The Blood Connection
1099 Bracken Road
Piedmont, SC 29673

Process Description

Title:	Emergency Release of Products with Incomplete Testing Status
Document Number	4200PD12
Scope:	HS, TS
Related procedures or processes:	4200P: Inspection of Products 4918P: Completion of the Transfer/Consignment Ticket 6216P: Manual Labeling 6235P: Adding a Manual Shipment 4200PDJA: Product Expirations 4208P: Handling Shipment Information on Imported Units 6065P: Hematrax Client Software
References:	NA
Prepared by:	Shonnon Bowen Trainer, Biologics Production and Distribution Specialist

Purpose: When blood is urgently needed, components may be released prior to the completion of testing if the requesting physician indicates that the clinical situation outweighs the risk of transfusing partially tested products. The ordering transfusion facility is required to sign an Emergency Release Form (4200PDF) verifying the receipt of partially or un-tested products. Required tests are completed as soon as possible (during the next scheduled testing run) and the results are forwarded to the transfusion facility.

NOTE: At times products are received (imported) from other facilities that may not perform the following tests: HBV by NAT, and/or Chagas. These tests are routinely performed on products collected by TBC, but are not required testing by FDA. See 4208P/current version for instructions on Importing Products from Other Facilities. Because TBC requires HBV NAT and Chagas testing, any product not tested requires following this Emergency Release process.

Process Description

Application: This process description applies to the following departments with responsibilities defined:

Department	Responsibility
Biologics Processing and Distribution	Receives request for blood products. Communicates with Testing Laboratory and the ordering transfusion facility regarding availability of tested products. Generates the form 4200PDF: *Emergency Release of Products with Incomplete Testing Status* and routes copies accordingly. Obtains the returned carbon copy of form bearing the signature of the transfusion facility representative.
Testing Laboratory	Performs testing of all blood units. Communicates to Biologics Processing and Distribution when testing is completed on units released prior to normal batch release.
QA / Management	Prior to emergency release of products with incomplete testing records, approval is obtained by one of the following members of management: Director of Technical Services, Vice President of Operations/COO, Vice President of Quality Systems, Medical Director, or CEO/President.

Process:

I. Receiving the Order

If a blood component is ordered and there is no fully tested product available (or scheduled to be available in a timely manner), the requesting transfusion facility is made aware that the requested product is unavailable. An estimated time of availability is given so that the ordering physician can make an informed decision whether to wait for the next scheduled batch release or request emergency release of products with incomplete testing records.

II. Completing the *Emergency Release of Products with Incomplete Testing Status Form*

If blood is urgently needed, components may be released prior to the completion of testing if the requesting physician indicates that the clinical situation outweighs the risk of transfusing partially tested products. The form ***4200PDF: Emergency Release of Products with Incomplete Testing Status*** is a four-part form completed by Biologics Processing and Distribution for each product released prior to completion of testing. It is routed in the following manner:

Approval is obtained by one of the following members of management prior to emergency release: Director of Technical Services, Vice President of Operations, Vice President of Quality Systems, Medical Director, or CEO/President. Approval is indicated by signature applied to the form prior to routing of copies. Verbal approval is adequate provided that it is documented by the person completing the form and the signature is obtained from the manager as soon as possible following the emergency release.
Exception: HLA matched Apheresis Platelets not tested for HBV NAT are acceptable and do not require the approval of the above listed management. (4200PDF/current version must still be completed and routed).

III. Minimum Testing Requirements for Emergency Release

For products released prior to the completion of testing, an ABO/Rh typing and antibody screen is performed prior to emergency release.

IV. Labeling and Tagging the Product

For each component released prior to completion of testing, an Emergency Release tie-tag is attached. This tag is used to indicate which of the required tests have not been performed at the time of release. A label must be obtained using Hematrax software (See 6065P/current version) The expiration date for the product is calculated as per 4200JA/current version.

NOTE/EXCEPTION: If the reason for the Emergency Release is due to an imported product which has not been tested for Chagas or HBV NAT, the product will have ABO/Rh labels present (as well as expiration date) and will not require additional testing or re-labeling of blood type. Record Not Tested in the Test Results field(s) for these Tests.

