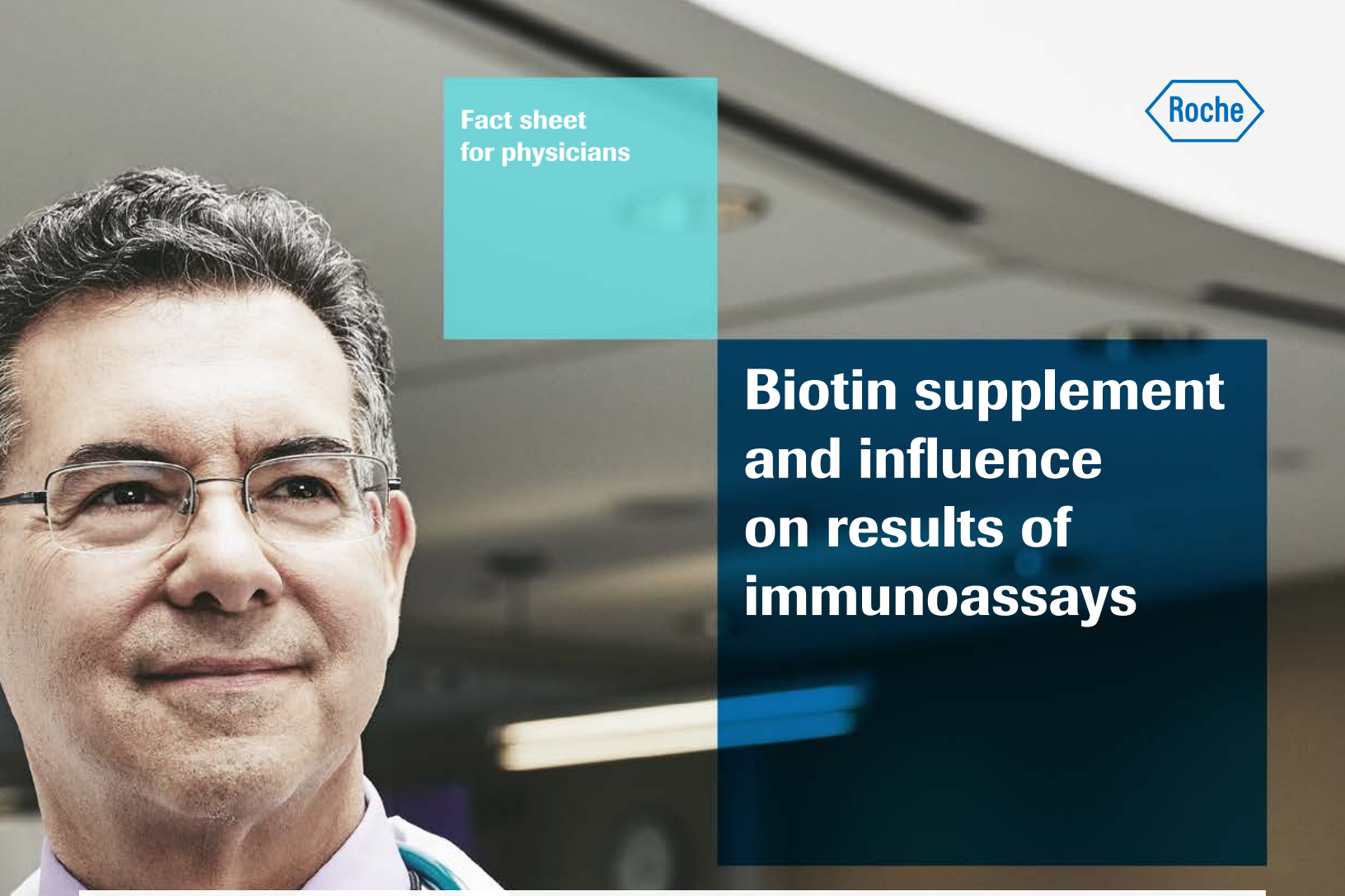


Fact sheet
for physicians

Biotin supplement and influence on results of immunoassays

ABOUT BIOTIN

Biotin (vitamin B7, vitamin H) is a water-soluble vitamin of the B complex that is used as supplementation and for medical treatment. While no recommended daily intake (RDI) for biotin supplementation exists, because biotin deficiency is extremely rare, suggested daily intake for adults in the U.S. is 30–100 mcg.[1] The effective half-life of biotin varies between 8 and 18 hours.[2]

BIOTIN AND LABORATORY RESULTS

Streptavidin and biotin naturally form a strong, highly specific and stable bond. This system has been used for many years and allows the development of sensitive, specific and accurate immunoassays. There are different types of interference and sources of error that can affect the accuracy of immunoassays.[3-5] While the intake of high doses of biotin can lead to interference with immunoassays, there is no risk for such assay interference associated with the intake of biotin as part of a standard multivitamin.[6]

BIOTIN USE: THREE PATIENT POPULATIONS

Because biotin deficiency is considered extremely rare, no RDI exists. Suggested biotin intake for adults ranges from 30–100 mcg per day.[1] When considering biotin use as a supplement, keep in mind three specific populations:

- **Daily multivitamin use**
- **Medical high-dose biotin therapy**
- **OTC lifestyle high-dose biotin supplementation**

Daily multivitamin use:
Many consumers take biotin as an ingredient within a standard daily multivitamin. This dose is typically 30–40 mcg.

