



hycor
Improving Lives

Pinpoint
Your
TRUE
Allergy
Triggers



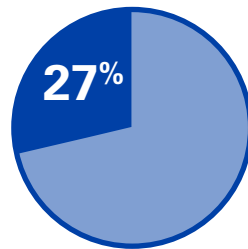
BIOTIN INTERFERENCE

Getting the right answer matters to make reliable clinical decisions.
The new standard to limit the impact of interference!

 **Noveos**

FDA warns biotin can significantly interfere with certain lab tests and cause incorrect results which may go undetected.¹

In the US adult population, 27- 31% are taking biotin supplements², which can decrease **IMMULITE 3G Allergy** results.



Asking patients to comply and stop taking dietary supplements is necessary for assays with interference problems.

Biotin interference is seen in competitive assay designs

Falsely high or falsely low values cause confusing or misleading patient results.

NOVEOS[®] IgE assays have a non-competitive indirect design that limit the impact of interference and produce accurate allergy tests results.

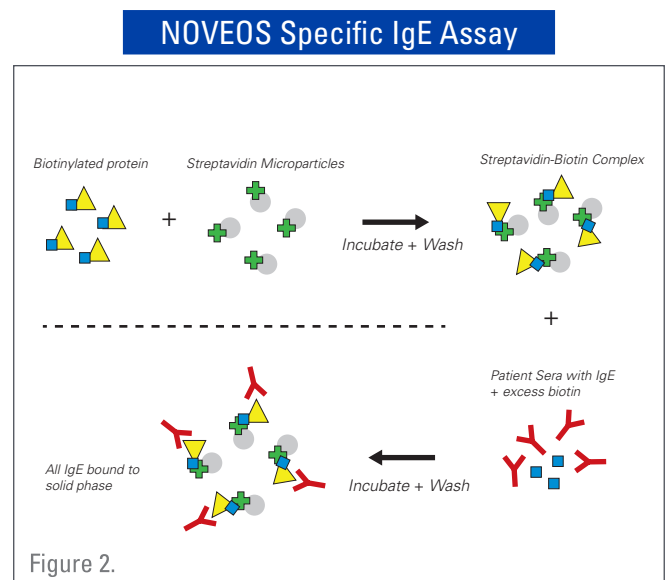
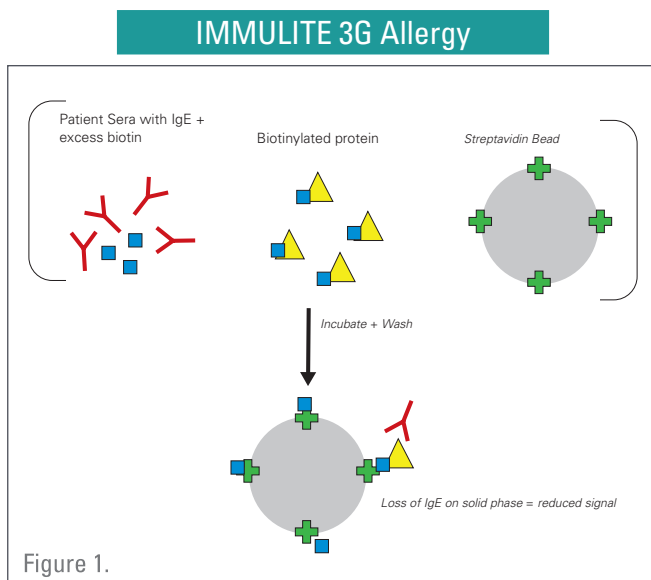


Figure 1: Biotin interference occurs in a competitive assay when the patient sample and the biotinylated analyte are co-incubated with the solid phase as it does in the IMMULITE 3G Allergy assay.

Figure 2: In non-competitive indirect assays like the NOVEOS assay, the biotinylated-protein is initially bound to the streptavidin-coated solid phase, followed by incubation with patient sample. Any biotin in the sample, therefore, does not compete for binding.

False negative results are dangerous when anaphylaxis causing allergens are not detected!



