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**Blood BPD Codes:**

Use the following list of Biological Product Deviation (BPD) Codes to assign a specific code to a reportable event when you submit the report to FDA. Use the guidance document, "Biological Product Deviation Reporting for Blood and Plasma Establishments," to determine if you must report an event. The list includes deviations from regulations, standards, and established specifications that may affect the safety, purity, or potency of a product. The use of BPD Codes will assist the FDA in analyzing the data submitted and streamline the trend analysis.

Use one of the following BPD Codes to report an event that was recognized by a staff member who determined, *prior to distribution*, that the event has the potential to affect the safety, purity, or potency of the distributed product and that the product was either not quarantined or inappropriately released from quarantine.

QC-94-** Distribution of product that did not meet specifications

QC-94-12 Product identified as unsuitable due to a collection deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

QC-94-13 Product identified as unsuitable due to a component preparation deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

QC-94-14 Product identified as unsuitable due to a labeling deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

QC-94-15 Product identified as unsuitable due to a donor screening deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

QC-94-16 Product identified as unsuitable due to a donor deferral deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

QC-94-17 Product identified as unsuitable due to a shipping or storage deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

QC-94-18 Product identified as unsuitable due to a transfusion-transmitted infection testing deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

If you are a transfusion service only, the deviation codes you should select from are Component Preparation (CP), Routine Testing (RT), Labeling (LA), Quality Control and Distribution (QC).

## 1. Revisions to Blood BPD Reporting Codes for FY2019

For FY2019, we implemented specific revisions to the deviation codes to improve our analysis of the submitted data. We evaluated the deviation codes to ensure they represent events related to FDA requirements. We modified codes to clarify specific events that are reportable. We deleted codes for events in which reporting is no longer required. In addition, we merged codes to consolidate similar events and decrease the number of deviation codes.

## 2. Summary of FY2019 Revisions

An overview of the changes that were made to the BPD codes for FY2019 is provided in the tables below. Refer to each section below for the complete list of BPD codes.

**Table 1: BPD Codes that were deleted because there is no FDA regulation associated with the event or a more specific code is used to capture the event.**

| FY2018 Code | Comments |
|---|---|
| **PD-12-67** Travel to Zika risk area<br>**DS-28-67** Travel to Zika risk area<br>**DS-29-67** Travel to Zika risk area<br>**DD-32-67** Travel to Zika risk area<br>**QC-91-68** Travel to Zika risk area | All units are either tested for ZIKV or pathogen reduced and screening donors for ZIKV risk factors is no longer recommended. |
| **DS-22-07** Donor confidentiality compromised<br>**BC-43-02** Collection time extended, discrepant, or not documented; not discovered prior to component preparation<br>**BC-43-04** Collection status not documented or discrepant<br>**CP-52-03** Resting time requirements not met for Platelets<br>**CP-53-05** A difficult collection or had an extended collection time<br>**CP-53-06** Collected from a donor with potential TRALI risk<br>**LA-82-11** HLA type incorrect or missing<br>**LA-82-16** Crossmatch tags or transfusion records switched, both units intended for the same patient<br>**QC-96-02** Arrived at consignee at unacceptable temperature<br>**QC-96-06** Shipment exceeded time allowed for shipping<br>**QC-97-14** ABO and/or Rh retype of unit not performed or performed incorrectly | Deleted because there is no FDA regulation associated with the event. |
| **LA-82-18** Biohazard or test status incorrect or missing | Deleted because there is no FDA regulation associated with labeling of crossmatch tag or record for this event. Reporting is specific to unit labeling using the BPD code LA-81-17. |
| **QC-94-03** Autologous unit not meeting homologous criteria | A report may be required, but the event would be reported using the BPD code for the reason the donor didn't meet homologous criteria. |

**Table 2: New BPD Codes that were added to capture specific reportable events.**

| FY2019 Code | Comments |
|---|---|
| Labeling; Anticoagulant volume on Whole Blood incorrect or missing<br>**LA-81-18**<br>**LA-82-21** | Added code to capture labeling requirement for Whole Blood. |
| **DS-27-10** West Nile Virus<br>**DD-31-10** West Nile Virus<br>**QC-92-18** West Nile Virus | Added specific code because West Nile Virus is an RTTI. |
| **DS-27-11** T. Cruzi (Chagas)<br>**DD-31-11** T. Cruzi (Chagas)<br>**QC-92-19** T. Cruzi (Chagas) | Added specific code because T. Cruzi is an RTTI. |
| **DS-27-12** Babesia<br>**DD-31-12** Babesia<br>**VT-71-21** Babesia<br>**QC-92-20** Babesia | Added specific code because Babesia is an RTTI. |
| **QC-97-22** Product not HLA matched as required *{includes testing positive, not performed, performed incorrectly, product labeled incorrectly}* | Added to clarify reporting is only required if a patient requires an HLA matched unit and the specification is not met. |