Access the Hematrax Client Software as per 6065P/current version.

- Choose connect
- Define the Printer port definitions: select a port that is not in use
- Enter the printer IP address
- Select the Printer Manufacturer/model
- Select SET

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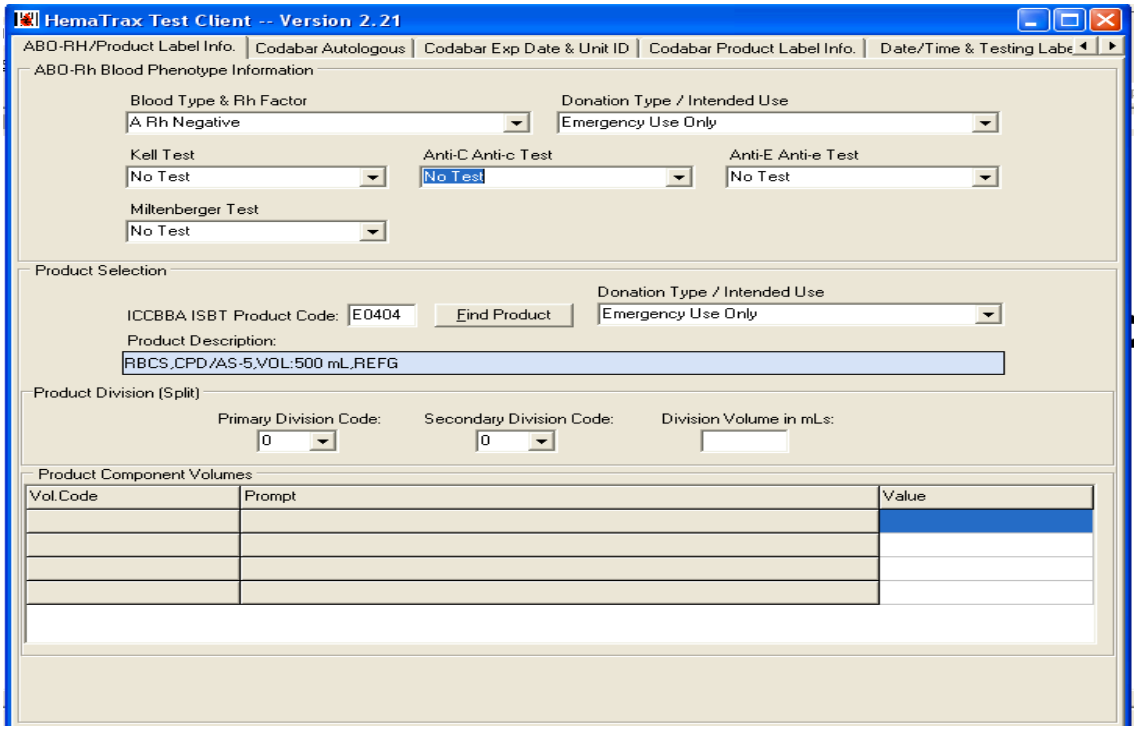
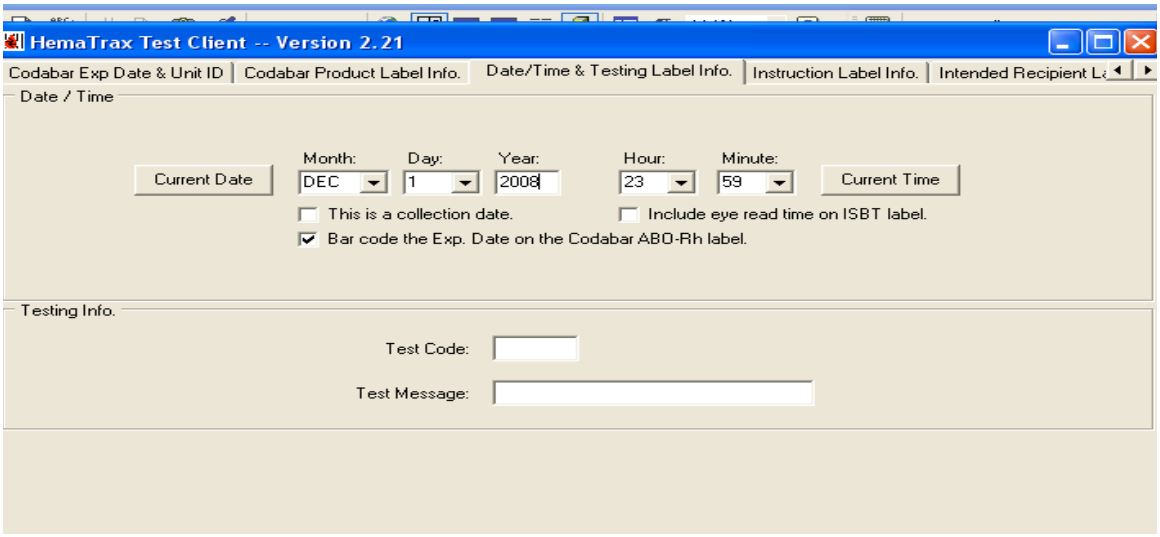
Printing Label Using Hematrax:

- Select Tab Labeled: *ABO/RH Product Label Information*
  - *Blood Type and Rh Factor*: Select the product ABO/Rh from the drop down list (obtain ABO/Rh from 4200PDF/current version)
  - *Donation Type/Intended Use*: Select **Emergency Use Only** from the drop down list
  - *ICCBBA ISBT Product Code*: Enter or scan Product Code and then select Find Product (this will populate the product description field)
  - *Donation Type/Intended Use*: Select **Emergency Use Only** from the drop down list



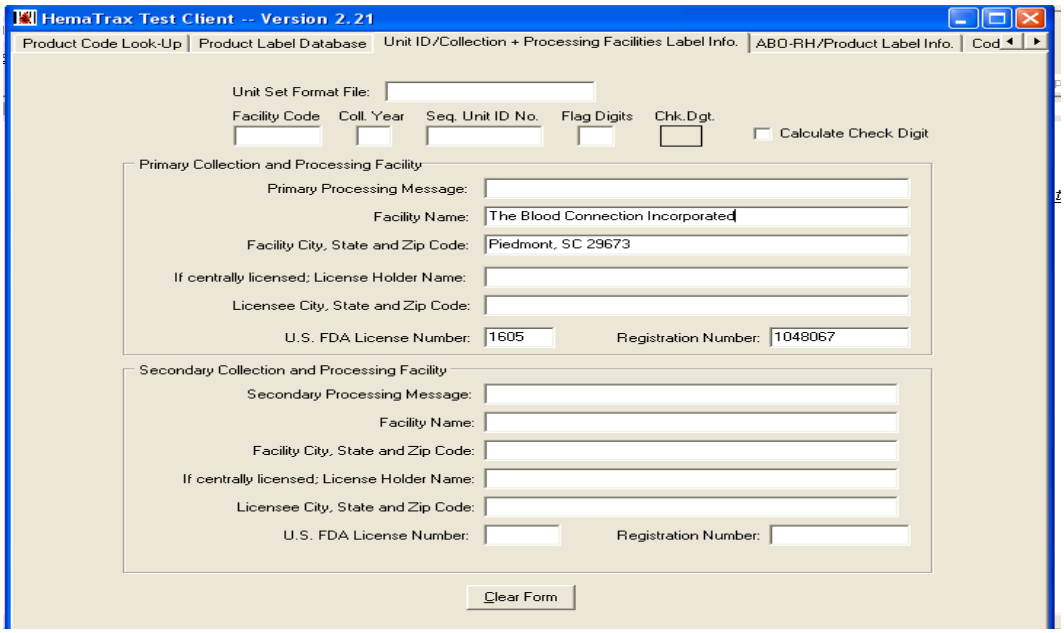
- Select Tab Labeled: *Date/Time & Testing Label Info*
  This section is intended to specify the EXPIRATION DATE for the product (obtain from 4200PDF/current version) not the collection date.
  - *Current Date*: Select the month/day/and year of **expiration** for the product from the drop-down list
  - *Current Time*: if product has an expiration time associated with it, select the time from the drop down list- otherwise, leave time set to: 23:59
    If an expiration time is entered (other than 23:59), select the box titled: Include Eye Read Time on the ISBT Label, otherwise, leave de-selected
  - Leave the box selected which reads: Bar Code the Exp. Date on the Codabar ABO-RH Label