→ The normal daily recommended intake for adults and teenagers is 30 to 100 mcg per day.³



→ Many consumers ingest biotin supplements that contain up to 650 times the recommended Dietary Reference Intake.¹



→ Concentrations of biotin up to 1200 ng/mL may be present in specimens collected from patients taking up to 300 mg per day.¹

→ Endogenous biotin in the patient sample competing for binding sites can cause false negative results in competitive assays.

IMMULITE 3G Allergy sIgE false negative results due to Biotin

IMMULITE 3G Allergy

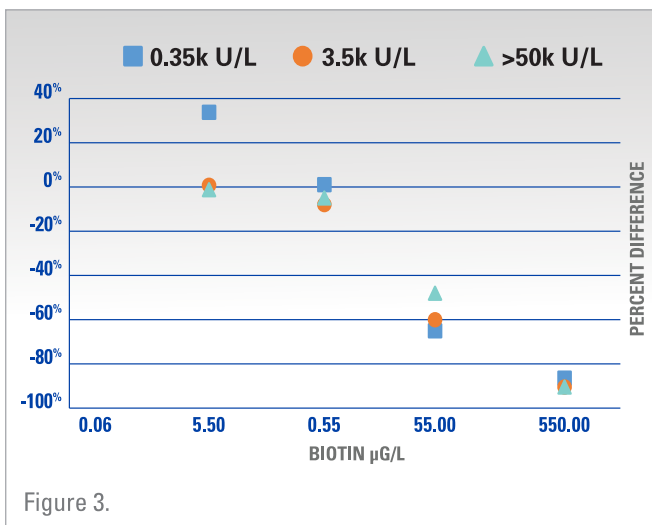


Figure 3.

Figure 3: IMMULITE 3G Allergy shows significant bias and resulted in all samples reporting as negative (<0.35 kU/L).

NOVEOS IgE results are

unaffected by Biotin⁴

NOVEOS Specific IgE Assay⁵

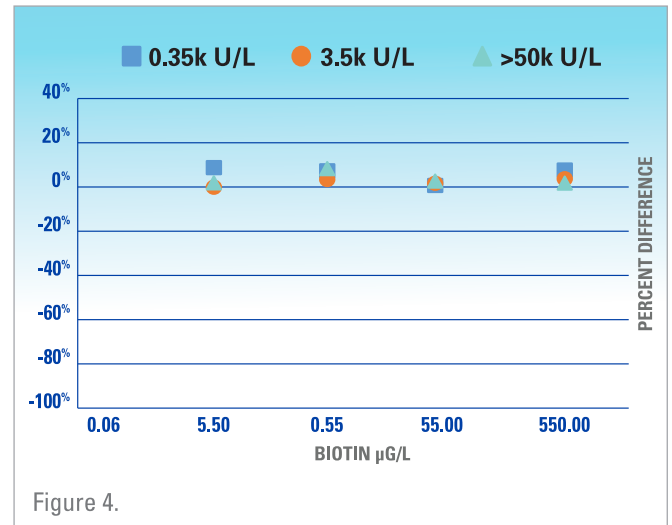


Figure 4.

Figure 4: NOVEOS specific IgE assay⁵ shows minimal bias with all samples retaining their positive values (≥ 0.35 kU/L).



The assay design, small sample size, and the high surface area of paramagnetic micro-particles minimize interferences.



**The NEW STANDARD in allergy testing,
solving shortcomings of current technologies.**



REFERENCES

1. <https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication>. Accessed February 3, 2020.
2. Kantor, et. al. Trends in Dietary Supplement Use among US Adults From 1999-2012, JAMA 2016 Oct 11; 316(14): 1464-1474.
3. <https://www.mayoclinic.org/drugs-supplements/biotin-oral-route/proper-use/drg-20062359>. Accessed January 23, 2020.
4. Data on File.
5. The NOVEOS Immunoassay System and NOVEOS Capture Reagent D001 and D002 are CE-marked and U.S. FDA 510(k) cleared.

Learn More! Schedule a Demo!

Improving the health, well-being and quality of life of individuals with allergies.

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