Donor and Client Support Center

The Transfusion Service Customer Handbook

RED CROSS REGIONS

RECIPIENTS

DONORS

DONOR AND CLIENT SUPPORT CENTER (DCSC)

REGULATIONS

HOSPITALS
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Introduction

Basic Information
This handbook is designed to provide a basic overview on the exchange of information between you (the customer) and the Donor and Client Support Center (DCSC).

The DCSC is a consolidation of donor management and product notification activities which are managed in two central locations, Charlotte, NC and Philadelphia, PA.

DCSC is responsible for interacting with hospital customers and other institutions that receive blood products from the American Red Cross. These interactions include:
- Communicating market withdrawal/recall/recipient traceback (lookback) notification activities
- Processing reports of patient adverse reactions/possible transfusion-related infections (recipient complications)
- Completing the required notifications and obtaining authorizations to referring physicians and transfusions services for any autologous donations with reactive test results or any other product suitability issues

This exchange of communication can take place in the format of a letter, a form, and in some cases, a report. Because there is a variety in the types of communications received from or sent to the DCSC it is important that the terminology used and the purpose for those communications in each case is clearly understood.

The appendices in the handbook provide supplemental information about Red Cross communications including common terms, a list of most frequently asked questions (FAQs) and samples of completed letters and forms. Because we are constantly working to improve our communications, these documents may change periodically and look different than the samples provided; however, the purpose for each document remains the same.

Customer Contact Information
Please note that in order to provide you with timely and efficient delivery of information it is important that DCSC has the correct contact information for your facility on file. Any change in this contact information should be reported to the DCSC by email (DCSCmailbox@redcross.org) or fax (888-719-3535).

Access to Handbook and Report Forms
This handbook, along with the recipient complication report forms, is available in both electronic or hard copy formats. See Appendix III for information about locating forms on the website.
- For a printed copy, send a request via e-mail to DCSCmailbox@redcross.org.
Communications Overview

Types of Communications
DCSC issues a number of communications when new or updated information is received about a product that was shipped to a customer. The purpose of these communications is to notify you that the suitability status of the product may have changed because of:

- A market withdrawal due to test results
- A retrieval or recall that has been triggered by information not related to test results
- Information received that meets the criteria of a recipient lookback investigation

Other types of letters or forms may be sent as well, including:

- Notification or a request to authorize the release of an autologous unit
- Information about a recipient complication case that was submitted for investigation
- An annual letter used as a reminder to report recipient reactions to the Red Cross

Appendix V provides detailed descriptions of the letters and forms sent by the DCSC, while Appendix X contains samples of communications that may be issued by the DCSC under a variety of situations. Each letter identifies the circumstances under which it is being sent and includes information regarding the identification of products received at your facility. All communications provide a contact name, phone number, and email address in case you have questions about the information provided.

Frequency of Communications
More than one type of communication may be sent for the same product or issue. In some cases, the same communication may be issued more than once; the letter itself will explain why it has been re-issued. Sometimes this occurs when a form included in the initial letter is not returned to DCSC with the requested information; in others it may be to inform you of a delay in obtaining final product or test status, to provide you with an update to the original communication, or to inform you of additional test results that have become available.

At the end of Appendix V is a summary of the more common situations when a letter or form is sent, the actions requested, and any follow-up that may be needed.
Appendix I: Contact Information - Donor and Client Support Center

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
<th>Contact Information (phone and email)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Director</td>
<td>Julie Hall</td>
<td>704-805-3013 <a href="mailto:Julie.Hall@redcross.org">Julie.Hall@redcross.org</a></td>
</tr>
<tr>
<td>Sr. Director</td>
<td>Artan Apostoli</td>
<td>704-805-3012 <a href="mailto:Artan.Apostoli@redcross.org">Artan.Apostoli@redcross.org</a></td>
</tr>
<tr>
<td>Managers</td>
<td>Sheila Bethea</td>
<td>704-805-3191 <a href="mailto:Sheila.Bethea@redcross.org">Sheila.Bethea@redcross.org</a></td>
</tr>
<tr>
<td></td>
<td>Donna Burke</td>
<td>215-451-4892 <a href="mailto:Donna.Burke@redcross.org">Donna.Burke@redcross.org</a></td>
</tr>
<tr>
<td></td>
<td>Debbie Derello</td>
<td>704-805-3046 <a href="mailto:Deborah.Derello@redcross.org">Deborah.Derello@redcross.org</a></td>
</tr>
<tr>
<td></td>
<td>Becky Kemplen</td>
<td>704-805-3044 <a href="mailto:Rebecca.Kemplen@redcross.org">Rebecca.Kemplen@redcross.org</a></td>
</tr>
</tbody>
</table>

| Medical Officers       |                 |                                       |
| Executive Medical Officers | Kathleen Grima, MD | 215-667-9039 Kathleen.Grima@redcross.org |
|                        | Yvette Miller, MD | 704-805-3020 Yvette.Miller@redcross.org |

General Contact Number
866-236-3276 (ask for a supervisor)

Fax: 888-719-3535 Email: DCSCmailbox@redcross.org
Appendix II: Terminology

Additional Test Results
Further testing, including confirmatory or NAT discriminatory, performed on donation samples that are reactive for any infectious disease screening tests. Other testing may be performed to provide additional information for donors, counselors, and physicians.

Autologous
A person who is both the donor and the intended recipient; the collection of autologous components requires a physician’s order.

Customer
A facility that receives goods or services provided by the American Red Cross.

The terms “customer,” “consignee,” and “client” are used interchangeably throughout this manual.

Gaining Control
A preliminary step in a component investigation; refers to the immediate actions taken to ensure that in-date components are held or placed in quarantine until the investigation is completed. Gaining control is not a recall.

Implicated Donation/Donor
A donor or a product that has been identified as the likely or certain cause of a recipient complication based on a Red Cross physician’s final case assessment of a transfusion investigation.

Indate (Component)
A whole blood or blood component that has not reached the expiration date stated on the label.

Index Donation/Sample
A sample from a donation that tests reactive by a specific screening assay and is used to trigger further investigation.

Investigation
An inspection conducted “for cause” when there is reason to believe that a recipient complication or a violation of a law, regulation, or facility standard operating procedure has occurred.

Involved Donation
A reported donation (sometimes referred to as index donation) that is part of an investigation, or could have been the cause of a recipient complication based on the evaluation of a Red Cross physician.

Lookback (Lookback/Traceback)
The tracking and identification of the location and disposition of blood component products that were manufactured from donations by a particular donor; the steps taken to track and quarantine unsuitable blood or blood components and to notify consignees when a donor subsequently tests positive or provides information regarding a diagnosis for the most significant infectious disease markers.
Market Withdrawal
A firm’s removal or correction of a distributed product that involves a minor violation subject to legal action by the Food and Drug Administration (FDA) or that involves no violation (for example, normal stock rotation practices, or routine equipment adjustments and repairs)

Nucleic Acid Testing (NAT)
Method of testing that detects genetic material of the virus, such as hepatitis C virus (HCV), human immunodeficiency virus (HIV), hepatitis B virus (HBV), West Nile virus (WNV), and Zika virus. Two types of NAT are the following:
- Transcription mediated amplification (TMA) – the type of NAT using the licensed Ultrio HIV-1/HCV/HBV Assay. TMA is also used as a screening test for WNV
- Polymerase chain reaction (PCR) – a type of NAT that may be performed as a supplemental assay to confirm a reactive TMA result

Reactive
For viral testing, a sample that has both an initial and repeat reactive screening result

Recall
A firm’s removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (for example, seizure). Recall does not include a market withdrawal or stock recovery.

Recipient Complication
The undesirable outcome of a blood transfusion; may be a transfusion-transmitted infection or a transfusion reaction.

Retrieval (Blood)
A general term used for an action taken (such as a recall or market withdrawal) to remove unsuitable blood or blood components from the marketplace

Screening Test
An FDA-approved assay used to test a donation for evidence of infection due to communicable agents

Transfusion Reaction
A recipient complication not related to an infection with a virus or similar transfusion-transmissible agents. Examples include transfusion related acute lung injury (TRALI), hemolytic reactions, and septic reactions.

Transfusion Service
A facility that performs one or more of the following activities:
- Compatibility testing
- Storage
- Selection
- Issuing of blood and components to intended recipients

This facility routinely does not collect blood or process whole blood into components, except red blood cells and recovered plasma.

*The terms “transfusion service” and “health care facility” are used interchangeably.*
Transfusion-Transmitted Infection
An infection predominately acquired by the transfusion of a virus or a parasite, in which a delay generally occurs between transfusion and manifestation of the symptoms and signs of infection. The infection does not pertain to a septic transfusion reaction that is associated with the bacterial contamination of a unit (See “Transfusion Reaction”).

Unsuitable Blood or Blood Products
Blood or blood components whose safety, purity, or potency ("quality") may have been affected
Appendix III: Information about the Red Cross Website and Links

The Red Cross website contains a large amount of information for our donors, the public, and our hospital customers. This appendix is not intended to be a tutorial for the website but only calls attention to those pages or links specifically referenced in the handbook or in a communication sent to our customers.

Accessing information useful to hospitals can be found by typing in the following address into the URL field: RedCrossBlood.org.

The homepage displays. The appearance of this page will change on a routine basis so can be different from what is shown below:

- Note: using the former address www.redcrossblood.org will prompt a different page to display but accessing information from that point is the same, no matter which address is used.