**Table 3: Changes that were made to consolidate codes (codes that were deleted and merged with an existing code, or codes that were deleted and new codes created).**

| FY2018 Code | Comments |
|---|---|
| **PD-11-**** Testing | PD-11-** codes were merged with PD-12-** codes – added **or tested reactive prior to donation** to:<br>• PD-12-02 History of hepatitis not specified**,**<br>• PD-12-04 History of Hepatitis B<br>• PD-12-05 History of Hepatitis C<br>• PD-12-06 History of syphilis<br>• PD-12-55 Donor deferred by another center |
| **DD-34-**** Donor incorrectly deleted from deferral list or donor not reentered properly, prior deferral due to testing for | DD-34-** codes were merged with DD-31-** codes, *Donor missing, **incorrectly deleted**, or incorrectly identified on deferral list, donor was or should have been previously deferred due to testing for* |
| **DD-35-**** Donor incorrectly deleted from deferral list, prior deferral due to history | DD-35-** codes were merged with DD-32-** codes, *Donor missing**, incorrectly deleted**, or incorrectly identified on deferral list, donor was or should have been previously deferred due to history* |
| **RT-63-**** Testing performed using reagents in which QC was unacceptable, not performed, not documented, or expired reagents were used | RT-63-** codes were merged with RT-61-** codes, *Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented for {includes **QC not performed or unacceptable; expired reagents used**}* |
| **QC-93-**** Testing not performed, incompletely performed or not documented for<br>QC-93-10 Antibody screen or identification<br>QC-93-11 Antigen screen<br>QC-93-14 Compatibility<br>QC-93-16 ABO and/or Rh<br>QC-93-17 ABO/Rh and antibody screen | The QC-93-** codes related to routine testing were merged with RT-61-** codes, *Testing performed, interpreted, or documented incorrectly; **not performed; or incompletely performed or not documented** for* |
| **QC-93-**** Testing not performed, incompletely performed or not documented for<br>QC-93-02 HIV<br>QC-93-03 HBV (HBsAg, HBV NAT)<br>QC-93-04 Anti-HBc<br>QC-93-05 HCV (anti-HCV, HCV NAT)<br>QC-93-06 Anti-HTLV<br>QC-93-12 Syphilis<br>QC-93-13 All viral markers<br>QC-93-15 Multiplex Nucleic Acid Test (NAT)<br>QC-93-18 Bacterial testing<br>QC-93-19 ZIKV | The QC-93-** codes related to transfusion - transmitted infection testing were merged with VT-71-** codes, *Testing performed, interpreted, or documented incorrectly; **not performed; or incompletely performed or not documented** for* |
| **QC-97-15** Visual inspection not performed, not documented, or inadequate | QC-97-15 was merged with QC-97-19 to focus on the visual inspection, **Visual inspection not performed, not documented or inadequate**, includes product not documented or incorrectly documented as issued in the computer |
| **MI-01-**** Donor implicated in transfusion transmitted disease | New code added: **QC-98-**** Distribution of unit collected from a donor implicated in relevant transfusion-transmitted disease |

| FY2018 Code | Comments |
|---|---|
| **MI-02-**** Lookback; subsequent unit tested confirmed positive for | New code added: **QC-99-**** Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease |

**Table 4: BPD Codes for which the description was modified to clarify reportable events or to maintain consistency with similar BPD Codes.**

| FY2018 Code | FY2019 Code | Comments |
|---|---|---|
| Labeling; Product or anticoagulant volume or weight incorrect or missing<br>**LA-81-11**<br>**LA-82-12** | Labeling; Product volume or weight incorrect or missing<br>**LA-81-11**<br>**LA-82-12** | Deleted '*anticoagulant*' because only Whole Blood requires labeling for the anticoagulant volume. |
| **LA-81-09** Donor/unit number or lot number incorrect or missing<br>**LA-82-06** Unit, lot or pool number incorrect or missing | **LA-81-09** Donor/unit number incorrect or missing *(lot number deleted)*<br>**LA-82-06** Unit or pool number incorrect or missing *(lot number deleted)* | A report is not required for a non-blood product distributed by a blood establishment. |
| **DS-29**-** and **QC-91**-**<br>**-**-02 History of hepatitis not specified<br>**-**-04 History of Hepatitis B<br>**-**-05 History of Hepatitis C<br>**-**-06 History of syphilis | DS-29-** and QC-91-** - added **or tested reactive prior to donation** to:<br>**-**-02 History of hepatitis not specified,<br>**-**-04 History of Hepatitis B<br>**-**-05 History of Hepatitis C<br>**-**-06 History of syphilis | The change was made to maintain consistency of code descriptions. |
| **-****43** Risk factors associated with Creutzfeldt-Jakob Disease - received insulin or other bovine derived product | **-**43 Risk factors associated with Creutzfeldt-Jakob Disease - **received bovine insulin** | Modified to limit reporting to specific risk. |
| **-**-**55** Deferred by another center - reason unknown | **-**-55 Donor deferred by another center **due to history or testing reactive, specific history or testing unknown** | The change was made to maintain consistency of code descriptions. |
| **QC-96-07** Product not packed in accordance with specifications or no documentation that product was packed appropriately | **QC-96-07** Product **shipped at incorrect temperature** | Modified to limit reporting to unacceptable temperature during shipment. |