Medical high-dose biotin therapy:
High-dose biotin is used as a therapy for inherited conditions such as biotinidase deficiency[7] biotin-thiamin-responsive basal ganglia disease[8] and holocarboxylase synthetase deficiency.[7] High-dose biotin is also currently being used in clinical trial settings as a potential treatment for patients with multiple sclerosis.[9]

OTC lifestyle high-dose biotin supplementation:
Some consumers take high-concentration biotin supplements (5,000–10,000 mcg) currently packaged to promote hair, skin and nail beauty.

BIOTIN INTERFERENCE IN ROCHE ELECSYS® IMMUNOASSAYS

To mitigate potential interference, patients taking biotin doses >5,000 mcg should wait at least 8 hours after the last biotin administration before a sample is taken as stated in all Roche immunoassay package inserts.

IDENTIFICATION OF PATIENTS UNDER BIOTIN TREATMENT

To ensure testing accuracy, it is important to ask patients about their use of all supplements, including biotin, before any laboratory tests are run. Patients may not know the exact does of biotin that they are taking, but the following flow chart will help guide conversations with your patient.

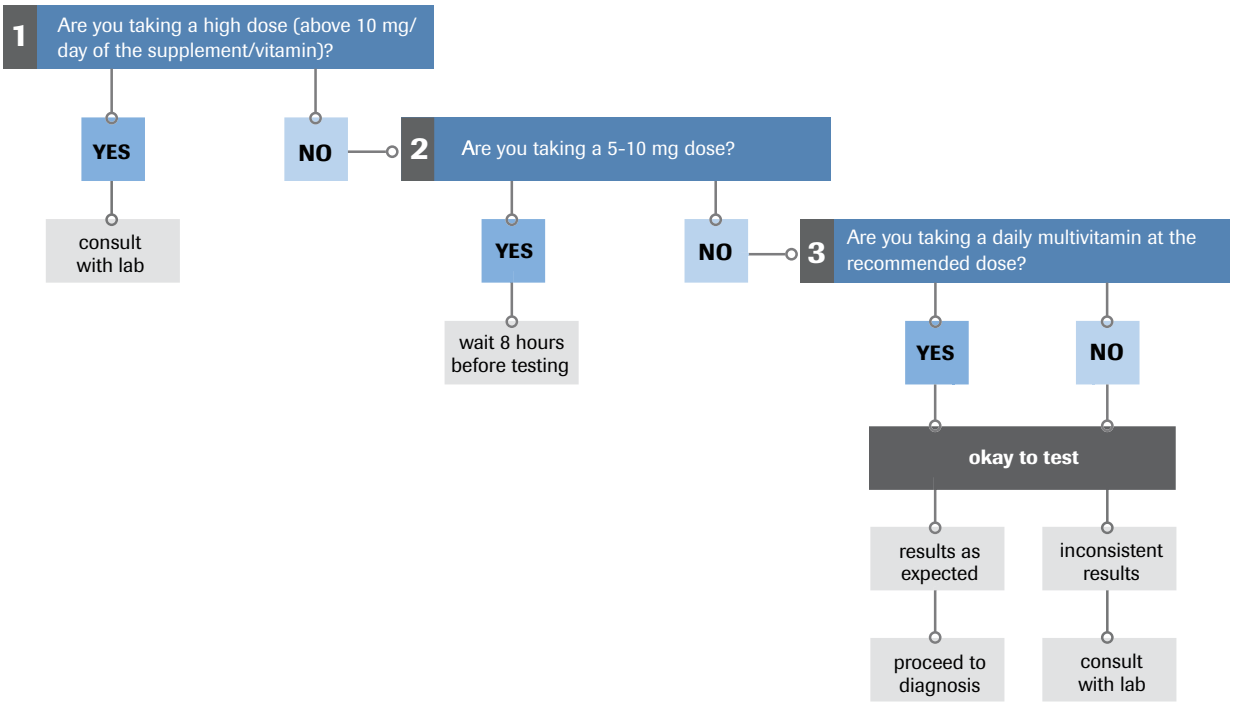
PATIENT TESTING

In both normal and emergency settings, it is important to ask patients the right questions ahead of testing. By asking patients about their biotin intake levels, you can be aware of potential interference from the outset and factor this into your diagnostic evaluation, alongside other key parameters. Diagnosis and a decision of treatment should be evaluated with regard to the clinical picture.

In an emergency setting, we recommend proceeding with testing, taking into account the full patient profile and undergoing re-testing if you suspect interference. The impact of the biotin interference results depends on specific aspects of the assay design. For further guidance and detail, contact your laboratory.

PHYSICIAN FLOW CHART

Establish high dose



1. http://www.mayoclinic.org/drugs-supplements/biotin-oral-route/description/drg-20062359, accessed on 5/26/2017.
2. Peyro Saint Paul et al, Expert Opin. Drug Metab-Txicol. 2016, 12: 327-344.
3. Boscato et al, Clin Chem 1998, 34(1): 27-33.
4. Kroll et al, Clin Chem 1994, 40(11 Pt 1): 1996-2005.
5. Kricka, Clin Chem 1999, 45(7): 942-956.
6. Internal data, manuscript in preparation.
7. Wolf B. Biotinidase Deficiency. 2000 Mar 24 [Updated 2016 Jun 9]. In: Pagon RA, Adam MP, Ardinger HH, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2017.
8. Kassem et al, AJNR 2014, 35 (10): 1990-1995.
9. Sedel et al, Mult. Scler. Relat. Disord. 2015, 4: 159-169.

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