Beaumont

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| **Document Contact:** | *Tamara Sabih: Medical Technologist Lead* |
| **Area:** | *Laboratory-Hematology* |
| **Key Words:** | |
| **Applicability:** | *Royal Oak* |

# Manufacturer's Product Insert Reference- RO

Document Type; Policy

# I. PURPOSE AND OBJECTIVE:

A. Manufacturers provide their customers with various printed materials to promote quality and that products are used as recommended. All printed information packaged with supplies, equipment, and various reagents should be reviewed to determine operational significance. Current manufacturers' directions for use of reagents and kits are maintained in a reference notebook.

B. The purpose of this document is to provide the Coagulation Staff with stepwise instructions for reviewing manufacturers' printed information and to catalog manufacturers' inserts in a notebook.

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# II. POLICY STATEMENT:

A. This manual contains the current manufacturer inserts of various kits and reagents used by the technical staff in the Coagulation Lab. Refer to the Coagulation Manufacturer's Insert Manual for a detailed description of how this manual is maintained.

B. The following policies apply when updating the Coagulation Manufacturers' Insert Manual:

1. Coagulation Manufacturer's Insert Manual must be updated and maintained on a weekly basis.
2. Each reagent or kit used in the Coagulation Laboratory will have a current manufacturer's insert in the Coagulation Manufacturer's Insert Manual.

# III. INTRODUCTION:

Manufacturer's inserts for review are retrieved from newly received products by the technologist processing the reagents into inventory, and placed in an identified basket. All other printed material retrieved when unpacking incoming products is forwarded to the supervisory staff for review.

# IV. ANNUAL REVIEW:

Once a year the technical staff member assigned the responsibility of updating the manufacturer's inserts will conduct a documented review of this manual. The annual review will ensure that all inserts from reagents for kits no longer in use have been removed from this manual. The Manufacturer's Product Insert Reference Policy will be followed whenever removing inserts for record storage. Coagulation management will acknowledge the completion of the annual review process by signing this policy.

# V. DEFINITIONS:

The following define terms used in this procedure:

A. Coagulation Manufacturer's Insert Manual: Three ring binder that catalogues manufacturer's inserts.

B. Manufacturer's Inserts: Document provided by manufacturer that contains pertinent information about the product including instructions for use.

C. Other manufacturers' printed materials: Any other (not including insert) printed materials provided by manufacturer of product.

# VI. SUPPLIES:

The following supplies are needed for this procedure:

A. Yellow highlighter pen

B. Coagulation Manufacturer's Insert Manual

# VII. PROCEDURE:

A. Follow the steps in the table(s) below to compare inserts and update the Coagulation Manufacturer's Insert Manual:

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| Step | Action | |
|---|---|---|
| 1 | Compare the date of each new product insert against the date of the existing product insert (located in the Coagulation Manufacturer's Insert Manual). | |
| | *If the document number of the new insert is…* | *Then…* |
| | Identical to the filed insert | No action taken, discard insert. |
| | Different than the filed insert, | Continue with step 2. |
| 2 | Review the technical procedure for change in directions, new procedure, revision date, or other revision. | |
| 3 | Review manufacturers' notes for any change. | |
| 4 | Highlight any pertinent information, including revision date. | |
| 5 | Date and initial the new insert. | |
| 6 | *If inserts have been changed and…* | *Then…* |
| | An old lot number requires use of previous insert instructions | Write "Use until lot number _____ is used up, then archive. Do this only if changes affect procedure of old lot number. |
| | No lot number remains requiring use of previous insert instructions | Mark old insert as "archived" and store in Removed Procedure File |
| 7 | **Place new insert in manual.** | |
| 8 | **Notify Management of any significant changes.** | |

B. Follow the table below for other manufacturers' printed materials:

| Step | Action |
|---|---|
| 1 | Place materials other than directions for use in Supervisors box for review. |
| 2 | Coagulation Management:  Review printed materials for information associated with quality control, storage or other conditions of use for the product. |
| 3 | Coagulation Management:  Determine and implement appropriate revisions to current practice required for use of the product. |

# VIII. INTERPRETATION:

A catalog of up to date manufacturer inserts to provide stepwise instructions to Coagulation staff for reagents.

# IX. REFERENCES:

The following items were used as sources of information. Beaumont Royal Oak Blood Bank Manufacturer's Insert Notebook Update Procedure (P319.00).

## Attachments

No Attachments

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## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| CP Chief Medical Director | Peter Millward: Chief, Pathology Service Line | 3/24/2021 |
| Coagulation Medical Director Designee | Marc Smith: System Med Dir, Coagulation | 3/24/2021 |
| Policy and Forms Steering Committee Approval (if needed) | Tamara Sabih: Medical Technologist Lead | 3/24/2021 |
| Policy and Forms Steering Committee Approval (if needed) | Gail Juleff: Project Mgr Policy | 3/19/2021 |
| System Manager | Rebecca Bacarella: Mgr Laboratory | 3/19/2021 |
| | Tamara Sabih: Medical Technologist Lead | 2/1/2021 |

## Applicability

Royal Oak