Using the mouse, click on the heading for Biomedical Services. A list of available options by category will then appear:
Selecting "Case Reports" from the Hospital Partners category takes you to a section that provides basic information about the regulatory requirements for reporting an adverse transfusion reaction (referenced in Appendix V), and allows for the download of the two forms used in reporting these reactions.

Also under the Hospital Partners category is an option called Blood Bank Resources. Clicking on this item provides electronic access to other items of interest, including the following:
- Red Cross Infectious Disease Testing Methodologies (referenced in Appendix IV) which includes the screening method and type of confirmatory test, when one is available, for each marker
- TRALI mitigation
- Transfusion Service Customer Handbook (this document)
Under the Blood and Diagnostic Testing category is a link to the Infectious Disease Testing used by the Red Cross. Clicking on the plus symbol (+) by each test listed expands the field to provide additional resource information.

![Image of Infectious Disease Testing](image.png)

Infectious Disease Testing
Blood donations are tested for multiple infectious disease markers. Current tests are featured below.


A review of the lists under each category shows additional information that could present itself in one of our communications, or prove useful resource material, such as reimbursements, blood products, molecular testing, and contact information.

The website is also a source of information for blood donors, allowing them to review the eligibility requirements for donating blood, and providing them with a better understanding of the donation process.
Appendix IV: Screening Tests and Additional Test Results

American Red Cross Donation Screening
All donations to the Red Cross are screened for relevant transfusion-transmitted infections, according to all applicable regulatory requirements and guidance, including 21 CFR 610.40 and AABB standards. When a donor sample is repeat-reactive (reactive) for a serologic screening test or reactive by NAT, samples are further tested using more specific tests (when available) to confirm, discriminate, or provide additional information about the screening result.

This additional testing may be performed at one of several American Red Cross laboratories or by an approved outside vendor.

Screening Test Results
The customer receives notification when the sample from a donor’s subsequent donation or from a donor’s current autologous donation is reactive for any of the following infectious disease screening tests:

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B surface antigen (HBsAg)</td>
<td>Multiplex NAT for HIV-1/HCV/HBV</td>
</tr>
<tr>
<td>Antibodies to hepatitis C virus (anti-HCV)</td>
<td>Antibodies to hepatitis B core antigen (anti-HBc)</td>
</tr>
<tr>
<td>Antibodies to human immunodeficiency viruses (anti-HIV-1/HIV-2)</td>
<td>West Nile virus (WNV)</td>
</tr>
<tr>
<td>Antibodies to human T-cell lymphotropic virus type I and type II (anti-HTLV-I/II)</td>
<td>Antibodies to <em>Trypanosoma cruzi</em> (T. cruzi /Chagas)</td>
</tr>
<tr>
<td>Serologic test for syphilis (STS)*</td>
<td>Zika virus</td>
</tr>
</tbody>
</table>

*Reactive syphilis tests are only reported on autologous donations

As other infectious disease agents, such as babesia and dengue, become present in certain geographic regions of the US and demonstrate to be transfusion transmitted, investigational protocols may be established so that testing for the disease agent can be performed.

Methodologies
Information about current test methods is available on our website in a PDF format titled Red Cross Infectious Disease Testing Methodologies. Go to [RedCrossBlood.org](http://RedCrossBlood.org) to locate the document or refer to Appendix III for help in locating the file.
Appendix V: Descriptions of DCSC Communications

Non-Retrieval (Information only) Overview
Some communications are in an information-only category. Any actions you will be asked to take will depend upon the reason for the communication. For example, you may be told that no actions on your part are needed or you may be asked to supply us with the status of the product or products sent to your facility. In the latter case, the letter will be accompanied by a form for documenting the product status (disposition).

A. Gain Control Requests
A notification that products distributed to you are now under investigation; the reasons behind an investigation vary widely. You will be asked to quarantine the indate products pending completion of the investigation, at which time you will be notified as to whether the product is acceptable for release or must be retrieved (discarded).

B. Consignee Notification Letter
Sent when distributed products are the subject of a notification action that falls short of market withdrawal or product retrieval, such as:
- A reported of diagnosis of West Nile virus
- Rh type discrepancy
- Red cell antigen typing discrepancy
Market Withdrawals and Recalls (Overview)
The retrieval process is intended to account for all components deemed unsuitable per Red Cross and FDA regulations whether from testing done on a subsequent donation by the donor or from other sources of information. In some cases the letter will ask that you supply us with the status of the product or products sent to your facility and include a product disposition form.

C. Product Retrieval Letter
Sent when distributed products are the subject of a retrieval action not associated with routine testing performed by the Red Cross. Retrievals include recalls and market withdrawals.

D. Product Disposition Form
Included in some communications in order to provide DCSC with information most routinely asked for by the Food and Drug Administration (FDA) regarding the final status of the product (issued, discarded, transferred, etc.).

E. Cover Letter for Non-Red Cross Product Retrieval
Sent to customers when distributed products collected by a non-Red Cross blood center are the subject of a retrieval action (including market withdrawal and recall) or for a notification.

F. Test Result Reactive – Market Withdrawal Letter
Sent when prior in-date components are subject to biologic market withdrawal due to a subsequent reactive screening test. The purpose is to retrieve in-date components which have not been transfused and provide the reason for the withdrawal.

G. Test Result – Follow-up Notification Letter
Sent when further testing has been completed subsequent to the initial retrieval notification; reported as follow-up testing to the specific screening test.
- In the case when a confirmatory result triggers a “Recipient Lookback,” the follow-up to the initial retrieval will be communicated to you by way of a letter for that specific purpose.
- If the result is positive for a particular test, then a reminder will be included in the letter that if the patient is diagnosed with the underlying pathogen/infection, the case must be reported to us as a potential transfusion-transmitted infection so that a full investigation is performed.

H. Positive Bacterial Detection First Notification
Sent when distributed products are the subject of an investigation that is due to a positive bacterial quality control test

I. Positive Bacterial Detection Follow-Up Notification
Sent when a final determination has been made about the products involved in the investigation of a positive bacterial quality control test
Recipient Lookback (Lookback/Traceback) Notifications (Overview)

A recipient investigation is conducted to notify individuals who may have been exposed to a transfusion-transmissible disease from a blood transfusion. These investigations are most commonly initiated subsequent to market withdrawal, and when the confirmatory test is positive for one of the following:
- Anti-HIV-1
- Anti-HIV-2
- HIV NAT
- Anti-HCV
- HCV NAT
- T. cruzi antibody (Chagas)
- Other positive markers for infectious disease determined to be medically significant by the Red Cross Biomedical Services Headquarters (BHQ) Medical Office

Federal regulations also require recipient lookback investigations in cases when the donor’s blood sample is:
- Reactive for NAT multiplex (HIV-1/HCV/HBV) but there is no supporting evidence to discriminate to one of the underlying pathogens
- Reactive for the HIV antibody screening test but a confirmatory test is not performed
- Reactive for the HCV antibody screening test but a confirmatory test is not performed

A recipient investigation would also be conducted immediately upon receipt of evidence that the donor of a distributed unit of blood now has an infection involving one of the above pathogens, including:
- A written report of a recipient having a positive infectious disease test result
- A written report from a reliable external source that a recipient has a positive test, is ill with, or has died from an associated disease
- A written report or verbal report from a reliable source that a recipient experienced a transfusion reaction
- Verifcation from the facility physician/designee that a verbal report is from a reliable source (a written report would be requested)
- When a recipient identified through an investigation is found to be confirmed positive and other transfused products may be involved

Please note that our term “lookback/traceback” or “traceback,” describes what the Code of Federation Regulations (CFR) refers to as “lookback” in 21 CFR 610.46, 21 CFR 610.47, along with other FDA guidance documents and AABB standards. Unlike market withdrawals, lookback investigations bring specific requirements for recipient tracing and notification, including but not limited to:
- Notifying the transfusion recipients of previous collections of blood and blood components at increased risk of a transmitted infection
- Notifying the recipient’s physician of record of the need for recipient testing and counseling
- Notifying the recipient’s physician of record or a legal representative or relative if the recipient is a minor, deceased, or adjudged incompetent by a State court
- Making reasonable attempts to perform the notification within 12 weeks after receiving the supplemental (additional, more specific) test results for evidence of infection from the collecting establishment, or after receiving the donor’s reactive screening test result if there is no available supplemental test that is approved for such use by the FDA
J. Traceback Notification Subsequent to Market Withdrawal
Sent when a recipient lookback investigation is being conducted subsequent to market withdrawal

K. Traceback Notification to Transfusion Service
Sent when a recipient lookback investigation is being conducted independent of infectious disease testing or a prior market withdrawal

L. Recipient Status Form
Sent when the unit has been identified as transfused or the unit’s status is not yet known; the information requested on the form is to help with determining whether the scope of the investigation needs to be expanded based on any testing performed on the recipients. (See also Appendix VIII, Recipient Testing.)

M. Traceback Follow-Up Request
Sent when a response has not been received from the customer after a period of days following the initial notification
Autologous Notifications (Overview)

The FDA and AABB require that referring physicians and transfusion services (other than the collection site) be notified when a unit tests reactive for a transfusion-transmitted disease. The FDA further requires that under certain circumstances (such as reactive HIV, HIV NAT, and HBsAg test results) autologous components be distributed only with written, dated, and signed authorization from the patient’s physician. In addition, the Red Cross requires that the transfusion services also authorize shipment of these units to their facility.