**Table 5: BPD codes for which the information within the parenthesis was modified to clarify reportable events.**

| FY2018 Code | FY2019 Code | Comments |
|---|---|---|
| **PD-12-01** Behavior/History; Other | Deleted: ***rape; donor did not meet specifications for TRALI risk mitigation*** | No FDA regulation associated with the event. |
| **DS-22-03** Donor history questions | Deleted: ***abbreviated questionnaire used instead of full-length questionnaire*** | No FDA regulation associated with the event. |

| FY2018 Code | FY2019 Code | Comments |
|---|---|---|
| **RT-61-01** Testing performed, interpreted, or documented incorrectly for; Other | Deleted: ***DAT; Hemoglobin S testing; HLA antibodies*** | No FDA regulation associated with the event. |
| Labeling; Product type or code incorrect or missing<br>**LA-81-04**<br>**LA-82-04** | Added: ***reporting is not required if part or container identification was incorrect or missing*** | Eliminated reporting of the incorrect or missing part or container identification. |
| **LA-82-01** Crossmatch tag, tie tag or transfusion record incorrect or missing information; Other | Deleted*:* ***Hemoglobin S*** | No FDA regulation associated with the event. |
| **QC-92-01** Positive testing for; Other | Deleted*:* ***Hemoglobin S; DAT; HLA antibody*** | No FDA regulation associated with hemoglobin S, DAT, HLA antibody testing.<br>*Added* specific codes for West Nile Virus, Babesia, Chagas. |
| **QC-94-01** Distribution of product that did not meet specifications; Other | Deleted: ***inappropriate release of Rh Immune Globulin*** | A report is not required for a non-blood product distributed by a blood establishment. |
| **QC-94-12** Product identified as unsuitable due to a collection deviation or unexpected event | Deleted*:* ***collection time extended, discrepant, or not documented*** | No FDA regulation associated with the event. |
| **QC-94-15** Product identified as unsuitable due to a donor screening deviation or unexpected event | Deleted: ***abbreviated donor history questionnaire used instead of full-length*** | No FDA regulation associated with the event. |
| **QC-97-21** Product not hemoglobin S negative as required | Added: *{****includes testing positive, not performed, performed incorrectly, product labeled incorrectly****}* | Modified to limit reporting specification not met for a patient who requires a Hemoglobin S negative unit. |
| Risk factor associated with Chagas<br>**PD-12-58**<br>**DS-28-58**<br>**DS-29-58**<br>**DD-32-58**<br>**QC-91-59** | Added: ***{includes tested reactive prior to donation}*** | Modified to include testing reactive as a risk factor for Chagas. |

### 3. Blood BPD Reporting Codes

Please use the appropriate code(s) from the listing below to report a deviation or unexpected event that occurred in a blood or plasma establishment.

Changes made on October 1, 2018 (the beginning of FY2019) are identified with a dagger (†).

The changes to the deviation codes for FY2019 are listed below.

**The following list is a summary of abbreviations used to identify each category of Blood BPD codes:**

Donor Eligibility
PD - Post Donation Information
DS - Donor Screening

DD - Donor Deferral

BC - Blood Collection
CP - Component Preparation

Laboratory Testing
VT - Transfusion-Transmitted Infection Testing
RT - Routine Testing

