



Deviation From SOP

Date: 6/16/21 **Affected SOPs:** LVDS Platelet Irradiation (SOP: Irradiation and ISBT Product Modification) and Use of Expired Platelets (SOP: Platelet Assign and Dispense)

Samples Involved:

Patients who need irradiated platelets and patients who have a critical need for platelets

Expired 6/13/21 platelets extend to 6/14/21 and given to

- Taylor, Dallas MRN 76665057 transfused W201821877160 (E8342) on 6/14/21
- Christiana, Gina MRN 77750884 transfused with W20182187760 (E3841) on 6/14/21

Description:

Due to low inventory currently and lack of LVDS codes in Cerner, AHC BB is implementing:

1) Extended outdate for platelets

- a. W201821877160 (E8342) expired 6/13/21 and used 6/14/21
 - i. Pre Platelet count = 6
 - ii. Post platelet count = < 4
 - iii. No transfusion complication documented
- b. W20182187760 (E3841) expired 6/13/21 and used 6/14/21
 - i. Pre platelet count = 6
 - ii. Post platelet count = 10
 - iii. No transfusion complication documented

Any additional platelets needed and used as expired will be documented using a Deviation from SOP and any post-transfusion issues will be documented and followed up on by BB Medical Team.

2) LVDS platelets being received from ARC are not generally irradiated. These LVDS codes are not in Cerner to date, and these LVDS codes cannot be modified with downtime printer or RS3400 Irradiation Software to an Irradiated product.

- a. Deviate from SOP since these cannot be ISBT labeled.
 - i. Irradiate using the designated RAD Sure per SOP, but do not modify the unit in Cerner.
 - ii. Document irradiation using Irradiation Log to verify that the unit is irradiated (RAD SURE change = black dot check) and verifying using a peer audit.
 - iii. Product will indicate irradiation on the downtime Transfusion document to match the RAD Sure black dot.
 - 1. BB Team will be notified.
 - 2. Clinical Team will receive the attached document with the alternately labeled platelet products to explain the deviation.



Deviation From SOP

- b. Deviation from SOP since these cannot be scanned into the RS3400 Irradiation Software.
 - i. LVDS platelet will not be scanned into the RS3400 software.
 - ii. LVDS platelets will be documented on an updated Irradiation Log which asks the peer audit to verify the Rad Sure black dot irradiation and the tagging documentation as “irradiated.”

Possible Effects:

For the extended outdate platelets, the risk is for bacterial contamination.

For the Irradiation of LVDS platelets, the risk is for a documentation error on the tag. This should be mitigated with the use of the peer audit. Another impact will be notification of clinical team and this should be mitigated with the attached education flyer.

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Technologist/Supervisor *Jay Slatyen*

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BLOOD IRRADIATION LOG: RS3400

Deviation SOP LVDS Irradiation Log

Form #: BBQC - F 027.08
Manual: Quality Control
Original Effective: 12/01/2016

Irradiate EA Coded Platelets (Bacterial monitoring)

NOT modified in Cerner

Date		Page #					
TIME	DIN	Y or N	Product Code	Tech	Y or N	Product Code	Tech
0940	W201321813918	(Y) N	EA010	TIME NO	(Y) N	EA137	TIME
	W201321814542	(Y) N	EA009	TIME NO	(Y) N	EA138	TIME
	W203821838868	(Y) N	EA138	TIME NO	(Y) N	EA138	TIME
	W203821838898	(Y) N	EA137	TIME NO	Y N		
	W201621809226	(Y) N	EA138	TIME NO	Y N		
	W201321816434	(Y) N	EA139	TIME NO	Y N		
1005	W203821838870	(Y) N	EA136	TIME NO	Y N		
	W201321813945	(Y) N	EA007	TIME NO	Y N		

Cerner Modification Expected response is Y(Yes) to update the labeling of the product with the new irradiation product code. **Sup Review:** _____



Indiana University Health

Department of Pathology Laboratory Medicine
Transfusion Service/Blood Bank Department

EFFECTIVE: June 16th, 2021

American Red Cross is providing Platelets for transfusion with new product codes. These new codes begin with EA####. The new platelet codes are currently being built and tested into the CERNER Lab Information System. Since the lab system currently does not allow for any modification of these products, we are manually processing them for patient use.

CHANGE: When reviewing transfusion document with product label prior to transfusion—the indication of irradiation will be from the RAD-SURE label on these new product codes (EA####) and not printed on the face label during this short term deviation process. Look for RAD-SURE IRRADIATION sticker for comparison with transfusion document.

Current: Modified product with Irradiation on Face label

Deviation: Product with Irradiation indicated by RAD-SURE Label only