Regulatory Requirements
The CFR and AABB standards require that all blood collection facilities inform the referring physician of the following:
- When an autologous donor is deferred from allogeneic donation based on a test result, and which test result caused the deferral
- When appropriate, the types of donations that the autologous donor should not give in the future
- Additional, more specific test results performed on the autologous donation

Notifications and authorizations must be communicated in writing. All notifications for additional test results must be complete within 8 weeks of the reactive test result.

N. Autologous Notification and Authorization Form
When a notification only is sent (authorization for the release of the autologous blood product is not required), no further action is needed.
When you’ve been informed that a signed authorization is required on the autologous notification and authorization form, then
- Complete the fields in the Transfusion Service section for name and title.
- Sign and date the appropriate line that indicates your acceptance of or refusal to accept the unit.
- Return the form to the DCSC.

Special Note on Authorizations
If the autologous test result requires a signed Authorization for Release from both the physician and the transfusion service, a form signed by both parties MUST be received prior to shipment of the component.

Physicians may change hospital locations for the surgery. In this case, a signed authorization from the new location is required.
Recipient Complications Notifications (Overview)

The FDA and AABB require transfusion facilities to document, investigate, and prepare a written report when a patient has an adverse reaction to transfusion (defined by the FDA as including transmission of infections). In cases where the adverse reaction is, or may be, due to a problem with the blood product itself, you must also promptly notify the collecting facility. The requirement to report transfusion complications when services have been provided by the Red Cross is specified in your contract with us.

As the collecting facility, the Red Cross is obligated to evaluate and assess reported potential transfusion complications. In order for us to accomplish this task, you will most likely be contacted by a case investigator or medical director of the involved Red Cross regional blood center for medical information about the patient. The medical information privacy standards in the Health Insurance Portability and Accountability Act (HIPAA) as outlined in the CFR specifically allows transfusion facilities to provide this information to the Red Cross without written authorization of the patient.

Patient information collected as part of a recipient complication investigation is kept confidential at the blood center, and used primarily by the case investigator and medical director for quality improvement and regulatory compliance. Any requests for additional information will generally be by telephone. The callers will identify themselves as staff of the Red Cross requesting additional information on a patient case, and will be prepared to provide the patient’s identifying information given in the initial case report from the hospital.

When it is questionable whether a recipient’s positive test status or adverse symptomology is the result of the transfusion or of some other risk factor, the Red Cross medical director is responsible for evaluating the recipient status and making the final determination.

The investigation and analysis of transfusion recipient complications allows blood centers over time to identify opportunities to decrease the number and severity of complications, which contributes to the efforts for maintaining a plentiful, safe blood supply. Your assistance over the course of each investigation is needed and appreciated.
Key Points
The forms used in these investigations are available at RedCrossBlood.org (see Appendix III).

The examples in Appendix X are designed to help with filling out the report forms. Fields that are vital to providing critical information are identified below and are in yellow highlights in the examples in the appendix. Completion of this information will aid in the immediate assessment of the report and prevent unnecessary delays in the investigation.

- Name of reporting health care facility
- Recipient identifier (for example, recipient ID, patient number, or reporting facility’s case number)
- Specific infection that may have been caused by transfusion or type of reaction that may have been caused by transfusion
- Clinical information and test results pertinent to the specified infection and date test performed, or clinical signs and symptoms of the transfusion reaction
- Total number of Red Cross products reported per case
- Unit numbers of products involved and product types
- Dates of transfusion
- Whether a recipient fatality is involved

O. Recipient Complications – Annual Notification Letter
A reminder sent once a year concerning the regulatory requirements for reporting recipient reactions to the blood collection facility. The letter also provides report forms and contact information. Information regarding Health Insurance Portability and Accountability Act (HIPAA) privacy standards is also included.

P. Recipient Complications – Infectious Disease Report
Used to document and report information associated with a possible recipient complication for infectious disease. The form is provided to transfusion services or health care facilities to report recipient complications that may be related to infectious disease.

Q. Recipient Complications – Transfusion Reaction Case Report
Used to document and report recipient complication information associated with a possible transfusion reaction. The form is made available to transfusion services or health care facilities to report recipient reactions that may be related to the blood products they received.
## Summary of Routine Communications and Follow-Up

(What happens as a result of sending a letter or a form)

<table>
<thead>
<tr>
<th>Type of notification</th>
<th>Reason for sending</th>
<th>Actions requested</th>
<th>What happens next (follow-up)</th>
</tr>
</thead>
</table>
| Products under investigation (gain control) | A discovery that calls into question the suitability of the product sent to your facility. | Quarantine any indate products still in stock. | Red Cross performs an investigation into the product's suitability; you will be notified of the decision from the investigation by either one of two letters:  
  - Letter of retrieval (See "Product retrieval, including recalls"), or  
  - Letter stating product is/was suitable for transfusion |
| Product retrieval including recalls | New or subsequent information that affects the suitability of the product sent to your facility. | Discard or return any indate products still in stock (preferred action stated in letter).  
A form requesting information about the product may be included; when included, complete the form and return it to DCSC within 30 days. | If there was no form included with the letter, then there are no additional actions we will ask of you.  
If we have requested but not received a response from you as to the product status then... a follow-up letter is sent as a reminder along with another form. |
| Reactive test results | The donor of the product sent to your facility has a subsequent donation with a reactive test result | Quarantine or discard any indate products still in stock. | Additional testing may be performed; when those results are available you will be sent a new letter with the additional test results.  
This letter may be accompanied by a form requesting information about the product; if included then complete the form and return it to DCSC within 30 days. |
| Recipient lookback (traceback) | The donor of the product sent to your facility has a test result or diagnosis meeting lookback criteria. | Discard any indate products still in stock.  
Notify the recipient of any transfused unit.  
Complete the form that accompanies the letter, and return it to DCSC within 30 days. | If we have not received a response from you as to the status of the recipient or product then... a follow-up letter is sent as a reminder along with another form. |
<table>
<thead>
<tr>
<th>Type of notification</th>
<th>Reason for sending</th>
<th>Actions requested</th>
<th>What happens next (follow-up)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autologous</td>
<td>The donor/recipient of the product has a reactive test result or the product does not meet release criteria.</td>
<td>If the form is a notification only, then no actions are needed.</td>
<td>For a reactive screening test result, additional testing may be performed. A second form is sent informing you of any additional test results.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If authorization is required before shipping the product then... you will be asked to sign the form and return it to DCSC.</td>
<td></td>
</tr>
</tbody>
</table>
Appendix VI: Descriptions of Regional Communications

Overview
You may also receive communications that originate from your local Red Cross facility rather than the DCSC. Most times, these are to request the completion of a form that is needed to process a unit. Some of these include requests to

- Document the completion of a correction or rework.
- Initiate the return of a product back to a Red Cross facility.

Examples of two common regional communications are included in Appendix X; questions concerning the completion of these forms need to be directed to the facility that issued the form.

Documentation of Correction or Rework
Most commonly used to request the field correction of a label or tag on a unit. A detailed description of the correction to be made is provided, along with instructions on submitting proof/documentation for the work performed.

Return Authorization Form
Used to process the return of a product back to the Red Cross. Information regarding product quality must be provided and signed as certified.
Appendix VII: Product Complaints and Order Discrepancies

If any of the situations below occur then... contact the Red Cross facility that routinely distributes products to you.

Complaint Types
Complaints could include, but are not limited to:
- Product contained clots
- Product hemolyzed
- Product leaking
- Positive direct anti-globulin test (DAT)
- pH/Gram stain reports
- Positive culture
- ABO discrepancies
- Late delivery
- Product not available

Order Discrepancies
Whenever an ordered shipment of blood products does not match your specifications or what is listed on the shipping form, please report it to the shipping facility immediately. Even when the discrepancy is in your favor, it is essential that the shipping facility be aware of the location of all blood products.
Appendix VIII: Recipient Testing

FDA Regulations

FDA regulations require that patients who may have been infected through a blood transfusion be informed and consider treatment options. The patient is to be notified of the need for follow-up testing and counseling as soon as possible.

It is extremely important to us that you provide the information requested on the Recipient Status form or any other document provided. Please complete the form, retain a copy for your files, and return the original within 60 days. Confidentiality of recipient information will be strictly maintained.

Steps for Recipient Testing

If you wish to have the recipient tested by the Red Cross cost-free, then the information below provides a description of the process when requesting recipient testing.

1. Notify the DCSC at 866-236-3276; choose option 4, and then option 2. Be prepared to provide the DCSC staff with the following:
   a. The phone number and address of the facility that will be collecting the sample
   b. Name and contact information of the person authorized to receive the test results

2. For infectious disease testing, DCSC notifies the Red Cross Scientific Support Office (SSO) that a request to test a recipient sample has been made. SSO staff then sends the facility (identified in 1a above) a letter with a kit containing all the items needed to collect and ship the sample, including instructions, supplies, a shipping container, and contact information.

   For all other test requests, including TRALI work-up, DCSC consults with the appropriate lab for sample collection information and shipping instructions, and then communicates the information back to the facility making the request.

3. **Before shipping the samples** and to help expedite the processing of these samples, the facility collecting the sample must be sure that
   a. Each sample collection tube is identified, for example with a bar code label from the supply kit or a case number supplied by the DCSC.

