



Deviation From SOP

Date: 4.9.24

Affected SOPs: Red Blood cell set-up for intrauterine transfusions (PUBS) and Specimen Requisition and sample processing

Description:

PUBS procedure was transfused without irradiation on 3/13/24. This was reportable to the FDA. This deviation from SOP is to implement immediate response to prevent this issue in the future.

Summary of Changes:

Requisition Printing
Per SOP for Requisitions:
VI.A.1.

Outreach and/or Client orders will be placed in Cerner or Life-Point by Registration/Client rep and may not generate a Requisition to print in Blood Bank. One may need to ‘print screen’ information in either “PPI” (Patient Product Inquiry) Cerner function or Power Chart to see tests ordered, unless copy of original order is delivered with specimen to Blood Bank.

This step needs to be changed and implemented to state:

Outreach and/or Client orders will be placed in Cerner or Life-Point by Registration/Client rep and may not generate a Requisition to print in Blood Bank.

- a. For patient sample orders : One may need to ‘print screen’ information in either “PPI” (Patient Product Inquiry) Cerner function or Power Chart to see tests ordered, unless copy of original order is delivered with specimen to Blood Bank.
- b. For product orders (example: Platelets, or Red Blood Cells), one may need to re-print the order via Virtual Printer (or) Power Chart Order Tab to see details for the products which is ordered. Details for how to get order details in Power Chart are below.
 - i. Log into Power Chart.

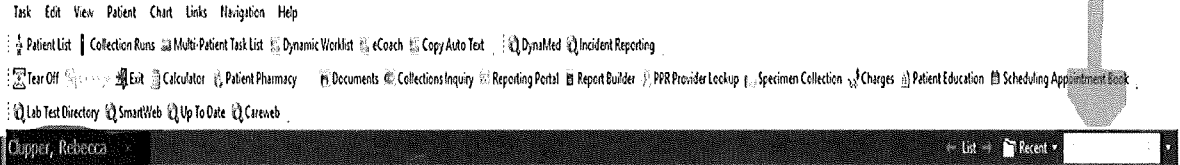


PowerChart PROD

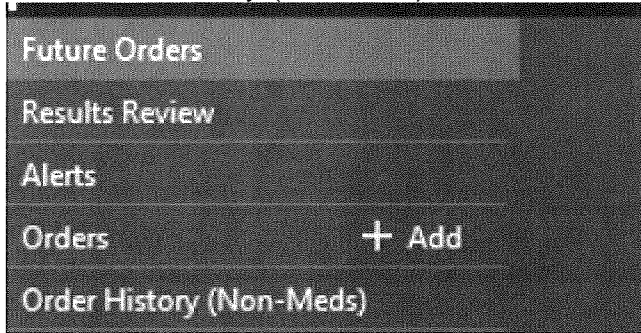


Deviation From SOP

- ii. Find patient in Powerchart by adding the MRN in the left corner



- iii. Click Order History (Non-Meds) or if order is current, Orders



- iv. Click on the Product Order Order History (Non-Meds)

| | | | | |
|-------------------------------------|------------------------|-----------------|----------------|------------|
| <input checked="" type="checkbox"/> | 2/15/2024 11:42:00 ... | Red Blood Cells | Riley Hosp ... | Outpatient |
| <input type="checkbox"/> | 2/15/2024 11:22:00 ... | CBC w/platelets | Riley Hosp ... | Outpatient |

Right Click the Red Blood Cell (any product order).

| | | | | | |
|-------------------------------------|------------------------|--------------------|----------------|------------|----------------------|
| <input checked="" type="checkbox"/> | 2/15/2024 11:42:00 ... | Red Blood Cells | Riley Hosp ... | Outpatient | |
| <input type="checkbox"/> | 2/15/2024 11:22:00 ... | CBC w/platelets | Riley Hosp ... | Outpatient | Order Information... |
| <input type="checkbox"/> | 2/15/2024 11:12:00 ... | Admit to Inpatient | Riley Hosp ... | Inpatient | Reference Text... |

Click on Order Information

- The details will appear (see below).
- The details are the same details which print on the requisition, in Virtual Printer.
- Use this method for attaining the details, when the requisition cannot be provided through the virtual printer.



Deviation From SOP

Red Blood Cells

Details History Results Comments Additional Info Validation

Details

| | |
|--|---------------------|
| BB Priority | Routine |
| Quantity/Volume | 1 |
| Quantity Unit of Measure | Unit |
| RBC Clinical Indication | Other (See Comment) |
| Modification 1 | CMV Neg |
| Modification 2 | Irradiated |
| Modification 3 | Washed |
| Additional Volume in mL for Tubing Prime | 0 mL |
| Print Label By Order Location | No |
| Print label Y/N | No |
| Preprocessing Script | pp_lab_print_route |
| Override Share Y/N | No |
| Date to be Given | 02/15/24 11:12 EST |
| Collected | No |
| Stop Date/Time | 02/15/24 11:42 EST |
| Results Needed | Routine |
| Collection Priority | Stat |
| Specimen Type | Blood |

Comment

Indication: PUBS
FETAL Anemia: O negative, Less than 7 days old, Crossmatched to maternal blood.
Notify blood bank at least 1 hour before blood is needed to allow for preparation

- v. Print the Screen to document the details for the product order.



