Beaumont Laboratory
Royal Oak

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Related Documents:

ABBOTT a3600 ACCELERATOR AUTOMATION

CENTRIFUGE VALIDATION PROCEDURE

RC.HM.CG.PR.100.r00

I. Purpose

A validation procedure is necessary to ensure that the settings utilized for the a3600 Accelerator Automation centrifuges are appropriate for the tube types and testing being performed. In addition, a validation procedure must be performed if the desired centrifugation conditions are outside the manufacturer recommendations as stated in the Instructions 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. Sodium citrate 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 the plasma samples for coagulation assays.

II. Procedure

A. All validation samples must be drawn in pairs, centrifuged, and analyzed within 2 hours of collection. For each pair, one sample will be spun according to BD Vacutainer recommended condition and the other will be spun at desired condition on Abbott a3600 Accelerator centrifuge. See Table 1. below for tube types and centrifuge conditions.

Table 1.

BD Vacutainer Tube	BD Vacutainer RPM (recommended)	BD Vacutainer TIME (recommended)	BD Vacutainer RPM (desired)	BD Vacutainer TIME (desired)
Sodium Citrate Plasma (for PPP)	3500	15 min	4000	5 min

B. A total of 20 samples per centrifuge are required for validation. Centrifuges 1 and 2 on the a3600 are designated for Chemistry and Immunochemistry. Centrifuge 3 on the a3600 is designated for Coagulation. All samples will be analyzed on designated reference analyzers as noted.

C. Coagulation

1. Collect 2 full 4.5 mL BD Blue Top Sodium Citrate tubes. Tubes which are not filled adequately will be rejected.
2. Label the pair of tubes with a sample validation number.

   a. Use an extension of -3500 and -4000 to distinguish between the tube spun at 3500 RPM and the tube spun at 4000 RPM.
3. Spin the first tube of the pair in a3600 Centrifuge 3 for the recommended RPM and time listed in Table 1.
4. Spin the second tube of the pair in a3600 Centrifuge 3 for the desired RPM and time listed in Table 1.
5. Run each sample in manual mode on the Hematology analyzer for PLT.
6. Record values for each tube in Centrifuge Validation Worksheet. See Attachment A.
7. **Acceptance criteria for a3600 settings: PLT < / = 10,000**

III. Notes

A. Centrifuges 1 and 2 on a3600 automation line are configured for all chemistry / immunochemistry sorting only. Coagulation samples will not be routed to this centrifuge unless automation configuration is updated.

B. Centrifuge 3 on a3600 automation line is configured for coagulation sorting only. Chemistry samples will not be routed to this centrifuge unless automation configuration is updated.

IV. Authorized Reviewers

Medical Director, Coagulation

Attachment A:
Centrifuge Validation Worksheet

	SPECIMEN ID	DATE	PLATELET COUNT 3500 RPM 15 MINUTES	PLATELET COUNT 4000 RPM 5 MINUTES	TECH INITIALS	MGMT REVIEW
SPECIMEN 1						
SPECIMEN 2						
SPECIMEN 3						
SPECIMEN 4						
SPECIMEN 5						
SPECIMEN 6						
SPECIMEN 7						
SPECIMEN 8						
SPECIMEN 9						
SPECIMEN 10						
SPECIMEN 11						
SPECIMEN 12						
SPECIMEN 13						
SPECIMEN 14						
SPECIMEN 15						
SPECIMEN 16						
SPECIMEN 17						
SPECIMEN 18						
SPECIMEN 19						
SPECIMEN 20						

MEDICAL DIRECTOR REVIEW _____ **DATE** _____

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Document History

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Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Marc Smith, MD	06/14/2019	**00**	New procedure	N/A
Peter Millward, MD	07/01/2019			