Process Description

- Select Tab Labeled: *Unit ID Collection + Processing Facilities Label Information*
  All information must be entered exactly as shown
  - *Facility Name*: Enter: The Blood Connection Incorporated
  - *Facility City, State and Zip Code*: Enter: Piedmont, SC 29673
  - *US FDA License Number:* Enter: 1605
  - *Registration Number:* Enter: 1048067

NOTE: Information must be entered EXACTLY as shown:



- Select Tab Labeled: *Print Labels*
  - *Print to Port:* Select appropriate port
  - *Number of Labels:* Select number of labels desire
  - *Select Label:* ONE WAY FULL FACE ISBT

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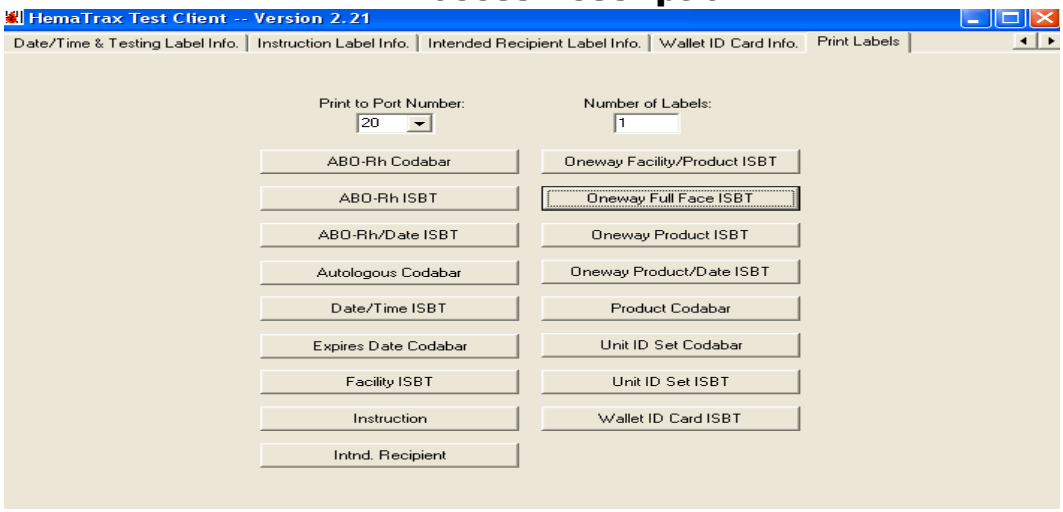


Place Label on Product with original donation (unit ID number) showing (remove the tear off section of the 4x4 full face label)
Verify that all information on the label is accurate/correct.
Label Example:

Emergency Release Tie-Tag

Complete the Emergency Release Tie tag and attach to product:
Record the Unit Number and testing information on the tag:

Place tag here

V. Distribution

Products released prior to completion of testing are shipped using manual methods to track the disposition of the product. (*6235P current version and 4918P current version)* (Exception: Imported products not tested for Chagas or HBV NAT will not require manual shipping. After testing is completed, the Transfer/Consigment Ticket is used to create a computer record in the Lifetec system. Inspection of Products (*4200P current version*) Must be performed prior to shipment.

