

**Title:** Emergency Release of Products with Incomplete Testing Status

**Principle:** 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 tests which are routinely performed by TBC. 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.

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

<b>Department</b>	<b>Responsibility</b>
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: <i>Emergency Release of Products with Incomplete Testing Status</i> 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 Hospital Services 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: Vice President of Business Development/Chief Technical Officer, Vice President of Operations/COO, Vice President of Quality Systems, Medical Director, or CEO/President.

**Process:**

**A. 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.

**B. 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

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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 Hospital Services for each product released prior to completion of testing. It is routed in the following manner:

Complete the 4200PDF/current version by documenting the following information:

- Date/Tech Code
- Unit Number/Product code/type of product intended for distribution (product type is used for designation of any special information: directed, HLA matched, ect.)
- Transfusion Facility: name of hospital placing the order
- Ordering Physician
- Date/Time product is needed (obtain this info from ordering hospital)
- Statement of Need- document the reason/circumstances which constitute shipping the product prior to testing being completed

TBC Management Approval:

Approval is obtained by one of the following members of management prior to emergency release: Vice President of Business Development/Chief Technical Officer, 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 management as soon as possible following the emergency release).

Route form to testing laboratory for completion of Testing Status Section:

- ABO/Rh: laboratory staff will document ABO/Rh of product
- Antibody Screen: laboratory staff will document results of ABS
- Document tech code

### **C. Minimum Testing Requirements for Emergency Release**

The following steps must be completed prior to a product being made available for emergency release:

Donor registration must be completed and Audit I and II completed.

Laboratory: Batching of sample (in Elite), ABO and Rh type completed and entered into Elite, and antibody screen must be completed and results entered into Elite (if antibody screen is positive the antibody must be identified and RBC units tagged with antibody information. Receiving transfusion facility must be notified. This is NA for plasma-based products, which must be discarded).

Component Processing: Product preparations or conversions must be performed/completed.

#### D. Creating the Order in Elite, Labeling and Shipping

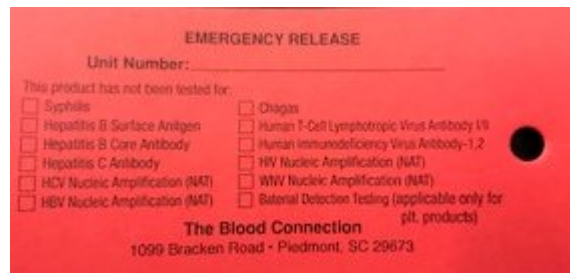
See SOP4243/current version for information on creating the order in Elite, labeling and shipping the product.

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.

#### Emergency Release Tie-Tag

Complete the Emergency Release Tie tag and attach to product:

Record the Unit Number and testing information on the tag:



The image shows a pink Emergency Release Tie-Tag form. At the top, it says "EMERGENCY RELEASE". Below that is a line for "Unit Number:". Underneath, it says "This product has not been tested for:" followed by a list of tests with checkboxes. The tests listed are: Syphilis, Chagas, Hepatitis B Surface Antigen, Human T-Cell Lymphotropic Virus Antibody I/II, Hepatitis B Core Antibody, Human Immunodeficiency Virus Antibody-1,2, Hepatitis C Antibody, HIV Nucleic Amplification (NAT), HCV Nucleic Amplification (NAT), WNV Nucleic Amplification (NAT), and HBV Nucleic Amplification (NAT). There is also a checkbox for "Bacterial Detection Testing (applicable only for plt. products)". At the bottom, it says "The Blood Connection" and "1099 Bracken Road - Piedmont, SC 29673".

#### E. Distribution

Products which are released as a result of an emergency release request will be shipped in Elite designating them as an Emergency Release shipment/product. See 4243P/current version.

Remove the Pink and Gold copy of the Emergency Release form (4200PDF/current version). Attach a copy of the shipping ticket to the Gold copy of 4200PDF/current version and route to The Manager of Hospital Services (or designee). Route the pink copy to the testing laboratory for completion.