      The bar code numbers or DCSC case number on the label will be sufficient to match the sample to the recipient in the case. There is no need to include the recipient name on the tubes or the form.
   b. The collection and packing information sections on the shipping form, when sent, are complete.
   c. When sending samples to the SSO, fax or email a copy of the completed shipping form to SSO. This alerts the SSO ahead of time to expect the receipt of a sample being submitted for testing:
      - E-mail: SSOLAB@redcross.org
      - Fax: 301- 977-8163

4. Send the tubes to the testing lab, along with the shipping form if supplied.

5. The DCSC will forward the test results directly to the requesting physician approximately 4 to 6 weeks after the sample is drawn.
Appendix IX: Frequently Asked Questions (FAQs)

1. **What are the most common notifications/letters that DCSC sends?**
   
   a. Product Retrievals, which include the following:
      
      i. The Test Result Reactive – Market Withdrawal: a communication that prior indate components are subject to biologic market withdrawal due to a subsequent reactive screening test.
      
      ii. Product Retrieval (most common communication): letter sent when distributed products are the subject of retrieval, including recalls and market withdrawals, due to post donation information (history of travel, reported infections, etc.), manufacturing issues, documentation discrepancies, etc.
      
      iii. Consignee Notification: letter sent when distributed products are the subject of a notification action that falls short of market withdrawal or product retrieval. These situations include: red cell antigen typing discrepancy, platelets in a malfunction of bacterial testing equipment, etc.
   
   b. Gaining Control Requests

   Notification for Product under Investigation: informs you of products that have been distributed to your facility and are now under investigation. You will be asked to “gain control” (quarantine) the identified products, if still in your inventory, while the investigation is in progress.

   c. Recipient Lookback (Traceback) Investigations

   Most commonly, recipient lookback investigations are initiated subsequent to market withdrawal when the confirmatory test is positive for one of the following: Anti-HIV-1, Anti-HIV-2, HIV NAT, Anti-HCV, HCV NAT, T. cruzi antibody (Chagas). Recipient tracing is also required in rare cases when the NAT results do not discriminate/cannot be attributed to one pathogen.

2. **What causes DCSC to send more than one letter for the same product?**

   This depends upon the circumstances for having notified a facility of a product issue.

   a. If the initial letter was sent because of an investigation into the suitability of the product shipped to your facility (gain control request), then a follow-up letter is sent to provide information on the final decision about the product’s suitability. This decision is communicated as one of two possible outcomes, either:
      
      i. Product release, when products were found suitable or
      
      ii. Product retrieval, when the products were deemed unsuitable
   
   b. If the initial letter was sent in the form of a market withdrawal due to a reactive screening test, then a follow-up letter may be sent with any confirmatory or additional testing that was performed subsequent to the initial notification. The results of this additional testing may be communicated in one of two possible letters:
      
      i. Test Result – Follow-Up Notification letter, or
      
      ii. Traceback Notification Subsequent to Market Withdrawal

   Because of the timing in receiving final test results, it may appear that duplicate notifications were sent for the same product. For additional information, please refer to the Summary of Routine Communications and Follow-Up table in Appendix V.
3. **What actions are expected to the notices listed above?**
   
   This will depend upon the type of issue discovered. In some cases, no action may be 
   required; for others, the following may apply:
   
   a. Quarantine, destroy, or return products (if in inventory)
   b. Completion of a form (product disposition/recipient status) when requested
   
   In the event the product has been transferred to another hospital/facility,
   please inform the other facility of the product retrieval/recipient lookback
   notification.

4. **How much time is allowed for responding back (returning a form) to DCSC?**
   
   Thirty days for product retrieval and recipient lookback cases; a second or final notice is sent 
   when the form has not been received at the DCSC by the 30 day mark.

5. **What methods does DCSC use to contact the blood bank?**
   
   a. For indate products we fax the letter (or email - if requested) and call the blood bank to 
      confirm receipt/provide instructions
   b. For outdated products, we fax (or email) the letters
   c. Because we process cases 24/7/365, the calls/faxes may take place at any time.
   d. Mailing is used only if a response to the initial notification is not received (see item 3).

   Be sure to notify DCSC of changes to the contact information for your facility 
   and any preferences/special instructions.

6. **What is the best method for reaching DCSC?**
   
   a. By phone, call 866-236-3276. (Letters will also identify which prompt to use)
      i. Option 1 for a lookback case or test result questions
      ii. Option 4, 1 for retrievals/recalls/notifications
      iii. Option 4, 2 for recipient complications; bacterial contamination/testing case, etc.
   b. By email, vFaxforDCSC@redcross.org for general questions or to return forms (see item 
      2b), or DCSCmailbox@redcross.org
   c. By fax at 888-719-3535
   d. By mail:

      Donor and Client Support Center
      American Red Cross
      9013-J Perimeter Woods Drive
      Charlotte, NC 28216
      
      Or

      Donor and Client Support Center
      American Red Cross
      700 Spring Garden Street
      Philadelphia, PA 19123

7. **Where can I obtain copies of case reports/forms for recipient complications?**
   
   a. You can access an MS Word version of forms for reporting possible recipient complications 
      for infectious disease and transfusion reactions from the website (see Appendix III) or by 
      entering RedCrossBlood.org into the URL field; or
   b. You may request hard copies from DCSC either via email or a phone call

8. **If I have an issue with a shipment/order or I have a product complaint do I 
   contact DCSC or the Red Cross distribution site?**
   
   Please contact the Red Cross facility that routinely distributes products to you. For examples 
   and details, refer to Appendix VII, Product Complaints and Order Discrepancies.
Appendix X: Sample Letters and Forms

The following are samples of the communications most commonly issued or available to customers. They are not meant to represent every situation in which a communication may be sent but are representative of actual scenarios. The letters, and in some cases the forms, have been populated with information that would be completed by staff at the DCSC or local Red Cross facility to help demonstrate the conditions in which the letter or form would be issued.

The critical or key fields that require your completion are identified in the samples with yellow highlights.

Letters

- Product Under Investigation (gain control)
- Notification of Investigation Decision to Release
- Consignee Notification
- Product Retrieval
- Cover Letter for Non-Red Cross Product Retrieval
- Test Result Reactive – Market Withdrawal
- Test Result - Follow-Up Notification
- Traceback Notification Subsequent to Market Withdrawal
- Traceback Notification to Transfusion Service

Forms (DCSC)

- Product Disposition
- Recipient Status
- Autologous Authorization and Notification
- Recipient Complications – Infectious Disease Case Report
- Recipient Complications – Transfusion Reaction Case Report

Forms (Regional Red Cross)

- Documentation of Correction or Rework
- Return Authorization
Product Under Investigation: Sample

03/31/2018

Atwood Community Hospital
ATTN: Blood Bank
123 Main Street
Anytown, NJ 11111

Re: Notification of product under investigation
Case ID: c2018051012340j

Dear Transfusion service director:

Our records indicate that the products in the following table are being investigated due to a question regarding the maintenance record for the equipment used to process the unit:

<table>
<thead>
<tr>
<th>Donation Identification Number (DIN)</th>
<th>Product Code/Description</th>
<th>ABO/Rh</th>
<th>Product Expiration Date</th>
<th>Distribution Date</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>W201218022282</td>
<td>00180/CP2D Whole Blood</td>
<td>A N</td>
<td>4/16/2018</td>
<td>3/10/2018</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Please take the following precautions:
- If the product is still in your distributable inventory, then please move it into quarantine pending completion of our investigation.
- If the product has been discarded, then no other action is required.
- If the product has been transfused, then no additional action is required at this time as there is not yet enough information to determine what impact there may be to the recipient.
- If any of these products have been transferred to another facility then... please notify them about the information in this letter.

We will inform you when the investigation is complete and product disposition is determined.

If you have any questions please call 1-866-236-3276, option 4 and ask to speak to a suspect product specialist. Please refer to the case ID documented at the top of the letter.

Thank you for your patience in this matter.

Sincerely,

Wanda Winters

Wanda Winters
Suspect Product Specialist
04/05/2018

Atwood Community Hospital
ATTN: Blood Bank
123 Main Street
Anytown, NJ 11111

Re: Result of product suitability investigation

Case ID: c2018051012340j

Dear Transfusion service director:

We previously notified you on 03/31/2015 of an investigation involving products distributed to your facility. The investigation is complete, and we have confirmed that the products listed below were suitable when initially shipped to your facility and acceptable for transfusion. No further action is required.

<table>
<thead>
<tr>
<th>Donation Identification Number (DIN)</th>
<th>Product Code/Description</th>
<th>ABO/Rh</th>
<th>Product Expiration Date</th>
<th>Distribution Date</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>W201218022282</td>
<td>001B0/ CP2D Whole Blood</td>
<td>A N</td>
<td>04/16/2018</td>
<td>03/10/2018</td>
<td>N/A</td>
</tr>
</tbody>
</table>

If any of these products have been transferred to another facility then... please notify them about the information in this letter.

If you have any questions, please call 1-866-236-3276, option 4 and ask to speak to a suspect product specialist. Please refer to the case ID documented at the top of the letter.

Thank you for your patience in this matter.

Sincerely,

Suzie Summers
Suzie Summers
Suspect Product Specialist
**Consignee Notification: Sample**

**Notification Letter**

06/30/2018

Cottonwood Hospital
ATTN: Blood Bank
456 Elm Street
Anytown, KS 65023

RE: Notification of West Nile Virus

Case ID: c2018051012340j

Dear Transfusion service director:

The American Red Cross has new information concerning blood products distributed to your facility that requires us to notify you. The products are listed below.