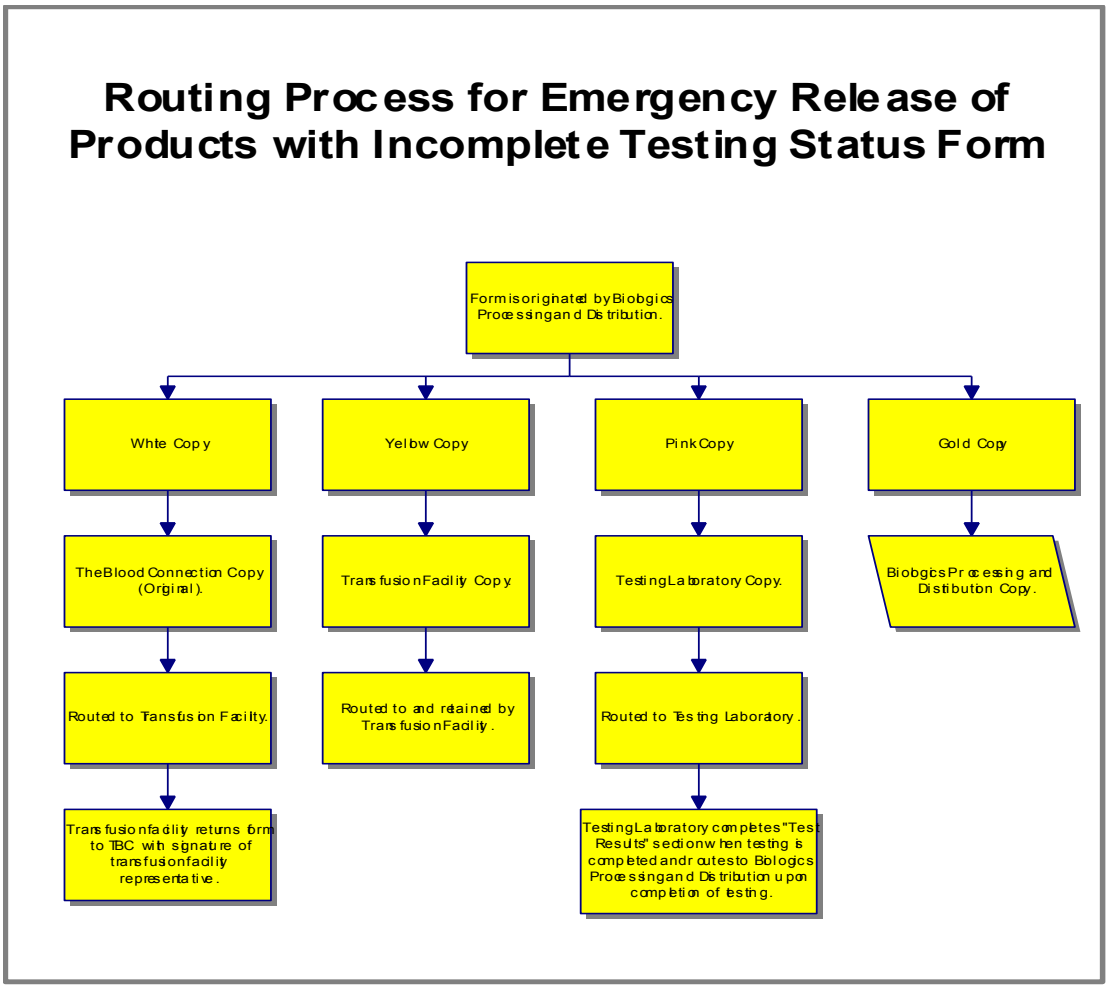
VI. Completion of Testing

When required testing is completed, Testing Laboratory completes the "Testing Results" section on the routed copy (Pink copy) of the emergency release form and then routes the form back to Biologics Processing and Distribution. Biologics Processing and Distribution then notifies the transfusion facility of the completed testing status. A manual labeling status is assigned to the unit by Hospital Services Supervisor, Director of Technical Services, or designee using the Manual Labeling function of the Lifetec computer system. (See *Lifetec SOP 6216P Manual Labeling*). Any non-conforming (reactive) test result is reported to the Vice President of Operations immediately.
NOTE: This is NA for imported products not tested for Chagas or HBV NAT. No further testing is performed.

VII. Compiling Carbon Copies

The Director of Technical Services or designee reviews returned copies of the emergency release form for appropriate completion.

NOTE: If copies are not returned, attempts are made to obtain the form from the responsible party (e.g. placing a call to the transfusion facility).



EXCEPTION: Imported products which are not tested (and are unable to be tested) for any test routinely performed and required by TBC will be documented as follows by recording in the space for the test result: Not Tested or NA.
No further action is taken by the Testing Lab.