

INFORMATION BULLETIN

Biotin interference associated with the Access BNP assay*

* For use with the Access 2, UniCel DxI 600, UniCel DxI 800, UniCel DxC 600i, UniCel DxC 880i, UniCel DxC 860i, UniCel DxC 680i and UniCel DxC 660i systems

This important information pertains to the Access BNP assay for use with the Access Family of Immunoassay Systems.

Assay	Catalog Number
Access BNP assay for use with 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 Access BNP assay
- > 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 Medicine¹

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 Access BNP for BCIS. See the following table:

Assay	Biotin Concentration that causes $\geq 10\%$ bias	Biotin Concentration that causes $\geq 20\%$ bias
Access BNP assay for the Beckman Coulter Access Family of Immunoassay Systems	76 ng/mL (5 mg/day)	313 ng/mL (20 mg/day)



Customer Action

- > Review this information with your Medical Director to determine if any actions are warranted
- > Beckman Coulter 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/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication>
 - 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 Access BNP to another laboratory, please provide them a copy of this information.

Contact Information

If you have any questions regarding the use of this product, contact Beckman Coulter Customer Technical Support at 1-800-854-3633 or from our website: <http://www.beckmancoulter.com>. Outside the United States and Canada, please visit the Beckman Coulter website (<http://www.beckmancoulter.com>) for Customer Service contract information, or contact your local Beckman Coulter representative or authorized distributor.

You can also visit the Beckman Coulter website or contact Customer Technical Support for information about the complete menu of Access assays that are available for use with the Access Family of Immunoassay Systems.

References

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