COLLEGE of AMERICAN PATHOLOGISTS

To whom it may concern:

The College of American Pathologists (CAP) provides quality improvement programs for laboratories. This includes proficiency testing (PT) programs, also referred to as external quality assessment or assurance (EQA). The CAP PT programs contain specimens and materials that are shipped to laboratories in the United States and worldwide. Laboratories test the PT specimens to regularly evaluate performance of their laboratory to help improve the accuracy of patient results.

CAP PT Programs are approved by the Centers for Medicare & Medicaid Services (CMS), a department of the U.S. Department of Health and Human Services. The CAP is also an accredited PT provider under ISO/IEC 17043:2010. CAP PT programs:

- have no commercial value
- are strictly used for educational and quality improvement purposes only and not for in vitro use
- are not used to calibrate instrumentation

In addition, U.S. Food and Drug Administration (FDA) registration is not required, as CAP PT specimens and materials are not used in the treatment or diagnosis of a human patient.

CAP PT programs include manufactured specimens intended to simulate patient samples. These specimens are manufactured to CAP targeted specifications. Laboratories test the PT specimens to regularly evaluate performance of their laboratory and to help improve the accuracy of the patient results.

- The CAP PT kits are packaged and shipped according to the International Air Transportation Association (IATA) regulations. The kits are also packaged in a way to ensure proper “in transit” storage temperature from release of the shipment by the CAP packager through normal customs clearance and delivery time to participant laboratories.
    - It is important that all CAP PT program shipments clear customs and be delivered to laboratories within 7 to 10 business days after shipment arrival in country.
    - CAP PT shipments that are time and temperature sensitive need to clear customs and be delivered to laboratories within 3 to 5 business days after shipment arrival in country.
- Each program provides kit instructions for use by the laboratory upon receipt of the shipment, and each specimen is labeled to match to the test result form used by the laboratory for results submission.
- Participants analyze the specimens and return the results to the CAP for evaluation. In return, the CAP provides each participating laboratory an evaluation report and a participant summary report that shows the laboratory performance as compared to its peers in obtaining intended results.

We hope this letter clarifies the educational nature and non-commercial intent of use of the CAP PT programs and specimens included in the kit shipments. Additional information on the CAP PT programs is available on the CAP website (www.cap.org). Please let us know if you have any additional questions or if we can be of further assistance.

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