



Technical Bulletin

Biotin Interference

This important information pertains to the Quidel Triage BNP Test for the Beckman Coulter® Access Family of Immunoassay Systems (Triage BNP for BCIS).

Assay	Catalog Number
Quidel Triage BNP Test for the Beckman Coulter Access Family of Immunoassay Systems	98200

Issue

- Specimens from patients who are ingesting biotin supplements may contain high levels of biotin. Elevated levels of serum biotin can cause interference with the Triage BNP for BCIS.
- Standard intake of biotin in the diet or the amount found in multivitamins does not cause an interference with laboratory tests. Over-the-counter supplements of biotin are 20 to >300 times greater than the adequate daily intake for adults of 30 mcg/day (microgram) established by the Institute of Medicine.¹

Impact

- Specimens that contain high levels of biotin (for example, individuals taking 5 or more milligrams per day) may cause falsely lowered results for the Triage BNP for BCIS. See table below.

Assay	Biotin concentration that causes ≥ 10% bias*	Biotin concentration that causes ≥ 20% bias
Triage BNP Test for the Beckman Coulter Access Family of Immunoassay Systems	76 ng/mL (5 mg/day)	313 ng/mL (20 mg/day)

Quidel Action

Quidel will update the Triage BNP for BCIS instructions for use with biotin interference information.

¹<https://ods.od.nih.gov/factsheets/Biotin-Consumer/>

Customer Action

- Review this information with your Medical Director to determine if any actions are warranted.
- Quidel supports the FDA Safety Communication recommendation for laboratory, clinician and patient education about reporting all prescription medication and supplements prior to blood draws.
- Patients should inform clinicians if they are taking the vitamin supplement Biotin (Vitamin B7).
- Clinicians should interpret results in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.
- The following references may be useful to help further manage biotin interference in your laboratory as well as communications with your clinicians:
 - ▶ FDA Safety Communication:
<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm586505.htm>
 - ▶ NIH Biotin Fact Sheet for Healthcare Professionals:
<https://www.ods.od.nih.gov/factsheets/Biotin-HealthProfessional/>

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded the Triage BNP for BCIS to another laboratory, please provide them a copy of this information.

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference quidel.com to see more options for Support.

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