<table>
<thead>
<tr>
<th>Donation Identification Number (DIN)</th>
<th>Product Code/Description</th>
<th>ABO/Rh</th>
<th>Product Expiration Date</th>
<th>Distribution Date</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>W200218825476</td>
<td>04210/ AS-1 Red Blood Cells</td>
<td>B N</td>
<td>05/30/2018</td>
<td>4/19/2018</td>
<td>NA</td>
</tr>
</tbody>
</table>

At the time of shipment, the donor health history on file and all test results were acceptable on the day of donation. This notification is being initiated for the following reason:

The donor has been diagnosed with clinical West Nile Virus.

The Red Cross is notifying clients of the potential for transmission of West Nile Virus (WNV) in the recipient of the component referenced above.

If the product was transfused then... please evaluate the need to inform the recipient of this new information.

There is the potential for transmission of WNV to the recipient of the component referenced above. WNV has been shown to be transmitted through blood and blood component transfusion; however, the final determination of recipient safety rests with the patient's physician. If the patient is diagnosed with WNV, the case must be reported to the Red Cross as a potential transfusion-transmitted infection so that a full investigation is performed.

Please complete the enclosed product disposition form and return it to the following fax number 888-719-3535 or email address FaxForDCSC@redcross.org no later than 30 days from the date of this letter. Specify the status and final disposition date of these blood products.

If any of these products have been transferred to another facility then... please inform this other facility.

If you have any questions, please call 1-866-236-3276, option 4 and ask to speak to a suspect product specialist. Please refer to the case ID documented at the top of the letter. Thank you for your assistance in this matter.

Sincerely,

*Diane Dixon*

Diane Dixon
Suspect Product Specialist

Enclosures: Product Disposition Form
MARKET WITHDRAWAL

06/01/2018

Lakeside Community Medical
1000 Southeast Blvd
Anytown, NE 68002

RE: Biological product retrieval

Dear Transfusion service director:

The American Red Cross distributed blood products to your facility and these products are now subject to a market withdrawal. Product information is provided on the following page.

At the time of shipment, the donor health history on file and all test results were acceptable on the day of donation. We have subsequently learned new information about the donor that affects the products.

The donor received an allogeneic dental graft. The reported date of exposure was 09/15/2017. Receipt of a graft requires a 12-month deferral to exclude potential infectious disease transmission to the recipient. Since the date of exposure the donor had 2 donations that tested negative for all required viral markers with the most recent negative donation on 05/31/2018. We believe the risk of disease transmission is negligible because all tests for infectious disease markers were negative for the component you received.

If the product has been transfused then... please evaluate the need to inform the recipient. If any of these products are in your inventory then... destroy them immediately.

If any of these products have been transferred to another facility then... please inform them of the information in this letter.

If you have any questions, please call 1-866-236-3276, option 4 to speak to a suspect product specialist, and refer to the case identification (ID) documented at the top of the letter. Thank you for your assistance in this matter.

Sincerely,

Edie Eckenberg
Edie Eckenberg
Suspect Product Specialist
Cover Letter for Non-Red Cross Product Retrieval: Sample

URGENT: BIOLOGICAL RECALL

May 15, 2018

St. Joseph Medical Center
316 Bridgeport Road
Anytown, CT 15641

RE: Biological product retrieval

Dear Transfusion service director:

The American Red Cross distributed to your facility blood products that had been manufactured by a non-Red Cross blood collection center. We have subsequently been notified by the other blood collection center that these products are the subject of a retrieval or notification action.

The involved products are provided in the attached letter.

Please discontinue use of these products. The letter from the blood center is attached; please refer to it for additional retrieval information.

If the blood product has been transferred to another facility then... inform this other facility of the non-Red Cross blood collection center’s retrieval action.

If the product has been transfused then... please notify the responsible physician of this matter so that he or she may evaluate the need to inform the recipient.

Complete the information on the attached form and return it to the email address or fax number provided. If you are sending the form directly to the other facility, please provide us with a copy so we can note your response for our files.

If you have any questions, please contact the blood center directly at the number listed in the attached letter. Thank you for your assistance in this matter.

Sincerely,

Jaime Jensen
Jaime Jensen
Suspect Product Specialist

Enclosure: Letter from non-Red Cross facility
Test Result Reactive – Market Withdrawal: Sample

Case ID: C2018081011400LJ

06/27/2018

Linden Community Hospital
ATTN: Blood Bank
123 Main Street
Anytown, NJ 11111

Re: Biological market withdrawal due to the donor’s subsequent reactive screening test result

Immediate Attention and Action Required

Dear Transfusion service director:

The American Red Cross is initiating a market withdrawal of blood products that were distributed to your facility and are identified below.

<table>
<thead>
<tr>
<th>Donation Identification Number (DIN)</th>
<th>Product Code</th>
<th>Donation Date</th>
<th>ABO/RH</th>
</tr>
</thead>
<tbody>
<tr>
<td>W200918112345</td>
<td>04210/ AS-1 Red Blood Cells</td>
<td>05/30/2018</td>
<td>A N</td>
</tr>
</tbody>
</table>

The market withdrawal of these products is precautionary because at the time of shipment the donor tested negative for all viral markers. There were 0 donations that were negative between the date the product was sent to your facility and the date of the reactive donation.

In this case the donor’s last donation with negative test results was on 05/30/2018; a subsequent donation on 06/10/2018 was found to have:

A reactive screening test for:
Anti-HCV

HIV-1/HCV/HBV NAT multiplex is nonreactive.

Please do not use these products. If the products are in your inventory then... destroy them immediately unless we have provided you with other instructions. Additional confirmatory, supplemental, or discriminatory testing will be performed and we will contact you again when those results are available.

If any of these products have been transferred to another facility then... please inform them of the information in this letter.

If you have any questions, please call 1-866-236-3276, option 4 and ask to speak to a suspect product specialist or to one of the Donor and Client Support Center medical directors. Please refer to the case ID documented at the top of the letter.

Thank you for your assistance in this matter.

Sincerely,

Larry Lockwood
Suspect Product Specialist
Test Result - Follow-Up Notification: Sample

Case ID: C2018081011400LJ

07/07/2018

Linden Community Hospital
ATTN: Blood Bank
123 Main Street
Anytown, NJ 11111

Re: Final test results

Immediate Attention and Action Required

Dear Transfusion service director:

This letter is a follow-up to a previous market withdrawal notification. As reported to you on 06/27/2018, the products below were determined to be suitable when shipped to your facility.

<table>
<thead>
<tr>
<th>Donation Identification Number (DIN)</th>
<th>Product Code</th>
<th>Donation Date</th>
<th>ABO/RH</th>
</tr>
</thead>
<tbody>
<tr>
<td>W200918112345</td>
<td>04210/ AS-1 Red Blood Cells</td>
<td>05/30/2018</td>
<td>A N</td>
</tr>
</tbody>
</table>

At the time of market withdrawal, the donor had:

- A reactive screening test for: Anti-HCV
- HIV-1/HCV/HBV NAT multiplex is nonreactive.

Additional supplemental/confirmatory testing has been completed and the results are as follows:

- Hepatitis C virus antibody Negative

If the product was transfused then... please evaluate the need to inform the recipient of this information.

If any of these products have been transferred to another facility then... please inform them of the information in this letter.

For additional information, including the test methodologies conducted on Red Cross donations, please visit our website at: RedCrossBlood.org.

If you have any questions, please call 1-866-236-3276, option 4 and ask to speak to a suspect product specialist or one of the DCSC medical directors. Please refer to the case ID documented at the top of the letter. Thank you for your assistance in this matter.

Sincerely,

Joanne Jamison
Suspect Product Specialist
Traceback Notification Subsequent to Market Withdrawal: Sample

Case ID: C2018081011404LJ

09/02/2018

Desert Dunes Comm Hosp
885 Granite St
Anytown, CA 90282
ATTN: Blood Bank

Re: Notification of recipient traceback investigation

Immediate Attention and Action Required

<table>
<thead>
<tr>
<th>Donation identification number: W200618825476</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product: 18201, Fresh Frozen Plasma</td>
</tr>
<tr>
<td>ABO/Rh: B POS</td>
</tr>
<tr>
<td>Expiration Date: 03/12/2019</td>
</tr>
<tr>
<td>Date Shipped: 3/19/2018</td>
</tr>
</tbody>
</table>

Dear Transfusion Service Director:

This letter is a follow-up to a previously reported market withdrawal C2018082511300LJ. The American Red Cross is conducting a recipient lookback investigation on recipients of this and other products prepared from donations made by the donor of the product referenced above.

As previously reported to you, at the time of the market withdrawal the donor had a

Reactive Nucleic Acid Test Multiplex and the screening test for:
Anti-HCV is Nonreactive
Anti-HIV is Nonreactive

Final test results have been received and the additional test is

HIV-1 NAT nonreactive
HCV NAT nonreactive
HBV NAT not tested

The donor’s last negative donation was on 6/17/2018. There has been 1 negative donation between the product you received and the current positive donation.

Please complete the information requested, indicating the final disposition even if the product was not transfused, retain a copy for your files, and return the form to the following fax: 888-719-3535 or to the following email address: vFaxforDCSC@redcross.org.

If any of these products have been transferred to another facility then... please inform them of the information in this letter.

Federal guidelines require us to notify you of these “non-discriminated” results but make no determination of their significance to the recipient’s health; if the product has been transfused, the recipient’s physician should be informed to determine any further actions.

