



Hospital of the University of Pennsylvania  
Department of Pathology and Laboratory Medicine  
Division of Hematopathology

To: Penn Medicine Physicians and Staff

Date: 10/14/2020

From: Adam Bagg, MD, Director of Hematology, Division of Hematopathology  
Joshua Edwards, MBA, Technical Manager- Hematopathology

Re: Temporary Change for Hemoglobin Identification Testing for Hemoglobinopathies

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On Friday, October 9, 2020, the Laboratory received notification that the FDA has recalled the Ultra2 instrumentation from Trinity Biotech. The Ultra2 is the platform used by the Laboratory to perform Hemoglobin Identification testing (HGID). Based on requirements from the FDA, the Laboratory at HUP will cease testing on this platform immediately.

To provide continuity of patient care, the Laboratory has identified comparable testing at ARUP Laboratories. Any patient specimen collected after Friday, October 9, 8:00 AM, will be sent out for testing, until further notice. Please continue using the same order in Penn Chart, and follow the same process of sending the specimen to the Laboratory. This testing change will not affect any routine CBC orders.

The Laboratory will perform a comparative study to ensure that the results generated by the Ultra2 instrument are consistent with those that are provided by ARUP. We anticipate results for this testing will be available in the patient's medical record approximately 2-7 days after collection. If you have concerns about result values that you are using to track patient disease or about expected turnaround time, please contact the Laboratory directly.

The Laboratory has already begun the process of evaluating a replacement platform from alternate vendors. Once we have identified a replacement and completed the validation process, another memorandum will be sent to all Penn Medicine Physicians and Staff to update the change in testing.

If you need any further clarification of this testing change, please contact Joshua Edwards, Manager of the Hematopathology Laboratory, for assistance at either [joshua.edwards@penntmedicine.upenn.edu](mailto:joshua.edwards@penntmedicine.upenn.edu) or 267-319-5622.

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