

## Biotin Interference in Roche-manufactured Immunoassays

Biotin (vitamin B7) doses of greater than 5mg may interfere with the Roche-manufactured immunoassay tests employed within Clinical Biochemistry at York Teaching Hospital NHS Foundation Trust and cause results that are inconsistent with the clinical picture. The interference may be positive or negative depending on assay design.

Dose of greater than 5mg are only generally used in over-the-counter supplements marketed for hair, skin and nails (typically 5 – 10mg) and in therapeutic high dose biotin regimes for the treatment of multiple sclerosis (normally >10mg). **Normal intake of biotin as part of a daily multivitamin poses no risk of interference.**

The assays that are particularly susceptible to interference from biotin at doses generally used in over-the-counter supplements marketed for hair, skin and nails are summarised in the table below. **The high doses employed in therapeutic regimes for the treatment of multiple sclerosis have the potential to cause significant interference in all Roche-manufactured immunoassays.**

Assay	Clinical Risk	Assay Design
TPO Antibodies	False positive results	Competitive
Serum Folate	Falsely normal results	Competitive

The risk of biotin interference can be mitigated by waiting at least 8 hours after biotin ingestion before sample collection. Biotin peaks in the bloodstream between 1-2 hours after ingestion and is then rapidly cleared from the body via the kidneys. Biotin clearance may take longer in patients with renal impairment.

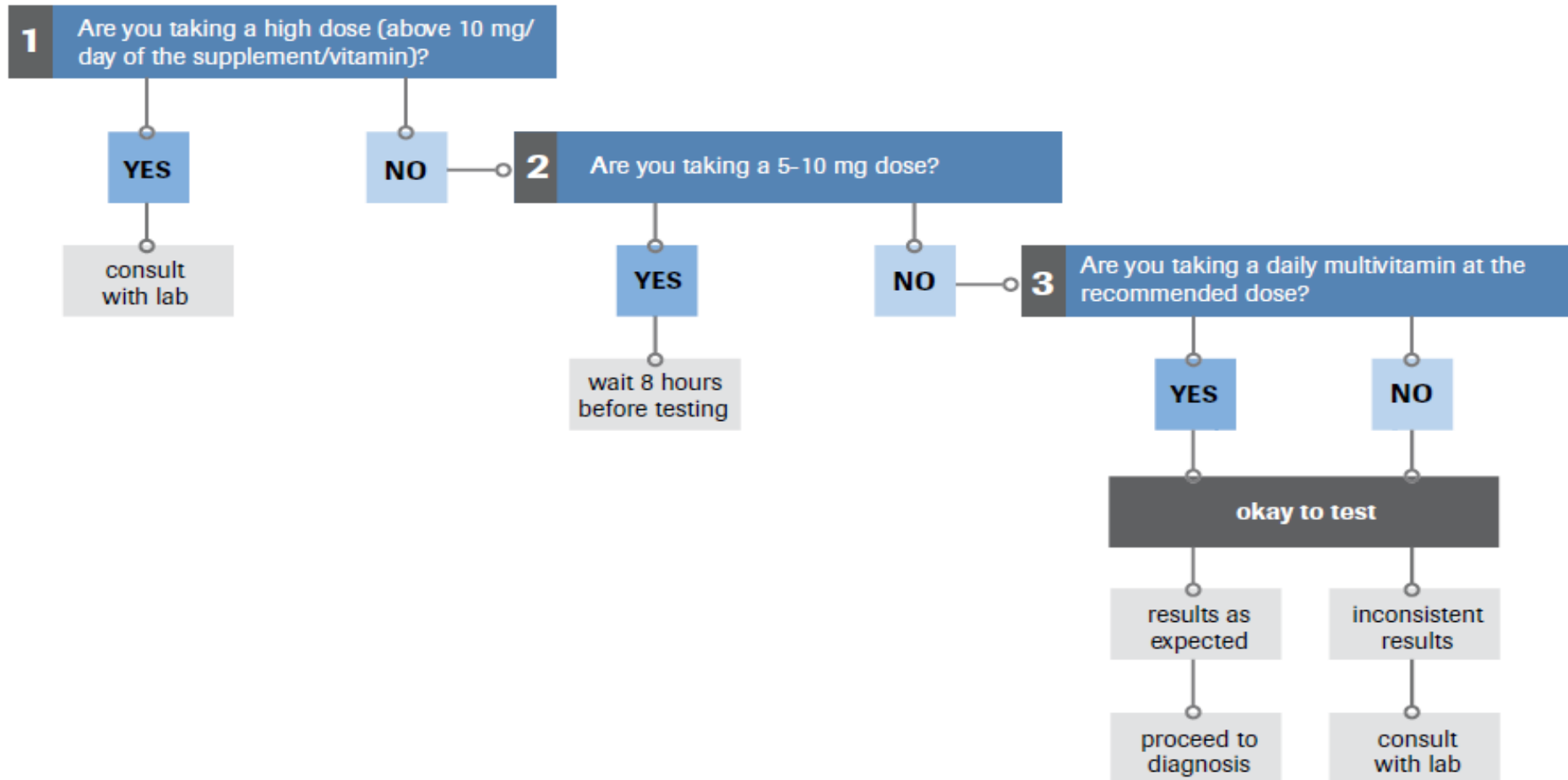
Please note that interference, not due to biotin, can occur in any assay. **Contact the laboratory on 01904 726366 if any test result is not consistent with the clinical picture.**

### **What can clinicians do to reduce the risk of biotin interference?**

1. **ASK** patients to report everything they are taking including prescriptions and over-the-counter medicines, vitamins and supplements prior to sample collection.
2. **UNDERSTAND** that many patients are not aware they are taking high dose biotin because it is packaged as a supplement for hair, skin and nail beauty.
3. **INFORM** your patients about how to prepare for sample collection. If they take biotin doses greater than 5mg then they must wait at least 8 hours after biotin ingestion before sample collection. Ideally they should avoid taking their supplement on the day of their blood test.

Please refer to the algorithm below when discussing the potential risk of biotin interference with your patients.

Grimsey P et al. *Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference.* Int. J. Pharmacokinet. 2017; 2 (4): 247 - 256



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Roche Website: <https://biotinfacts.roche.com/>