The Red Cross’ interpretation is that this combination of test results most likely indicates a false-positive. There has never been a transmission of hepatitis C virus (HCV) or human immunodeficiency virus (HIV) through blood products from a donor who has tested nonreactive for HIV or HCV antibodies and nonreactive by the NAT discriminatory assay. Therefore, we believe that there is negligible, if any, risk of transmission.

For information about the test methodologies conducted on Red Cross donations, please visit our website at: RedCrossBlood.org

If you have any questions, please call 1-866-236-3276, select option 1, ask to speak to a Donor and Client Support Center counselor, and reference the above Case ID.

Sincerely,

Kiley Kurtenbach
Kiley Kurtenbach
Case Investigator
Enclosures: Traceback Recipient Status Form
Traceback Notification to Transfusion Service: Sample

Case ID: C2018081510360LJ
08/28/2018

Vanderham Medical Center
1000 Parkway West
Anytown, CA 90002
ATTN: Blood Bank

Re: Notification of recipient traceback investigation

Immediate Attention and Action Required

Donation Identification Number (DIN): P2015181011600

Product: 04210
A5-1 Red Blood Cells

Expiration date: 07/05/2018
Date shipped: 5/31/2018

Dear Transfusion service director:

The purpose of this letter is to provide you with information concerning a traceback investigation the American Red Cross is conducting. In 2007, the American Red Cross introduced universal testing for Chagas (T. cruzi antibody) and in 2009 transitioned to a selective one-time testing strategy for Chagas. A donor is tested at least once using a licensed test for T. cruzi antibody. If the result is negative, subsequent donations are not routinely tested for Chagas. The donation referenced above was from a donor who met these criteria. However, in certain circumstances a donor may again be selected for testing. If that donation tests positive for Chagas, then a notification for recipient tracing is triggered.

As of 8/10/2018 the donor now has a

<table>
<thead>
<tr>
<th>Reactive screening test for</th>
<th>With a final test result of</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trypanosoma cruzi (T. cruzi) antibody</td>
<td>Final interpretation: Concordant Positive</td>
</tr>
</tbody>
</table>

The donor’s last negative donation was on 9/9/2009.

If the product is still in your inventory then... please discard it immediately. Please complete the information requested on the attached traceback recipient status form and indicate the final disposition on the form, even if the product was not transfused. Retain a copy for your files and return the form to the following fax number: 888-719-3535 or to the following email address:vFaxForDCSC@redcross.org within 60 days. We will maintain strict confidentiality of the recipient information.

If the product has been transfused then... please inform the patient's physician of this information. We believe it is prudent to inform people who may have been infected in order for them to consider treatment options and prevent possible spread of infection. If we receive additional test results we will notify you again.

For additional information, including the screening test methodologies conducted on American Red Cross donations, please visit our Web site at RedCrossBlood.org.

If you have any questions, please call 1-866-236-3276, select option 1, ask to speak to a Donor and Client Support Center counselor, and reference the above case ID.

Sincerely,
Tim Thompson
Tim Thompson
Case Investigator

Enclosures: Traceback Recipient Status Form
Product Disposition form: Sample

American Red Cross Biomedical Services
Washington, DC 20006

Form: Product Disposition

Case ID: P20180610112001k
Date: May 15, 2018

To: St. Joseph Medical Center
316 Bridgeport Road
Anytown, CT 15641

Return form to: Donor and Client Support Center
Fax vFaxforDCSC@redcross.org or
Email DCSCmailbox@redcross.org

Information in blue will have been completed by DCSC staff

Information in yellow is to be completed by customer

Consignee: For each product listed, complete the information for product disposition and date (see the codes provided in the KEY); when the product has been transfused, please provide patient status information.

<table>
<thead>
<tr>
<th>Donation Identification Number</th>
<th>Product Code/Description</th>
<th>ABO/Rh</th>
<th>Product Expiration Date</th>
<th>Distribution Date</th>
<th>Other Information</th>
<th>Product Disposition Code</th>
<th>Disposition Date</th>
<th>Patient status</th>
</tr>
</thead>
<tbody>
<tr>
<td>W200218825476</td>
<td>04210/AS-1 Red Blood Cells</td>
<td>B N</td>
<td>04/30/2018</td>
<td>4/19/2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Completed by consignee (Print or type)

Name of staff completing form: __________________________ Title: __________________________ Date: ____________

KEY

<table>
<thead>
<tr>
<th>When Product Disposition is</th>
<th>Use Code</th>
<th>KEY</th>
<th>When Product Disposition is</th>
<th>Use Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Transfusion Services Only</td>
<td></td>
<td></td>
<td>Put into production</td>
<td>P</td>
</tr>
<tr>
<td>Transfused</td>
<td>T</td>
<td></td>
<td>Destroyed</td>
<td>D</td>
</tr>
<tr>
<td>Expired</td>
<td>E</td>
<td></td>
<td>Records no longer available only</td>
<td>RNL</td>
</tr>
<tr>
<td>Destroyed</td>
<td>D</td>
<td></td>
<td>Other (provide information)</td>
<td>OTH</td>
</tr>
<tr>
<td>Records no longer available</td>
<td>RNL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (provide information)</td>
<td>OTH</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Recipient Status form: Sample

American Red Cross
Washington, DC  20006

<table>
<thead>
<tr>
<th>Recipient Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ American Red Cross</td>
</tr>
</tbody>
</table>

To: Vanderham Medical Center
1000 Parkway West, Anytown, CA  90002
A15123

Return completed form to: Donor and Client Support Center
Fax vFaxforDCSC@redcross.org or Email DCSCmailbox@redcross.org

Recipient Traceback Case Information
Case ID: C20180810114000J  Date: June 16, 2018
Donation No.: W200618825476  Product: 18201
Fresh Frozen Plasma

Information in blue will have been completed by DCSC staff

Complete Sections A, B, and C with as much information as is available. Retain a copy for your records before returning form.

Section A: Product and Recipient Information

<table>
<thead>
<tr>
<th>Product Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Not transfused: product discarded, expired in storage</td>
</tr>
<tr>
<td>☐ Record no longer available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of transfusion:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipient identifier (e.g. MR#):</td>
</tr>
</tbody>
</table>

Section B: Laboratory/Clinical Findings

Please provide any clinical information (symptoms, diagnosis, etc.) or testing performed on the recipient that is relevant to the case. For tests, include the test name, results, and date the sample was drawn.

Section C: Transfusion Service Contact Information

(include the name of the facility only if different than the one named at the top of the form)

<table>
<thead>
<tr>
<th>Form completed by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>Title</td>
</tr>
</tbody>
</table>

Name of Facility:

Name of responding physician:
Autologous Authorization and Notification: Sample

**Patient Information**

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Donation ID Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sally Smith</td>
<td>022KP12345</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth</th>
<th>Collection Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/15/1945</td>
<td>6/10/2018</td>
</tr>
</tbody>
</table>

**Contact Information**

<table>
<thead>
<tr>
<th>TO</th>
<th>Ordering Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion Service Director</td>
<td>J J Johnson, MD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TO</th>
<th>Transfusion Service Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kirk Korman</td>
<td>Emerson Center</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone</th>
<th>Fax</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>(704) 555-1212</td>
<td>(704) 555-2222</td>
<td></td>
</tr>
</tbody>
</table>

**FROM**

<table>
<thead>
<tr>
<th>American Red Cross Medical Director/Designee</th>
<th>Linda James</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Street Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>9013-J Perimeter Woods Dr.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zipcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charlotte</td>
<td>NC</td>
<td>28216</td>
</tr>
</tbody>
</table>

**DCSC Phone**

<table>
<thead>
<tr>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-866-236-3276</td>
</tr>
</tbody>
</table>

**DCSC Fax**

<table>
<thead>
<tr>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>888-719-3535</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:vFaxForDCSC@redcross.org">vFaxForDCSC@redcross.org</a></td>
</tr>
</tbody>
</table>

**Re:** Test results for an autologous unit

**Report Status**

Preliminary

**Donor Eligibility**

Based on the test results listed below, the donor is no longer eligible to donate blood for others.
## Test Results

<table>
<thead>
<tr>
<th>Preliminary Reactive Tests</th>
<th>Additional Tests</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg REACTIVE</td>
<td>Confirmatory Test</td>
<td>Pending</td>
</tr>
<tr>
<td>HBsAg REACTIVE</td>
<td>Anti-HBc</td>
<td>Nonreactive</td>
</tr>
<tr>
<td>HBsAg REACTIVE</td>
<td>NAT Multiplex</td>
<td>Nonreactive</td>
</tr>
</tbody>
</table>

**Optional comments:**

For more information about the screening test methodologies conducted on Red Cross donations, please visit our website at: [RedCrossBlood.org](http://RedCrossBlood.org).
**Patient Name**: Sally Smith  
**Donation ID Number**: 022KP12345

### Physician

**Physician Authorization/Signature Is Required**

By regulation, signed authorizations for release from both the physician and the hospital transfusion service are required before we ship components with human immunodeficiency virus (HIV) or hepatitis B surface antigen (HBsAg) reactive results and nucleic acid test (NAT) multiplex reactive with negative discriminatory results. Both authorizations are also required for the release of incompletely tested donations. If the transfusion service does not provide authorization, the components will not be available for transfusion even if you request release. Please check with the hospital transfusion service if you have any questions about the authorization.