LA - Labeling
QC - Quality Control and Distribution

**PD/DS/DD DONOR ELIGIBILITY**
**PD-**-** POST DONATION INFORMATION**
PD-10-** Miscellaneous
PD-10-01 Other

PD-12-** Behavior/History
†PD-12-01 Other *{includes type of behavior or history unknown or not specified; unacceptable address; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions}*
†PD-12-02 History of hepatitis not specified, or tested reactive prior to donation
PD-12-03 History of jaundice
†PD-12-04 History of Hepatitis B, or tested reactive prior to donation
†PD-12-05 History of Hepatitis C, or tested reactive prior to donation
†PD-12-06 History of syphilis, or tested reactive prior to donation
PD-12-07 Intimate contact with risk for a relevant transfusion-transmitted infection -syphilis
PD-12-13 Non-specific intimate contact with risk for a relevant transfusion-transmitted infection *{includes contact with an individual who was deferred by another center, on a national deferral list, or tested reactive for an unknown viral marker}*
PD-12-14 Male donor had sex with another man
PD-12-15 Female had sex with a man who had sex with another man
PD-12-16 IV drug use not prescribed by a doctor *{includes taking illegal drugs by needle, e.g., IM}*
PD-12-17 Sex partner used IV drugs not prescribed by a doctor
PD-12-22 Exchanged sex for drugs or money
PD-12-23 Sex partner exchanged sex for drugs or money
PD-12-28 Donor received transfusion
PD-12-29 Donor received xenotransplantation product (specify product)
PD-12-36 Travel to or residence in a malaria endemic area/history of malaria
PD-12-37 History of disease *{donor was aware of condition or disease **prior** to donation; does not include diseases that do not affect the safety, purity, or potency of the product e.g., heart disease, hemochromatosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*
PD-12-40 Risk factors associated with Creutzfeldt-Jakob Disease - received dura mater transplant
PD-12-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history
PD-12-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel
†PD-12-43 Risk factors associated with Creutzfeldt-Jakob Disease - received bovine insulin
PD-12-44 Received growth hormone (derived from human pituitary glands)
PD-12-45 Received finasteride, etretinate, isotretinoin, dutasteride (specify medication) *{e.g., Proscar, Propecia, Tegison, Accutane, Avodart, Jalyn, or Absorica}*
PD-12-46 Received antibiotics or medication which may adversely affect the product (specify medication) *{e.g., platelet inhibitor drugs; drugs with teratogenic effect}*
PD-12-47 Received vaccine or immune globulin
PD-12-48 Exposure to a disease
PD-12-49 Incarcerated
PD-12-53 Multiple high risk behaviors/contacts

†PD-12-55 Donor deferred by another center due to history or tested reactive, specific history or testing unknown *{reason for deferral unknown or not provided by the other center – use more specific PD code if reason known}*
†PD-12-58 Risk factor associated with Chagas *{includes tested reactive prior to donation}*
PD-12-59 Donor received tattoo and/or piercing *{includes tattoo, any type of piercing or a combination of tattoo and/or piercing and any other type of potential blood exposure}*
PD-12-60 Donor was exposed to blood or body fluids other than tattoo or piercing *{includes accidental needlestick, animal bite; human bite; occupational exposure; scarification; branding; exposure not specified; multiple exposures, not including tattoo or piercing}*
PD-12-61 Intimate contact with risk for a relevant transfusion-transmitted infection - HIV
PD-12-62 Intimate contact with risk for a relevant transfusion-transmitted infection - HTLV
PD-12-63 Intimate contact with risk for a relevant transfusion-transmitted infection - HBV
PD-12-64 Intimate contact with risk for a relevant transfusion-transmitted infection – HCV
PD-12-65 Intimate contact with risk for a relevant transfusion-transmitted infection - hepatitis, not specified
PD-12-66 Intimate contact with risk for a relevant transfusion-transmitted infection – Other

PD-13-** Illness
†PD-13-01 Post donation illness (not hepatitis, HIV, HTLV, STD, cancer or cold/flu related) *{information **not known** by donor prior to donation, but diagnosed **after** donation; includes Babesia; West Nile Virus, Chagas}*
PD-13-02 Post donation diagnosis or symptoms of Hepatitis B, or reactive test for Hepatitis B
PD-13-03 Post donation diagnosis or symptoms of Hepatitis C, or reactive test for Hepatitis C
PD-13-04 Post donation diagnosis or symptoms of HIV, or reactive test for HIV
PD-13-05 Post donation diagnosis or symptoms of HTLV, or reactive test for HTLV
PD-13-06 Post donation diagnosis or symptoms of syphilis, or reactive test for syphilis
PD-13-07 Post donation diagnosis or symptoms of non-specific hepatitis, or reactive test for non-specific hepatitis
PD-13-10 Post donation diagnosis or possible diagnosis of Creutzfeldt-Jakob Disease *{includes variant CJD; please provide the donor's age at time of death, if known}*

PD-14-** Not specifically related to high risk behavior, unsuitable history, or post donation illness
PD-14-01 Other *{use PD-12** for unsuitable behavior or history; use PD13** for post donation illness}*
PD-14-02 Donor does not want their blood used
PD-14-03 Donated to be tested or called back for test results

**DS-**-** DONOR SCREENING**
DS-20-** Miscellaneous
DS-20-01 Other

†DS-21-** Donor did not meet eligibility criteria
†DS-21-01 Other
DS-21-02 Hemoglobin or Hematocrit unacceptable, not documented, or testing performed incorrectly *{includes use of expired reagents for hemoglobin or hematocrit}*
DS-21-03 Temperature unacceptable or not documented
†DS-21-04 Medical review or physical examination not performed or inadequate
DS-21-05 Platelet count, no documented platelet count for product

