



# Indiana University Health

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**Owner:** Heather Vaught: Dir-Transfusion Medicine-Lab  
**Area:** Lab - Blood Bank  
**Tags:**  
**Applicability:** Indiana University Health Pathology Laboratory

## COVID-19 Convalescent Plasma

### I. PURPOSE

To describe the policies and procedures for use of COVID-19 Convalescent Plasma.

### II. SCOPE

These instructions apply to all Blood Bank team members.

### III. EXCEPTIONS

Exceptions must be approved by Blood Bank administrative and medical leadership.

### IV. DEFINITION

**A. COVID-19 Convalescent plasma:**

Plasma that has been collected from a patient who has recovered from COVID-19. Plasma from these donors contains antibodies that may help to improve outcomes for patients who are critically ill with COVID-19. In order to qualify as a donor for COVID-19 convalescent plasma, a prospective donor must:

1. Meet all of the routine criteria for blood donation AND
2. Be asymptomatic for at least 14 days AND have a negative test for COVID-19 (viral RNA is no longer detectable), OR
3. Be asymptomatic for less than 14 days AND have TWO negative tests for COVID-19, performed from samples collected on two different days, OR
4. Be asymptomatic for at least 28 days.

**B. Investigational New Drug (IND):**

A **drug (or product) that has not been approved for general use by the Food and Drug Administration** but under investigation in clinical trials regarding its safety and effectiveness first by clinical investigators and then by practicing physicians using patients who have given informed consent to participate.

1. The IND number has to be with the product order (see example below)
  - a. IND = standard IND
  - b. eIND = expedited IND
2. If there are questions from the clinical team on how to order COVID-19 Convalescent plasma, then refer them to the Transfusion Medicine physician.

# V. POLICY STATEMENTS

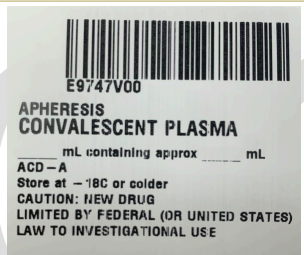
None

# VI. PROCEDURES

1. Receipt of products into inventory -

A. Versiti Indiana:

1. Products will be collected at Versiti Indiana from donors who have been recruited by IU Health physicians.
2. After processing and testing, Versiti Indiana will send the products to IU Health for storage in IU Health inventory.
3. Versiti Indiana will ship the plasma frozen and on dry ice, labeled with Product Code E9747V00, E9747VA0, E9747VB0, or E9747VC0.
4. Versiti Indiana will place a bright orange placard on the outside of the shipping container, indicating that there is convalescent plasma inside.
5. Versiti Indiana will include a tie tag on each COVID-19 Convalescent Plasma product indicating that it is an investigational new drug.

Product Label	Tie Tag	Shipping Container
	<p style="text-align: center;"><b>Convalescent Plasma</b></p> <p style="text-align: center;"><b>Caution-New Drug-Limited by Federal law to investigational use</b></p> <p>eIND/IND # _____</p>	<p style="text-align: center; color: red;">CAUTION-NEW DRUG-LIMITED BY FEDERAL LAW TO INVESTIGATIONAL USE</p> <p style="text-align: center; font-size: 2em; color: blue;"><b>CONVALESCENT PLASMA</b></p>

B. American Red Cross

1. Products will be provided from a national pool of donors.
2. Possible products from American Red Cross are:

Frozen Products	Liquid Products
E9735	E9738
E9736	E9750
E9740	
E9747	

3. Additional labeling and identification may be available for these products, but that has not yet been determined.

C. Place the orange and white Convalescent Plasma sticker on the outside of each individual plasma box (see Attachments for label template).

D. [Receive the products in Cerner](#) and store in the designated Convalescent Plasma drawer in the freezer.

2. Product order: Physicians will enter an order for FFP with Special Instructions for COVID-19 Convalescent Plasma and the IND or eIND number.

<b>Product Order</b>	
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Example

Order Details			
Order:	Fresh Frozen Plasma	Order Status:	Ordered
Order ID:	20562029383.00	Accession:	
Date to be Given:		04/07/20 11:04:00 EDT	
Number of Units:		1	
Clinical Indication:		COVID-19 Convalescent Plasma	
Special Instructions:		IND# 1234567	

1. Plasma Selection and Preparation: Refer to [Plasma Preparation for Issue](#) with the following notes:
  - A. Compatibility between donor and recipient should follow the established guidelines.
    - a. If compatible plasma is not available for Group B or AB patients, then adult patients and pediatric patients over 40 kg may receive up to **2 units of Group A plasma transfused per day**.
    - b. Pediatric patients 40 kg or under must receive compatible plasma **only**.
    - c. Contact the Blood Bank physician on service/call if requests to transfuse products and the need to transfuse incompatible products exceeds the allowed threshold.
  - B. Preparation of products:
    1. E9738 or E9750 (Liquid Plasma): Product is stored refrigerated. No thawing or relabeling is required.
    2. E9747 (frozen plasma):
      1. [Thaw, modify, relabel and verify label in Cerner per current procedure](#).  
It is advisable to remove "investigational new drug" tag prior to placing in water bath and reapply once thawed to ensure the tag does not get wet.
      2. Thawed E9752 is stored refrigerated for up to 5 days after thawed on a designated shelf.
    3. E9735, E9736, and E9740 (frozen plasma):
      1. [Thaw product in the water bath](#).  
It is advisable to remove "investigational new drug" tag prior to placing in water bath and reapply once thawed to ensure the tag does not get wet.
      2. Use [Correct Inventory](#) to change the expiration of the product to 24 hours after thaw (there are no "Thawed" 5-day product codes for these products).
      3. [Reprint ISBT label, relabel product and validate label in Cerner](#).
      4. Store thawed products in the refrigerator for up to 24 hours after thaw on a designated shelf.
  - C. [Assign and dispense](#) products in Cerner using the "Transfusion" assign and dispense reasons.
  - D. Hand write the IND/eIND# from the patient order requisition on the "investigational new drug" tag attached to product

Product Dispense Example	Order Details			
	Order:	Deliver Blood Product (BB Deliver Blood Product)	Order Status:	Completed
	Order ID:	20562027687.00		
	Priority:		Now	
	Requested Start Date/Time:		04/07/20 10:56:00 EDT	
	Product Requested:		COVID19 Plasma	

- A. File the component requisition in the Sup Review Tray. At Supervisory Review these will be collected and maintained separately.

## VII. REFERENCES/CITATIONS

A. <https://covidplasma.org/resources-for-collectors/>

## VIII. FORMS/APPENDICES

None

### Attachments

[Convalescent Plasma box labels.pdf](#)

### Approval Signatures

Step Description	Approver	Date
Supervisors (QA Unit)	Tracie Ingle: Supervisor-Lab	pending
Supervisors (QA Unit)	Evangeline Miguel: Supervisor-Lab	pending
Supervisors (QA Unit)	Jayanna Slayten: Supervisor-Lab	pending
Director	Heather Vaught: Dir-Transfusion Medicine-Lab	04/2020

### Applicability

Indiana University Health Pathology Laboratory

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