Physician authorization is also required for the release of reactive West Nile virus (WNV), T. cruzi, dengue, or Zika virus donations.

The donation listed on this form was sent for routine donor testing and found to have one or more positive results or incomplete testing, as indicated. If the donor has additional test results, we will contact you. We will also notify the patient of the results when all testing is complete and instruct him or her to contact you for follow-up evaluation and future autologous donation.

In the section below, please sign and date the line next to the statement that represents your request to release the component. Fax or email the signed copy to the Red Cross facility listed on page 1. Thank you!

### Transfusion Service

**Transfusion Service Authorization is Required**

The donation listed on this form was sent for routine donor testing and was either found to have one or more positive test results or incomplete testing, as indicated. The referring physician has been informed about the status of the requested donation. The components will be available unless otherwise indicated.

In the section below, please sign and date the line next to the statement that represents your facility’s acceptance of the component. Fax or email the signed copy to the Red Cross facility listed on page 1.

### Table 1: Physician Authorization

<table>
<thead>
<tr>
<th>Physician Name</th>
<th>Error! Reference source not found. J J Johnson</th>
</tr>
</thead>
<tbody>
<tr>
<td>I request the release of the component</td>
<td><strong>Physician Signature</strong> J J Johnson, M.D.</td>
</tr>
<tr>
<td>Do NOT release the component</td>
<td><strong>Physician Signature</strong></td>
</tr>
</tbody>
</table>

### Representative Name

<table>
<thead>
<tr>
<th>Representative Name</th>
<th>Error! Reference source not found.</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our facility will accept the component</td>
<td><strong>Signature</strong></td>
<td>Date</td>
</tr>
<tr>
<td>Our facility <strong>WILL NOT</strong> accept the component</td>
<td><strong>Signature</strong></td>
<td>Date</td>
</tr>
</tbody>
</table>

### FOR RED CROSS USE ONLY: Quality Assurance Approval to Remove Hold

<table>
<thead>
<tr>
<th>Initials</th>
<th>Date</th>
</tr>
</thead>
</table>
Recipient Complications – Infectious Disease Report: Sample

American Red Cross Biomedical Services
Washington, DC 20006

Form: Recipient Complications - Infectious Disease Case Report

Information in yellow is to be completed by customer

Reporting health care facility: ________________________________

Address: __________________________________________________

Report date: ________________

FOR RED CROSS USE ONLY

Case ID number: ______________________________

Date report received: ________________

DCSC phone #: Toll Free: 866-236-3276
DCSC fax #: 888-719-3535
DCSC email: vFaxForDCSC@redcross.org

Section I: Clinical Information

Recipient/Patient Information:

Recipient ID (patient #): ________________________________

Age or DOB: ________________________________

Gender: [ ] Female [ ] Male

Primary diagnoses:

Attending physician: ________________________________

Phone: ________________________________ Email: ________________________________

Transfusion service medical director: ________________________________

Phone: ________________________________ Email: ________________________________

Contact for additional information: ________________________________

Phone: ________________________________ Email: ________________________________

Patient status (at time of report)

☐ Living, asymptomatic from infection

☐ Living, symptomatic from infection

☐ Deceased, unrelated to transfusion

☐ Deceased, related to possible transfusion transmitted infection*

Date and time of death: ________________________________

Will autopsy be performed? [ ] No [ ] Yes

*Transfusion service must report fatalities to the Food and Drug Administration (FDA); transfusion-related fatalities must be investigated urgently.

Infection that may have been transfusion-acquired

☐ Hepatitis A

☐ Hepatitis, non-A, B, or C

☐ Babesiosis

☐ Malaria

☐ Hepatitis B

☐ HIV

☐ Chagas disease

☐ West Nile Virus

☐ Hepatitis C

☐ HTLV

☐ Other (specify):

First indication of infection

☐ Clinical disease, mild/moderate

☐ Clinical disease, severe

☐ Positive infectious disease test result

State why recipient was tested for this disease:

☐ Other abnormal laboratory tests (specify):

☐ Other (specify):
### Section I: Clinical Information (continued)

List ALL test results pertinent to infection, including confirmatory testing if performed.

#### HEPATITIS CASES (result and date)

<table>
<thead>
<tr>
<th>Test</th>
<th>Pre-transfusion (results and date)</th>
<th>Post-transfusion (results and date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bili total (normal range: ______ to ______)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bili conjugated (normal range: ______ to ______)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST/SGOT (normal range: ______ to ______)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALT/SGPT (normal range: ______ to ______)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alk phos (normal range: ______ to ______)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBsAg neutralization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBeAg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBc total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBc IgM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccinated for hepatitis B (Y/N)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBV by PCR (or comparable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HAV total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HAV IgM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HCV by EIA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HCV by RIBA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV by PCR (or comparable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other hepatitis tests (specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### HIV CASES (result and date)

<table>
<thead>
<tr>
<th>Test</th>
<th>Pre-transfusion (results and date)</th>
<th>Post-transfusion (results and date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV by EIA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HIV by Western Blot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV by PCR (or comparable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other HIV tests (specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### OTHER INFECTIONS (result and date)

<table>
<thead>
<tr>
<th>Test</th>
<th>Test method used</th>
<th>Pre-transfusion (results and date)</th>
<th>Post-transfusion (results and date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babesia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WNV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (identify):</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please indicate why confirmatory tests, if applicable, were not performed:
Recipient Complications -
Infectious Disease Case Report

**Section I: Clinical Information (continued)**

<table>
<thead>
<tr>
<th>Risk factors; record any risk factors that were present prior to the first evidence of infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Drug use (injected drugs not prescribed by a physician)</td>
</tr>
<tr>
<td>☐ Sexual behavior (male-to-male contact, payment for sex, partners with risk factor)</td>
</tr>
<tr>
<td>☐ Sexual partner with past or current history of infection with HIV or hepatitis</td>
</tr>
<tr>
<td>☐ Rape/sexual assault victim (unknown HIV/hepatitis status)</td>
</tr>
<tr>
<td>☐ Lived with individual with hepatitis</td>
</tr>
<tr>
<td>☐ Received transplant (for example, organ, tissue, bone marrow) or tissue graft (for example, bone or skin)</td>
</tr>
<tr>
<td>☐ Accidental needle stick or contact with someone else’s blood</td>
</tr>
<tr>
<td>☐ Tattoo (in what state?): ______________________ (Regulated facility?): ______________________</td>
</tr>
<tr>
<td>☐ Piercing (with unsterile needles?): ______________________</td>
</tr>
<tr>
<td>☐ Juvenile detention/lockup/jail or prison &gt;72 hours or residence in halfway house/group home</td>
</tr>
<tr>
<td>☐ Dialysis</td>
</tr>
<tr>
<td>☐ Pooled factor concentrates for bleeding disorder</td>
</tr>
<tr>
<td>☐ Transfusions before 1990 (date of transfusion): ______________________</td>
</tr>
<tr>
<td>☐ Travel to pertinent risk area for reported infection (risk area): ______________________</td>
</tr>
<tr>
<td>☐ Resided in endemic country for reported infection (country): ______________________</td>
</tr>
<tr>
<td>☐ If disease is congenitally spread, mother resided in risk area during prenatal period</td>
</tr>
<tr>
<td>☐ Other known risk factors for reported infection: ______________________</td>
</tr>
</tbody>
</table>

**Did this patient receive products from other blood suppliers?**  ☐ No  ☐ Yes
(If yes, separate notification of suppliers may be required)

Please describe any other significant clinical details of the case not yet provided:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>

Rank the likelihood that this infection was transfusion-acquired based on the initial clinical impression (check one):

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Highly probable</td>
<td>☐ Likely</td>
<td>☐ Possible</td>
<td>☐ Cannot exclude</td>
<td>☐ Unlikely</td>
</tr>
</tbody>
</table>

**Transfusion Service Medical Director Name (print):**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Signature/Date:**
Recipient Complications -
Infectious Disease Case Report

<table>
<thead>
<tr>
<th>FOR RED CROSS USE ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case ID number:</td>
</tr>
</tbody>
</table>

Section II: Transfusion History

Total number of Red Cross products you are reporting: __________
(If the total number of products exceeds the lines available, use additional copies of this page to record).