DS-22-** Donor record incomplete or incorrect
DS-22-01 Other *{includes missing donor records}*
DS-22-02 Donor identification *{includes donor using false identification, e.g., twins}*
†DS-22-03 Donor history questions *{includes response to educational material/AIDS questions not documented; incorrect gender specific question asked; donor comprehension questionable}*
DS-22-04 Arm inspection

DS-26-** Deferral screening not done or incorrectly performed, including incorrect ID used during search

DS-26-01 Donor not previously deferred *{use DS2601 when the deferral file is not searched or searched using incorrect donor identification information, or the deferral file was incorrectly searched and the donor was not previously deferred}*

DS-27-** Deferral screening not done or incorrectly performed, including incorrect ID used during search, prior deferral due to testing for: *{use DS27** when the deferral file is not searched or searched using incorrect donor identification information, or the deferral file was incorrectly searched and the donor was previously deferred due to testing}*

DS-27-01 Other
DS-27-02 HIV
DS-27-03 HBV
DS-27-04 Anti-HBc
DS-27-05 HCV
DS-27-06 Anti-HTLV
DS-27-08 Syphilis
DS-27-09 ZIKV
†DS-27-10 West Nile Virus
†DS-27-11 T. Cruzi (Chagas)
†DS-27-12 Babesia

DS-28-** Deferral screening not done or incorrectly performed, including incorrect ID used during search, prior deferral due to history *{use DS28** when the deferral file is not searched or searched using incorrect donor identification information, or the deferral file was incorrectly searched and the donor was previously deferred due to history}*

†DS-28-01 Other *{includes type of behavior or history unknown or not specified; unacceptable address; donor unreliable, for example mental status questionable}*
DS-28-02 History of hepatitis, not specified
DS-28-03 History of jaundice
DS-28-04 History of Hepatitis B
DS-28-05 History of Hepatitis C
DS-28-06 History of syphilis
DS-28-07 Intimate contact with risk for a relevant transfusion-transmitted infection - syphilis
DS-28-13 Non-specific intimate contact with risk for a relevant transfusion-transmitted infection *{includes contact with an individual who was deferred by another center, on a national deferral list, or tested reactive for an unknown viral marker}*
DS-28-14 Male donor had sex with another man
DS-28-15 Female had sex with a man who had sex with another man
DS-28-16 IV drug use not prescribed by a doctor *{includes taking illegal drugs by needle, e.g., IM}*
DS-28-17 Sex partner used IV drugs not prescribed by a doctor
DS-28-22 Exchanged sex for drugs or money
DS-28-23 Sex partner exchanged sex for drugs or money
DS-28-28 Donor received transfusion
DS-28-29 Donor received xenotransplantation product (specify product)
DS-28-36 Travel to or residence in a malaria endemic area/history of malaria
DS-28-37 History of disease *{donor was aware of condition or disease **prior** to donation; does not include diseases that do not affect the safety, purity, or potency of the product e.g., heart disease, hemochromatosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*
DS-28-40 Risk factors associated with Creutzfeldt-Jakob Disease - received dura mater transplant
DS-28-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history
DS-28-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel
†DS-28-43 Risk factors associated with Creutzfeldt-Jakob Disease - received bovine insulin
DS-28-44 Received growth hormone (derived from human pituitary glands)
DS-28-45 Received finasteride, etretinate, isotretinoin, dutasteride (specify medication) *{e.g., Proscar, Propecia, Tegison, Accutane, Avodart, Jalyn, or Absorica}*

DS-28-46 Received antibiotics or medication which may adversely affect the product (specify medication) *{e.g., platelet inhibitor drugs; drugs with teratogenic effect}*
DS-28-47 Received vaccine or immune globulin
DS-28-48 Exposure to a disease
DS-28-49 Incarcerated
DS-28-53 Multiple high risk behaviors/contacts
†DS-28-55 Donor deferred by another center due to history or tested reactive, specific history or testing unknown *{reason for deferral unknown or not provided by the other center – use more specific DS code if reason known}*
†DS-28-58 Risk factor associated with Chagas *{includes tested reactive prior to donation}*
DS-28-59 Donor received tattoo and/or piercing *{includes tattoo, any type of piercing or a combination of tattoo and/or piercing and any other type of potential blood exposure}*
DS-28-60 Donor was exposed to blood or body fluids other than tattoo or piercing *{includes: accidental needlestick, animal bite; human bite; occupational exposure; scarification; branding; exposure not specified; multiple exposures, not including tattoo or piercing}*
DS-28-61 Intimate contact with risk for a relevant transfusion-transmitted infection - HIV
DS-28-62 Intimate contact with risk for a relevant transfusion-transmitted infection - HTLV
DS-28-63 Intimate contact with risk for a relevant transfusion-transmitted infection - HBV
DS-28-64 Intimate contact with risk for a relevant transfusion-transmitted infection - HCV
DS-28-65 Intimate contact with risk for a relevant transfusion-transmitted infection - hepatitis, not specified
DS-28-66 Intimate contact with risk for a relevant transfusion-transmitted infection – Other

