PathGroup
Physician Centered. Patient Focused.

TEST UPDATE
ARUP COMPLIANCE STATEMENT

Mary M. Mayo, PhD, DABCC, FACB, BCLD (ABB), Medical Director

Dear Valued Client,

PathGroup has been notified by our reference laboratory partner, ARUP Laboratories, of a resulting issue affecting specific send out testing that was processed through their facility. A compliance statement on results released from August 14, 2014 through November 13, 2015 was omitted while performing an interface coding change to the following tests:

- Giardia lamblia Antibodies by ELISA (GLABS)
- Glutathione, Total (GLUTH)
- Vitamin B5 (B5A)

The omission of the compliance statement did not affect the test result and all test results remain unchanged. ARUP Laboratories' interface team was not properly notified of this coding change and therefore the compliance statement was not properly mapped to transmit onto patient reports. Measures have been implemented by ARUP Laboratories to prevent future coding errors. The compliance statement reads as follows:

> *"The performance characteristics of the listed assay were validated by Cambridge Biomedical Inc. The US FDA has not approved or cleared this test. The results of this assay can be used for clinical diagnosis without GDA approval. 'Cambridge Biomedical Inc. is a CLIA certified, CAP accredited laboratory for performing high complexity assays such as this one."*

We apologize for any inconvenience this may cause and assure you that test quality matters are handled as a top priority.

For further questions, please contact Client Services at 615-562-9300 or 1-888-474-5227.