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**UPDATE: Potential for Biotin (Vitamin B7) Interference with Select Laboratory Test Results**

The purpose of this communication is to remind Yale-New Haven Health providers and team members that biotin, often found in dietary supplements, can significantly interfere with certain laboratory tests and cause incorrect results that may go undetected. The recent trend of consuming high dose biotin supplements for both cosmetic and health-related reasons has drawn attention to the potential for biotin interference in laboratory tests.

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| **Table 1: Timeline of published recommendations and communications** |
| November 28, 2017:  | The FDA issued a Safety Communication that discussed concerns with biotin interference in certain laboratory tests.[[1]](#footnote-1) |
| November 5, 2019:  | The FDA published this updated Safety Communication because the FDA remains concerned about certain laboratory tests that have not addressed the risk of biotin interference.[[2]](#footnote-2)  |
| January 13, 2020:  | The American Association for Clinical Chemistry (AACC) Academy published guidance for clinical laboratories.[[3]](#footnote-3)  |

In accordance with available recommendations, unless medically contraindicated, AACC’s guidance document recommends that patients abstain for a minimum of either 8 or 72 hours before blood collection, respectively, depending on whether they are taking a lower (5-10 mg/day) or high (≥100 mg/day) dose of biotin.

The following table list the tests, which are affected by biotin interference as per the assay package insert. The direction of bias is indicated if provided by the manufacturer. Interference thresholds for biotin-mediated interference as obtained from manufacturers’ assay package inserts. Interference threshold refers to the concentration of biotin in the sample, above which, error can be expected.

If there are concerns regarding biotin interference, please contact the performing laboratory. Biotin cannot be measured by the laboratory. Interference thresholds are to provide a general sense of when bias can occur.

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**Table 1**: All laboratory tests which are performed within the Yale New Haven Health System which may be affected by biotin interference as specified by the package insert.

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|  | **Yale New Haven Hospital** | **Bridgeport Hospital** | **Greenwich Hospital** | **L&M, Westerly Hospitals** |
| **Assay Name** | **Direction of error** | **Interference Threshold (ng/mL)** | **Direction of error** | **Interference Threshold (ng/mL)** | **Direction of error** | **Interference Threshold (ng/mL)** | **Direction of error** | **Interference Threshold (ng/mL)** |
| Alpha-Feto Protein (AFP) |  |  | ↓ | 60 | n/a | 3500 | ↓ | 500 |
| Anti-TPO  | ↑ | 10 |  |  | n/a | 1500 |  |  |
| C-Peptide | ↓ | 60 |  |  | n/a | 1500 |  |  |
| Cancer Antigen 15-3 | ↓ | 100 |  |  | ↓ | 100 |  |  |
| Cancer Antigen 19-9 | ↓ | 100 |  |  |  |  |  |  |
| Cancer Antigen 125 | ↓ | 35 | ↓ | 35 | ↑ | 5 |  |  |
| Carcinoembryonic Antigen (CEA) | ↓ | 120 | ↓ | 120 | ↑ | 2 | ↓ | 500 |
| Cortisol II | ↑ | 30 | ↑ | 30 | n/a | 1500 |  |  |
| DHEA-S  | ↑ | 30 |  |  |  |  |  |  |
| Digoxin | ↑ | 100 |  |  | ↑ | 500 | ↑ | 500 |
| Estradiol |  |  | ↑ | 30 | ↑ | 100 | ↑ | 1500 |
| Ferritin | ↓ | 50 | ↓ | 50 | ↓ | 500 |  |  |
| Folate  | ↑ | 21 | ↑ | 21 | ↑ | 500 |  |  |
| FSH | ↓ | 60 | ↓ | 60 | ↓ | 500 |  |  |
| Growth Hormone | ↓ | 30 |  |  |  |  |  |  |
| HAV Antibody, IgM |  |  | ↓ | 50 | ↓ | 500 |  |  |
| HAV Antibody, Total |  |  | ↑ | 50 | ↑ | 25 |  |  |
| Hepatitis B Core Antibody, IgM |  |  | ↓ | 100 |  |  |  |  |
| Hepatitis B Core Antibody, Total |  |  | ↑ | 30 |  |  |  |  |
| Hepatitis B Surface Antibody |  |  | ↓ | 50 | ↓ | 500 |  |  |
| Hepatitis B Surface Antigen |  |  | ↓ | 44 |  |  |  |  |
| HCV Antibody |  |  | ↓ | 44 |  |  |  |  |
| HCG + Beta | ↓ | 80 | ↓ | 80 | ↓ | 1500 | ↓ | 1500 |