DS-29-** Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked *{use DS29** when a donor gives disqualifying information during the screening process and was not appropriately deferred or provides some information that requires further questioning to determine donor eligibility and follow up questioning was not done}*
†DS-29-01 Other *{includes type of behavior or history unknown or not specified; donor unreliable, for example mental status questionable; unacceptable address}*
†DS-29-02 History of hepatitis, not specified, or tested reactive prior to donation
DS-29-03 History of jaundice
†DS-29-04 History of Hepatitis B, or tested reactive prior to donation
†DS-29-05 History of Hepatitis C, or tested reactive prior to donation
†DS-29-06 History of syphilis, or tested reactive prior to donation
DS-29-07 Intimate contact with risk for a relevant transfusion-transmitted infection -syphilis
DS-29-13 Non-specific intimate contact with risk for a relevant transfusion-transmitted infection *{includes contact with an individual who was deferred by another center, on a national deferral list, or tested reactive for an unknown viral marker}*
DS-29-14 Male donor had sex with another man
DS-29-15 Female had sex with a man who had sex with another man
DS-29-16 IV drug use not prescribed by a doctor *{includes taking illegal drugs by needle, e.g., IM}*
DS-29-17 Sex partner used IV drugs not prescribed by a doctor
DS-29-22 Exchanged sex for drugs or money
DS-29-23 Sex partner exchanged sex for drugs or money
DS-29-28 Donor received transfusion
DS-29-29 Donor received xenotransplantation product (specify product)
DS-29-36 Travel to or resided in a malaria endemic area/history of malaria
DS-29-37 History of disease *{donor was aware of condition or disease **prior** to donation; does not include diseases that do not affect the safety, purity, or potency of the product e.g., heart disease, hemochromatosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*
DS-29-40 Risk factors associated with Creutzfeldt-Jakob Disease - received dura mater transplant
DS-29-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history
DS-29-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel
†DS-29-43 Risk factors associated with Creutzfeldt-Jakob Disease - received bovine insulin
DS-29-44 Received growth hormone (derived from human pituitary glands)

DS-29-45 Received finasteride, etretinate, isotretinoin, dutasteride (specify medication) *{e.g., Proscar, Propecia, Tegison, Accutane, Avodart, Jalyn, or Absorica}*
DS-29-46 Received antibiotics or medication which may adversely affect the product (specify medication) *{e.g., platelet inhibitor drugs; drugs with teratogenic effect}*
DS-29-47 Received vaccine or immune globulin
DS-29-48 Exposure to a disease
DS-29-49 Incarcerated
DS-29-53 Multiple high risk behaviors/contacts
†DS-29-55 Donor deferred by another center due to history or tested reactive, specific history or testing unknown *{reason for deferral unknown or not provided by the other center – use more specific DS code if reason known}*
†DS-29-58 Risk factor associated with Chagas *{includes tested reactive prior to donation}*
DS-29-59 Donor received tattoo and/or piercing *{includes tattoo, any type of piercing or a combination of tattoo and/or piercing and any other type of potential blood exposure}*
DS-29-60 Donor was exposed to blood or body fluids other than tattoo or piercing *{includes accidental needlestick, animal bite; human bite; occupational exposure; scarification; branding; exposure not specified; multiple exposures, not including tattoo or piercing}*
DS-29-61 Intimate contact with risk for a relevant transfusion-transmitted infection - HIV
DS-29-62 Intimate contact with risk for a relevant transfusion-transmitted infection – HTLV
DS-29-63 Intimate contact with risk for a relevant transfusion-transmitted infection - HBV
DS-29-64 Intimate contact with risk for a relevant transfusion-transmitted infection - HCV
DS-29-65 Intimate contact with risk for a relevant transfusion-transmitted infection - hepatitis, not specified
DS-29-66 Intimate contact with risk for a relevant transfusion-transmitted infection – Other

**DD-**-** DONOR DEFERRAL**
DD-30-** Miscellaneous
DD-30-01 Other

†DD-31-** Donor missing, incorrectly deleted, or incorrectly identified on deferral list, donor was or should have been previously deferred due to testing for *{use DD31** if the donor should have been deferred due to testing at a previous donation and was either not on the deferral list or incorrectly identified on the deferral list, e.g. listed as temporary deferral instead of permanent deferral; also, includes if the donor was not reentered appropriately}*
DD-31-01 Other
DD-31-02 HIV
DD-31-03 HBV
DD-31-04 Anti-HBc
DD-31-05 HCV
DD-31-06 Anti-HTLV
DD-31-08 Syphilis
DD-31-09 ZIKV
†DD-31-10 West Nile Virus
†DD-31-11 T. Cruzi (Chagas)
†DD-31-12 Babesia

