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Area: *Laboratory-Hematology*
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Platelet Function Analysis New Lot # - RO

Document Type: Guideline

I. PURPOSE AND OBJECTIVE:

- A. To verify the consistency of the introduction of new lot numbers of platelet function analysis (PFA) reagents. It is performed by coagulation staff

II. ACRONYM:

- A. Coefficient of variation (CV)
B. Platelet Function Analysis (PFA)
C. Quality Control (QC)

III. PROCEDURE:

A. **Procedure**

1. **Materials**

- a. PFA reagents; "New Lot# Tags".

2. **Expected Performance**

- a. It is expected that this process will verify that new lot numbers of PFA reagents are handled consistently.

3. **Upon arrival of PFA reagents:**

a. **Coagulation Staff Responsibilities:**

- i. Approves and signs receiver with their name and date.
- ii. Places received date on each reagent box.
- iii. Fills out the "NEW LOT# TAG" (top part only) and places it on the reagent(s) before putting it in the walk-in refrigerator.
- iv. Wraps reagent boxes with red tape to verify that it is not used prematurely.
- v. Delivers receiver to Coag management.

b. **Assigned QC Tech Responsibilities:**

- i. Runs the QC in duplicate on one PFA analyzer.
- ii. Verify that the duplicate CV is $\leq 15\%$ to be considered "OK FOR USE".
- iii. Completes the bottom portion of "NEW LOT# TAG". ***The tag remains on the reagent.***
- iv. Removes red tape from reagent boxes and wraps with green tape (available for use).
- v. Fills out the "PFA Reagent New Lot# Log".

c. When placing the PFA reagent into use:

i. Coagulation Staff Responsibilities:

- a. Removes and discards the "NEW LOT# TAG".
- b. Records the date/time in use in the PFA Reagent Lot book associated with that particular lot #.

4. Quality Control:

- a. When running the normal control, verify the control falls within the established normal ranges. If not, run another control before proceeding with patients. If control still does not fall within the established normal ranges, notify coag management.

Attachments

No Attachments

Approval Signatures

| Step Description | Approver | Date |
|--|---|-----------|
| CP Chief Medical Director | Peter Millward: Chief, Pathology Service Line | 5/1/2021 |
| Coagulation Medical Director Designee | Marc Smith: System Med Dir, Coagulation | 4/30/2021 |
| Policy and Forms Steering Committee Approval (if needed) | Gail Juleff: Project Mgr Policy | 4/22/2021 |
| Policy and Forms Steering Committee Approval (if needed) | Tamara Sabih: Medical Technologist Lead | 4/22/2021 |
| System Manager | Rebecca Bacarella: Mgr Laboratory | 4/22/2021 |
| | Tamara Sabih: Medical Technologist Lead | 3/31/2021 |

Applicability

Royal Oak