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|  | **Yale New Haven Hospital** | **Bridgeport Hospital** | **Greenwich Hospital** | **L&M, Westerly Hospitals** |
| **Assay Name** | **Direction of error** | **Interference Threshold (ng/mL)** | **Direction of error** | **Interference Threshold (ng/mL)** | **Direction of error** | **Interference Threshold (ng/mL)** | **Direction of error** | **Interference Threshold (ng/mL)** |
| HIV 1/2 Ab/Ag |  |  | ↓ | 49 | ↓ | 500 |  |  |
| Homocysteine |  |  |  |  | n/a | 1500 |  |  |
| Insulin | ↓ | 60 | ↓ | 60 | n/a | 1500 |  |  |
| Intact PTH | ↓ | 50 | ↓ | 50 | ↓ | 1500 | ↓ | 1500 |
| LH | ↓ | 50 | ↓ | 50 | ↓ | 500 |  |  |
| Mass Creatinine Kinase Isoenzyme |  |  |  |  | ↓ | 250 |  |  |
| NT-proBNP  |  |  | ↓ | 50 | ↓ | 100 |  |  |
| proBNP  | ↓ | 50 |  |  |  |  | ↓ | 50 |
| Procalcitonin | ↓ | 30 | ↓ | 30 |  |  |  |  |
| Progesterone |  |  | ↑ | 30 |  |  |  |  |
| Prolactin | ↓ | 40 | ↓ | 40 | ↓ | 250 | ↓ | 40 |
| PSA, Total |  |  | ↓ | 60 | ↓ | 1500 | ↓ | 1500 |
| PSA, Free |  |  |  |  | ↓ | 1500 | ↓ | 1500 |
| Sex Hormone Binding Globulin |  |  |  |  | n/a | 1500 |  |  |
| Troponin 4th Generation¥ | ↓ | 50 | ↓ | 50 |  |  |  |  |
| Troponin I |  |  |  |  | ↓ | 100 | ↓ | 100 |
| Thyroglobulin | ↓ | 100 |  |  | n/a | 5 |  |  |
| T3, Total | ↑ | 10 | ↑ | 10 | n/a | 1500 |  |  |
| T4, Total | ↑ | 100 | ↑ | 100 |  |  |  |  |
| T3, Free |  |  |  |  | ↑ | 50 |  |  |
| T4, Free | ↑ | 20 | ↑ | 20 | ↑ | 100 | ↑ | 100 |
| Total IgE |  |  |  |  | n/a | 1500 |  |  |
| Total Testosterone | ↑ | 30 | ↑ | 30 |  |  | ↑ | 30 |
| TSH | ↓ | 1200 | ↓ | 1200 | ↓ | 100 | ↓ | 1200 |
| VitB12 | ↑ | 50 | ↑ | 50 | n/a | 1500 | ↑ | 1500 |

1. <https://www.fda.gov/medical-devices/safety-communications/fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication> [↑](#footnote-ref-1)
2. <https://www.fda.gov/medical-devices/safety-communications/update-fda-warns-biotin-may-interfere-lab-tests-fda-safety-communication> [↑](#footnote-ref-2)
3. Li D, Ferguson A, Cervinski MA, Lynch KL, Kyle PB. AACC guidance document on biotin interference in laboratory tests. [Epub] J Appl Lab Med January 13, 2020, as doi:10.1373/10.1093/jalm/jfz010. [↑](#footnote-ref-3)