†DD-32-** Donor missing, incorrectly deleted, or incorrectly identified on deferral list, donor was or should have been previously deferred due to history *{use DD32** if the donor should have been deferred due to history at a previous donation and was either not on the deferral list or incorrectly identified on the deferral list, e.g. listed as temporary deferral instead of permanent deferral; also, includes if the donor was not reentered appropriately}*
DD-32-01 Other *{includes type of behavior or history unknown or not specified; unacceptable address; donor unreliable, for example mental status questionable}*
DD-32-02 History of hepatitis, not specified
DD-32-03 History of jaundice
DD-32-04 History of Hepatitis B

DD-32-05 History of Hepatitis C
DD-32-06 History of syphilis
DD-32-07 - Intimate contact with risk for a relevant transfusion-transmitted infection - syphilis
DD-32-13 Non-specific intimate contact with risk for a relevant transfusion-transmitted infection *{includes contact with an individual who was deferred by another center, on a national deferral list, or tested reactive for an unknown viral marker}*
DD-32-14 Male donor had sex with another man
DD-32-15 Female had sex with a man who had sex with another man
DD-32-16 IV drug use not prescribed by a doctor *{includes taking illegal drugs by needle, e.g., IM}*
DD-32-17 Sex partner used IV drugs not prescribed by a doctor
DD-32-22 Exchanged sex for drugs or money
DD-32-23 Sex partner exchanged sex for drugs or money
DD-32-28 Donor received transfusion
DD-32-29 Donor received xenotransplantation product (specify product)
DD-32-36 Travel to or residence in a malaria endemic area/history of malaria
DD-32-37 History of disease *{donor was aware of condition or disease **prior** to donation; does not include diseases that do not affect the safety, purity, or potency of the product e.g., heart disease, hemochromatosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*
DD-32-40 Risk factors associated with Creutzfeldt-Jakob Disease - received dura mater transplant
DD-32-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history
DD-32-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel
†DD-32-43 Risk factors associated with Creutzfeldt-Jakob Disease - received bovine insulin
DD-32-44 Received growth hormone (derived from human pituitary glands)
DD-32-45 Received finasteride, etretinate, isotretinoin, dutasteride (specify medication) *{e.g., Proscar, Propecia, Tegison, Accutane, Avodart, Jalyn, or Absorica}*
DD-32-46 Received antibiotics or medication which may adversely affect the product (specify medication) *{e.g., platelet inhibitor drugs; drugs with teratogenic effect}*
DD-32-47 Received vaccine or immune globulin
DD-32-48 Exposure to a disease
DD-32-49 Incarcerated
DD-32-53 Multiple high risk behaviors/contacts
†DD-32-55 Donor deferred by another center due to history or tested reactive, specific history or testing unknown *{reason for deferral unknown or not provided by the other center – use more specific DD code if reason known}*
†DD-32-58 Risk factor associated with Chagas *{includes tested reactive prior to donation}*
DD-32-59 Donor received tattoo and/or piercing *{includes tattoo, any type of piercing or a combination of tattoo and/or piercing and any other type of potential blood exposure}*
DD-32-60 Donor was exposed to blood or body fluids other than tattoo or piercing *{includes accidental needlestick, animal bite; human bite; occupational exposure; scarification; branding; exposure not specified; multiple exposures, not including tattoo or piercing}*
DD-32-61 Intimate contact with risk for a relevant transfusion-transmitted infection - HIV
DD-32-62 Intimate contact with risk for a relevant transfusion-transmitted infection - HTLV
DD-32-63 Intimate contact with risk for a relevant transfusion-transmitted infection - HBV
DD-32-64 Intimate contact with risk for a relevant transfusion-transmitted infection - HCV
DD-32-65 Intimate contact with risk for a relevant transfusion-transmitted infection - hepatitis, not specified
DD-32-66 Intimate contact with risk for a relevant transfusion-transmitted infection – Other

**BC-**-** BLOOD COLLECTION**

BC-40-** Miscellaneous
BC-40-01 Other

BC-41-** Sterility compromised
BC-41-01 Other

BC-41-02 Bacterial contamination (identify organism if possible) *{use BC4102 if contamination is discovered as a result of a patient transfusion reaction; if contamination was found during Bacterial Detection Testing, use QC9216}*
BC-41-03 Air contamination *{includes system open during collection process, e.g., during sample collection}*
BC-41-04 Arm prep not performed or performed inappropriately *{includes the use of incorrect arm preparation supplies; supplies not maintained appropriately, e.g. stored at unacceptable temperature}*

BC-42-** Collection bag
BC-42-01 Other
BC-42-02 Blood drawn into outdated bag
BC-42-03 Incorrect anticoagulant
BC-42-04 Outdated anticoagulant
BC-42-05 Potential collection set (bag, tubing) defect (e.g., product leaking) *{use BC4205 if event not related to component preparation}*
BC-42-06 Incorrect collection bag used (e.g., 500 ml bag instead of 450ml bag)