Red Cross-Supplied Blood Products

<table>
<thead>
<tr>
<th>For Transfusion Service Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit number</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Recipient Complications – Transfusion Reaction Case Report

American Red Cross Biomedical Services
Washington, DC 20006

Information in yellow is to be completed by customer

Reporting health care facility: ________________________________

Address: ________________________________________________

Report date: ________________________________

FOR RED CROSS USE ONLY

Case ID number:
Date report received:
DCSC phone #: Toll Free: 866-236-3276
DCSC fax #: 888-719-3535
DCSC email: vFaxForDCSC@redcross.org

Section I: Clinical Information

Recipient/Patient Information:

Recipient ID (patient #): Age or DOB: Gender: □ Female □ Male

Primary diagnoses:

Attending physician: Phone: Email:

Transfusion service medical director: Phone: Email:

Contact for additional information: Phone: Email:

Date of reaction: Time: □ AM □ PM

Transfusion–related fatality*? □ No □ Yes ▶ Date and time of death:

If yes, will autopsy be performed? □ No □ Yes

*Transfusion service must report fatalities to the Food and Drug Administration (FDA); transfusion-related fatalities must be investigated urgently.
### Section I: Clinical Information (continued)

#### Reaction Vital Signs
Indicate which of the following developed during or within 6 hours following transfusion. Check all that apply. *(The signs/symptoms of a septic reaction may be delayed for as long as 24 hours post transfusion).*

<table>
<thead>
<tr>
<th></th>
<th>Pre-Transfusion</th>
<th>During Reaction</th>
<th>Post-Transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fever</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(≥39°C or ≥2°C rise)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood pressure, drop in systolic &gt;30 mmHg</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood pressure, rise in systolic &gt;30 mmHg</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypoxemia (PaO₂&lt;60, O₂ sat. &lt;90%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rapid breathing (&gt;28/min)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Tachycardia (&gt;120/min or &gt;40/min rise)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Additional signs/ symptoms

<table>
<thead>
<tr>
<th>Additional signs/symptoms</th>
<th>Describe in more detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td></td>
</tr>
<tr>
<td>Bronchospasm/wheezing</td>
<td></td>
</tr>
<tr>
<td>Cardiac arrhythmia</td>
<td></td>
</tr>
<tr>
<td>Chest pain</td>
<td></td>
</tr>
<tr>
<td>Hematuria</td>
<td></td>
</tr>
<tr>
<td>Hemoglobinuria</td>
<td></td>
</tr>
<tr>
<td>Jugular venous distension</td>
<td></td>
</tr>
<tr>
<td>Lumbar pain</td>
<td></td>
</tr>
<tr>
<td>Nausea or vomiting</td>
<td></td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td></td>
</tr>
<tr>
<td>Rigors</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

#### Medications/Treatments
Indicate which of the following were administered. Check all that apply.

- Acetaminophen
- Bronchodilators
- Epinephrine
- Oxygen supplementation
- Antihistamines
- Diuretics
- Intubation/ventilatory support
- Steroids
- Other (specify):
**Section II: Transfusion History**

Did the patient receive any non-Red Cross-provided products?  □ No □ Yes

Did the Red Cross perform the compatibility testing of record?  □ No □ Yes

---

**List all products transfused in the 24 hours prior to the transfusion reaction. (Attach additional sheets as needed)**

<table>
<thead>
<tr>
<th>Unit number</th>
<th>Product name</th>
<th>Transfusion</th>
<th>Unit modified*</th>
<th>Volume transfused</th>
<th>Residual product available</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Date</td>
<td>Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
<td>Yes</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

*Provide brief description of modification, for example: pooled, aliquoted, warmed, irradiated, washed, leukocyte-reduced by filtration

Please hold any residual product pending additional instructions by Red Cross staff.
Recipient Complications - Transfusion
Reaction Case Report

Section II: Transfusion History (continued)

Previous transfusion history in this patient (summarize, including types of products and nature of prior reactions):

<table>
<thead>
<tr>
<th>Was a post-transfusion chest X-ray performed?</th>
<th>☐ No</th>
<th>☐ Yes ► Result:</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, please attach copy of radiology report.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Summary of treatment, response, and patient status at the time of this report:

Routine transfusion reaction workup

<table>
<thead>
<tr>
<th>Description</th>
<th>Correct</th>
<th>Incorrect</th>
<th>Normal</th>
<th>Abnormal</th>
<th>Not returned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clerical check of transfusion (right unit, right recipient?):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearance of returned blood bag and contents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearance of returned solutions, tubing, and filters:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Describe any problems:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Confirmation of compatibility

<table>
<thead>
<tr>
<th>Test</th>
<th>Pre-transfusion</th>
<th>Post-transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO/RH type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibody screen</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crossmatch (if applicable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct antiglobulin test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Special transfusion reaction workup

<table>
<thead>
<tr>
<th>Description</th>
<th>☐ Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify other special studies of blood products performed. (For example, measurement of IgA, red cell antibody titers, red cell phenotyping, measurement of free hemoglobin, or supernatant potassium)</td>
<td></td>
</tr>
</tbody>
</table>
### Section II: Transfusion History (continued)

#### For potential septic reactions due to bacterial contamination of the blood product:

<table>
<thead>
<tr>
<th>Residual product/blood bag</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample source:</td>
</tr>
<tr>
<td>- Bag</td>
</tr>
<tr>
<td>- Segment</td>
</tr>
<tr>
<td>- Infusion set/tubing</td>
</tr>
<tr>
<td>Sample collection:</td>
</tr>
<tr>
<td>- Aseptic</td>
</tr>
<tr>
<td>- Clean</td>
</tr>
<tr>
<td>- Retrieved from trash</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gram stain:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Negative</td>
</tr>
<tr>
<td>- Not done</td>
</tr>
<tr>
<td>- Positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Culture:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Negative</td>
</tr>
<tr>
<td>- Not done</td>
</tr>
<tr>
<td>- Positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient blood cultures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-transfusion</td>
</tr>
<tr>
<td>- Not done</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>- Negative</td>
</tr>
<tr>
<td>- Positive for:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Not done</td>
</tr>
<tr>
<td>Date:</td>
</tr>
<tr>
<td>- Negative</td>
</tr>
<tr>
<td>- Positive for:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does patient have history of fever or other infections related to his/her underlying medical condition?</td>
</tr>
<tr>
<td>- Y</td>
</tr>
<tr>
<td>- N</td>
</tr>
</tbody>
</table>

| Did patient have absolute neutropenia (neutrophil < 500 /μL) prior to transfusion? |
| - Y                          |
| - N                          |

#### What other event could explain the findings in this patient other than the transfusion?

- [ ] Sepsis
- [ ] Drug reaction
- [ ] Volume overload
- [ ] Heart failure
- [ ] Hemorrhagic shock
- [ ] Allergic or anaphylactic reaction
- [ ] Other:

#### Transfusion Service: Medical Director's Summary

**Suspect Cause: (check appropriate box)**

- [ ] Septic reaction
- [ ] Hemolytic reaction
- [ ] Transfusion-related acute lung injury (TRALI)
- [ ] Electrolyte abnormality (K+, Ca++)
- [ ] Anaphylaxis
- [ ] Volume overload
- [ ] Other: __________

From your perspective, what is the likelihood that the transfusion caused this event?

- [ ] Certain
- [ ] Likely
- [ ] Possible
- [ ] Cannot exclude
- [ ] Unlikely

#### Transfusion Service Medical Director Name (print):

__________________________

__________________________

Signature/Date:
### Documentation of Correction or Rework: Sample

<table>
<thead>
<tr>
<th>Region Name:</th>
<th>Central Plains</th>
<th>Fax Number:</th>
<th>1-800-555-7777</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region Address:</td>
<td>Wichita, KS</td>
<td>Email Address:</td>
<td><a href="mailto:brctmcp@redcross.org">brctmcp@redcross.org</a></td>
</tr>
<tr>
<td>Case ID:</td>
<td>2018MIR-121212</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detailed description of the correction or rework needed:</td>
<td>Line thru the donor/patient last name on the tie tag for autologous unit W200218456987; add the correct last name, and initial and date the entry.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptable forms of documentation:</td>
<td>Print a copy of the corrected tie tag and either scan/email or fax copy for sending to region</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of the item that requires the correction or rework: (Examples: unit numbers, product codes, lot numbers)</td>
<td>Correct the spelling of the donor/patient’s last name to Johanson on the tie tag for red cell unit W200218456987.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Printed contact name:</td>
<td>Barb Bain</td>
<td>Contact Phone:</td>
<td>1-800-555-7878</td>
</tr>
</tbody>
</table>

**Description or results of the correction or rework performed:**
Include copies or photocopies of any corrections made (before and after images, as directed).

**Performed by:**
(signature)

**Date:**

**REVIEW**

*This section completed by American Red Cross staff only*

<table>
<thead>
<tr>
<th>Evaluation determined correction or rework is</th>
<th>□ successful</th>
<th>□ unsuccessful</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Operations Supervisor: (signature)</th>
<th>Date:</th>
</tr>
</thead>
</table>
**Return Authorization Form: Sample**

**Section 1A: Pre-Assessment - Completed by American Red Cross Staff**

<table>
<thead>
<tr>
<th>Customer</th>
<th>University Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Contact (Name)</td>
<td>Andrew Armstrong</td>
</tr>
</tbody>
</table>

Return for Reissue [ ] Return for Quality Issue [x] Comment: Requested by Red Cross as part of investigation into equipment issue

**Section 1B: Products Authorized for Return**

<table>
<thead>
<tr>
<th>Donation Identification Number (DIN)</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>W2021814264168007</td>
<td>Red cells</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acceptable for Reissue?</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Section 2: Customer Product Quality Certification - Completed by Customer**

- [ ] Products acceptable for Reissue
  - I certify that the products listed above being returned have not been out of control of the customer and have been stored continuously at the appropriate temperature in accordance with the Code of Federal Regulations and have been examined and found satisfactory for reissue.

- [ ] Products for investigation or non-conformance
  - I certify that the products listed above being returned have not been out of control of the customer and have been stored continuously at the appropriate temperature in accordance with the Code of Federal Regulations. The products have been examined and may not be satisfactory for reissue pending further investigation.

**Section 3: Receiving Returned Product - Completed by American Red Cross Staff**

<table>
<thead>
<tr>
<th>Ending Transit Time</th>
<th>Date</th>
<th>Time</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products Placed into Controlled Environment</td>
<td>Date</td>
<td>Time</td>
<td>Initials</td>
</tr>
</tbody>
</table>

Comments:____________________________________________________________

____________________________________________________________

____________________________________________________________