

Dr. John F. Foley

Founder, Rocky Mountain Multiple Sclerosis Clinic

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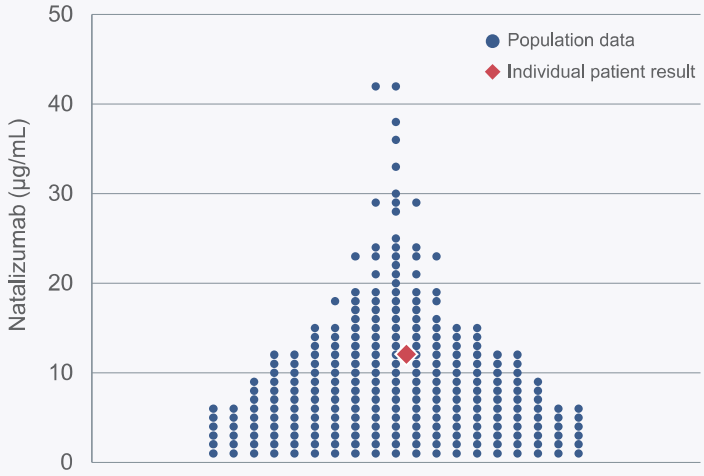
Personalized Results for Precision Care

Dose monitoring in individual patients undergoing natalizumab therapy is informative when considering a personalized approach to treatment.

MONATOR reports the serum drug level of natalizumab in your patient and where that result falls within an ever-growing population of MS patients. Initially analytically validated with a cohort of 155 patients, the MONATOR test also utilizes a live dataset updated in real time with patient use.

Example Test Result — Reported Serum Natalizumab Level within Distribution



- High variation in serum drug levels may relate to safety and efficacy
- Results incorporate live dataset that is updated in real time.

MONATOR Test Features

Sample type: serum

Results within three to five days

CLIA-certified, CAP-accredited lab-developed test

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Contact us for details:

Website: www.aegirbio.com

Email: info@aegirbio.com

About Aegirbio

Aegirbio is a precision medicine company, focused on therapeutic drug monitoring of biologic therapies. Leveraging the proprietary Veritope™ and Magnia® Reader platforms for laboratory-based, Point-of-Care and Point-of-Need assays, Aegirbio is setting new standards in precision dosing. Our ambition is to develop diagnostic and analytic solutions for a wide portfolio of therapies, providing clinical insights within minutes. Aegirbio is offering the moNATor test in partnership with ResearchDx's CLIA-certified lab in California.

To learn more, visit **www.aegirbio.com.**

References

1. Foley J. Progressive escalation of natalizumab serum concentration as a potential kinetic marker for PML risk assessment. Oral communication, abstract S51.004, April 2011. American Academy of Neurology. 2011. 2. Bomprezzi R, Pawate S. Extended interval dosing of natalizumab: a two-center, 7-year experience. Ther Adv Neurol Disord. 2014;7(5):227–231. doi:10.1177/1756285614540224 3. Zhovtis Ryerson L, Frohman TC, Foley J, et al Extended interval dosing of natalizumab in multiple sclerosis. Journal of Neurology, Neurosurgery & Psychiatry 2016;87:885-889. doi: 10.1136/jnnp-2015-312940. 4. Ryerson, L. Z. et al. Risk of natalizumab-associated PML in patients with MS is reduced with extended interval dosing. Neurology 93, e1452–e1462 (2019).