Deviation From SOP

Second immediate action is the addition of the use of the PUBS Yellow Sticker.

This sticker should be placed on the

- 1) Requisition *by the tech performing the XM*
Fill out the sticker as a visible reminder of the PUBS unit is completed as requested.
- 2) Unit - *tech in components*
Fill out a second sticker to ensure the unit provided for PUBS is
 - a) Antigen matched
 - b) Washed
 - c) CMV negative
 - d) Irradiated
 - e) Hct completed and documented.

Last adjustment in practice for PUBS requests is that the BB Leadership will notify the team when these requests are received to document a plan for the completion of the order.

- a) If there are questions about the orders received, then speak to your supervisor.
- b) If there are clinical questions, then contact the medical director on call.

Implementation of Change

The updated process will be verified by order completion for a PUBS on 4/10/24.

After the validation of the change, then this will be shared with all team members for training via MTS to be completed no later than 5/10/24.

The SOPs will be updated to add the steps outlined in this procedure no later than 6/1/24.

Jayanna Slayten

QA Coordinator
Jayanna Slayten, MS, MLS(ASCP)SBBcm
4/9/2024 | 5:11 PM EDT

Amy Galbard, MD

Approved By: BB Medical Director
4/9/2024 | 6:21 PM EDT


Certificate Of Completion

| | |
|--|--------------------------|
| Envelope Id: C24D230CD8604FFAB5F35FC59C226655 | Status: Completed |
| Subject: Complete with DocuSign: SOP Deviation for PUBS Procedure 04.10.24 with Labels included 04.09.24.pdf | |
| Source Envelope: | |
| Document Pages: 5 | Signatures: 2 |
| Certificate Pages: 5 | Initials: 0 |
| AutoNav: Enabled | Envelope Originator: |
| Envelope Stamping: Disabled | Jayanna Slayten |
| Time Zone: (UTC-05:00) Eastern Time (US & Canada) | 950 N Meridian St |
| | Indianapolis, IN 46204 |
| | jslayten@iuhealth.org |
| | IP Address: 162.1.162.41 |

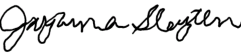
Record Tracking

| | | |
|---------------------|-------------------------|--------------------|
| Status: Original | Holder: Jayanna Slayten | Location: DocuSign |
| 4/9/2024 5:09:41 PM | jslayten@iuhealth.org | |

Signer Events

| Signer Events | Signature | Timestamp |
|---|---|---|
| Amy Gabbard, MD agabbard1@iuhealth.org Security Level: Email, Account Authentication (None) |  Signature Adoption: Pre-selected Style Using IP Address: 174.238.48.45 Signed using mobile | Sent: 4/9/2024 5:10:55 PM Viewed: 4/9/2024 6:21:34 PM Signed: 4/9/2024 6:21:50 PM |

Electronic Record and Signature Disclosure:
Accepted: 10/3/2023 10:16:13 AM
ID: 8c148896-8b04-4925-9368-fa3f809ec999

| | | |
|--|--|---|
| Jayanna Slayten jslayten@iuhealth.org Coordinator-Quality Reporting IU Health Security Level: Email, Account Authentication (None) |  Signature Adoption: Drawn on Device Using IP Address: 162.1.159.41 | Sent: 4/9/2024 5:10:55 PM Viewed: 4/9/2024 5:11:07 PM Signed: 4/9/2024 5:11:14 PM |
|--|--|---|

Electronic Record and Signature Disclosure:
Not Offered via DocuSign

| In Person Signer Events | Signature | Timestamp |
|------------------------------|------------------|---------------------|
| | | |
| Editor Delivery Events | Status | Timestamp |
| | | |
| Agent Delivery Events | Status | Timestamp |
| | | |
| Intermediary Delivery Events | Status | Timestamp |
| | | |
| Certified Delivery Events | Status | Timestamp |
| | | |
| Carbon Copy Events | Status | Timestamp |
| | | |
| Witness Events | Signature | Timestamp |
| | | |
| Notary Events | Signature | Timestamp |
| | | |
| Envelope Summary Events | Status | Timestamps |
| Envelope Sent | Hashed/Encrypted | 4/9/2024 5:10:55 PM |
| Certified Delivered | Security Checked | 4/9/2024 5:11:07 PM |
| Signing Complete | Security Checked | 4/9/2024 5:11:14 PM |

| Envelope Summary Events | Status | Timestamps |
|--|------------------|---------------------|
| Completed | Security Checked | 4/9/2024 6:21:50 PM |
| Payment Events | Status | Timestamps |
| Electronic Record and Signature Disclosure | | |

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