Take the white and yellow copy (these copies are not separated at this time) with the emergency released product (and accompanying paperwork/shipping tickets) to the transfusion facility. The transfusion facility representative/employee **MUST** sign in the indicated area of 4200PDF/current version at the time of delivery (note: it is highly recommended that a TBC staff member make this delivery and obtain signatures. **DO NOT** leave the product at the transfusion facility without first obtaining the signature.

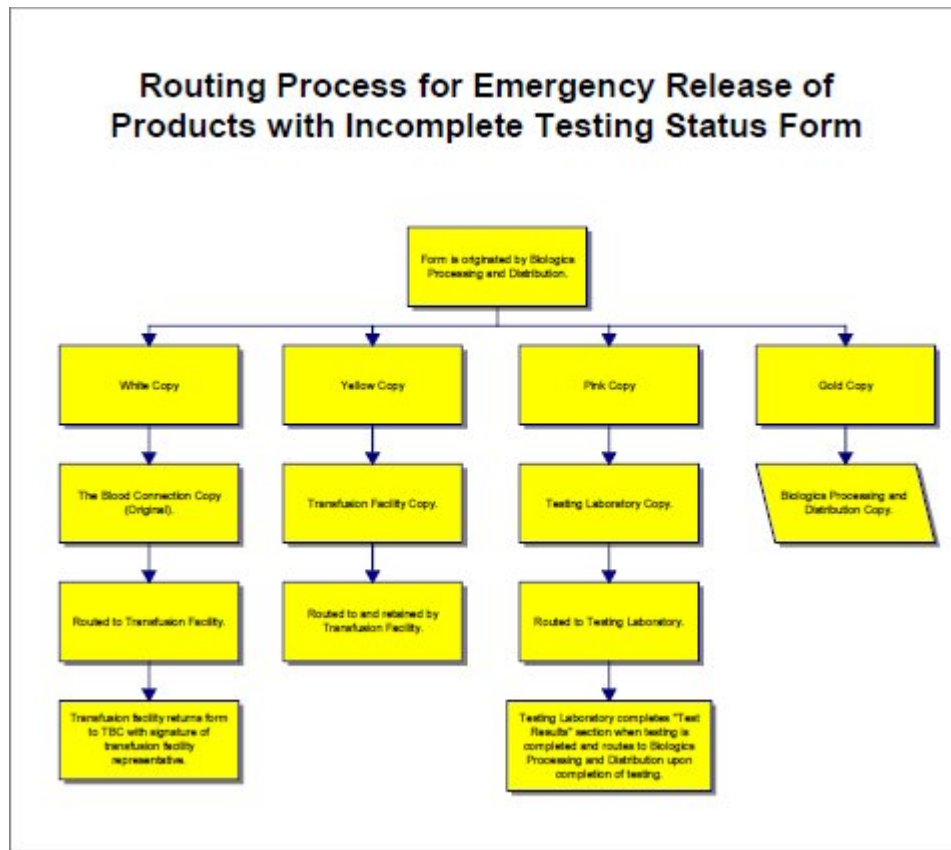
Leave the yellow copy of 4200PDF/current version with the transfusion facility and return the white copy to Manager of Hospital Services.

**F. Completion of Testing/Routing Form**

When required testing is completed, Testing Laboratory completes the “Testing Results” section on the routed copy (Pink copy) of the emergency release form. The testing laboratory is to call the receiving facility with the testing information and record the information under the NOTIFICATION section (on the pink copy) along with the date/time and tech code. The pink copy is then routed back to Hospital Services.

NOTE: The testing laboratory is also responsible for assuring that the completed testing information is entered into Elite for the unit.

Any non-conforming (reactive) test result is reported to the VP, Business Development/Chief Technical Officer or Vice President of Operations immediately.



### G. Review

The VP of Business Development/Chief Technical Officer or Manager, of Hospital Services is responsible for reviewing all paperwork/forms for this process. As part of the review process, the pink and white copy of the Emergency Release form 4200PDF/current version is scanned and saved as a pdf and then uploaded to the original order in Elite. See 4243P/current version.