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Area	Laboratory-Chemistry
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Dearborn Laboratory Auto Technical Abbott A3600 Accelerator Automation Centrifuge Validation

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A validation procedure is necessary to verify that the settings utilized for the a3600 Accelerator Automation centrifuges are appropriate for the tests being performed. In addition, a validation procedure must be performed if the desired centrifugation conditions are outside the manufacturer recommendations as stated in the Instruction for Use. Changes in centrifugation conditions are typically only an issue regarding gel tubes used in chemistry and immunochemistry but may involve other tube types as well. Anticoagulant tubes for platelet-poor plasma will be assessed on the a3600 automation line for coagulation testing. This validation procedure defines the desired centrifugation conditions for the a3600 Accelerator centrifuges, and the method comparison studies required to validate both serum and plasma samples for chemistry, immunochemistry and coagulation assays.

II. PROCEDURE:

Validation samples must be drawn in pairs (Chemistry/Immunochemistry only), centrifuged, and analyzed within 2 hours of collection. For each pair, one sample will be spun according to Vacutainer specifications in the appropriate centrifuge and the other will be spun at desired condition on Abbott a3600 Accelerator centrifuges. See table below for tube types and centrifuge conditions.

Vacutainer Tube	Vacutainer RPM (IFU)	Vacutainer Time (IFU)	Desired a3600 RPM	Desired a3600 Time

Serum Clot Activator w/ Gel (SST)	1000 - 3000 g	10 min	4000	5 min
Non-Gel Tubes (Serum)	1000 – 3000 g	10 min	4000	5 min
Anticoagulated Plasma (for PPP)	1500 g	15 min	4000	5 min

A total of 20 patients for each workstation are required which can be divided over four days. Centrifuges 1, 2 and 3 on the a3600 are designated for Chemistry, Immunochemistry and Coagulation. Centrifuge 3 on the a3600 is designated for Coagulation.

All samples will be analyzed in parallel in a single run on designated reference analyzers.

A. Chemistry and Immunochemistry

1. Collect 2 full (minimum volume 4.0 mL) 7mL DB Gold Top Serum Separator Tubes (SST) from patient
2. Label tubes will sample validation number and A (BD specification) or B (a3600 settings). For example: Patient 1: Tube 1 = 1A, Tube 2 =1B
3. Spin tube labeled '#A' for BD specification in the appropriate Centrifuge for the RPM and Time listed in Table 1
4. Spin tube labeled '#B' for a3600 settings in Centrifuge 1 for the RPM and Time listed in Table 1
5. Run the following tests in parallel (i.e. both tubes) in single run on appropriate Chemistry analyzer: AST, Glucose, NA, K, CL, CO2, TSH
6. Record values for each analyte and tube in Centrifuge Validation Worksheet – Chemistry and Immunochemistry (see Attachment 1)
7. Repeat Steps a.-f. for a3600 Centrifuge 2 and 3
8. Acceptance criteria for a3600 settings:
    a. All analytes must have R2 value of >/=0.98

B. Coagulation

1. Collect 1 full anticoagulated tube. Tubes which are not filled adequately will be rejected
2. Label tube with sample validation number
3. Spin labeled tube in a3600 Centrifuge 1 for the RPM and Time listed in Table 1
4. Run sample in single presentation mode in duplicate on appropriate Hematology analyzer for PLT
    a. Ensure that sample probe aspirates sample at equivalent depth as coagulation analyzer
5. Record values for each tube in Centrifuge Validation Worksheet – Coagulation (see Attachment 2). Calculate and record average between both runs and record on

worksheet

6. Repeat Steps a. - e. for a3600 centrifuge 2 and 3
7. Acceptance criteria for a3600 settings:
    a. AVG PLT </= 10,000 for 95% of sample runs

Notes

A. Centrifuges 1, 2 and 3 on a3600 automation line are configured for all Chemistry, Immunochemistry and Coagulation samples. Samples will be sorted and routed to all 3 centrifuges.

Attachments

Attachment 2: Abbott a3600 Accelerator Automation Centrifuge validation worksheets 2.pdf

Attachment A: Abbott a3600 Accelerator Automation Centrifuge validation worksheets.pdf

Approval Signatures

Step Description	Approver	Date
Medical Director	Jeremy Powers: Chief, Pathology	5/16/2022
Policy and Forms Steering Committee Approval (if needed)	Michelle Alexander: Medical Technologist Lead	5/13/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	5/12/2022
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	Michelle Alexander: Medical Technologist Lead	5/12/2022

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