BC-43-** Collection process
BC-43-01 Other *{includes use of incorrect collection supplies; use of supplies that were not maintained appropriately; product contained clots and was hemolyzed which was not discovered prior to distribution}*
BC-43-03 Overweight collection (anticoagulant ratio unacceptable); not discovered prior to component preparation
BC-43-05 Product contained clots or fibrin, not discovered prior to distribution *{includes clots discovered by consignee upon receipt of product or during transfusion}*
BC-43-06 Product hemolyzed, not discovered prior to distribution *{reporting is not required if hemolyzed product discovered after consignee accepted it into their inventory}*
BC-43-08 Donor sample tube mix-up or donor sample tube mislabeled
BC-43-09 Apheresis collection process

BC-44-** Apheresis collection device
BC-44-01 Other *{includes collection kits not used within acceptable time period (or not documented) after loading or priming}*
BC-44-02 Device defect
BC-44-03 Softgoods defect (bags, tubing, etc.)

**CP-**-** COMPONENT PREPARATION**
CP-50-** Miscellaneous
CP-50-01 Other

CP-51-** Sterility compromised
CP-51-01 Other
CP-51-03 Air contamination
CP-51-04 Product integrity compromised during component preparation (e.g., leaking at sterile connection site)

CP-52-** Component not prepared in accordance with specifications
CP-52-01 Other *{includes insufficient or excessive plasma volume}*
CP-52-02 Platelets made from Whole Blood collected from donor who took medication that may affect platelet function
CP-52-04 Platelets not agitated
CP-52-05 Platelet count or platelet yield not acceptable as a result of a component preparation deviation or unexpected event *{includes platelet count too high to store in one bag or platelet count too low to store in multiple bags}*
CP-52-06 Product processed at incorrect centrifuge setting

CP-52-07 Product not frozen within the appropriate time frame or freezing time not documented
CP-52-08 Product prepared at incorrect temperature or held at incorrect temperature during component preparation
CP-52-09 Washing/deglycerolization not performed in accordance with specifications *{includes expired saline or incorrect wash solution used}*
CP-52-10 Leukoreduction not performed in accordance with specifications *{includes time component returned to controlled temperature not documented or discrepant; product not leukoreduced within allowable time frame; filtration process incomplete or performed incorrectly}*
CP-52-11 Irradiation not performed in accordance with specifications *{includes time component returned to controlled temperature not documented or discrepant; documentation of irradiation process incomplete; product irradiated more than once; irradiation process incomplete or inadequate}*
CP-52-12 Components not prepared within appropriate time frame after collection
CP-52-13 Additive solution not added, added incorrectly, or added to incorrect product or expired additive solution added
CP-52-14 Thawing frozen product not performed in accordance with specifications
CP-52-15 Pooling not performed in accordance with specifications *{includes incorrect number of units pooled}*
CP-52-16 Aliquot preparation not performed in accordance with specifications
CP-52-17 Sterile docking procedure not performed in accordance with specifications *{includes incorrect, missing, or discrepant documentation of weld inspection}*
CP-52-18 Pathogen reduction not performed in accordance with specifications

CP-53-** Component prepared from a unit that was
CP-53-01 Other
CP-53-02 Overweight
CP-53-03 Underweight
CP-53-04 Collected or stored at unacceptable or undocumented temperature

CP-54-** Component manufactured that was
CP-54-01 Other
CP-54-02 Overweight
CP-54-03 Underweight
CP-54-04 Lipemic
CP-54-05 Bloody

**VT/RT LABORATORY TESTING**
**VT-**-** TRANSFUSION-TRANSMITTED INFECTION TESTING**
VT-70-** Miscellaneous
VT-70-01 Other

†VT-71-** Testing performed, interpreted or documented incorrectly; not performed; incompletely performed; or not documented for *{includes QC not performed or unacceptable*, *expired reagents used*; *use QC92** if testing is positive}*
VT-71-00 Other
VT-71-01 HBV
VT-71-02 HIV
VT-71-06 Syphilis
VT-71-07 HTLV
VT-71-10 HCV
VT-71-11 More than 1 test, e.g., all viral markers
VT-71-12 Cytomegalovirus
VT-71-15 Multiplex Nucleic Acid Test (NAT)
VT-71-17 West Nile Virus
VT-71-18 T. Cruzi (Chagas)
VT-71-19 Bacterial testing

VT-71-20 ZIKV
†VT-71-21 Babesia

VT-72-** Sample identification
VT-72-01 Other
VT-72-02 Incorrect sample tested
VT-72-03 Sample used for testing was incorrectly or incompletely labeled
VT-72-04 Unsuitable sample used for testing

**RT-**-** ROUTINE TESTING**
RT-60-** Miscellaneous
RT-60-01 Other

†RT-61-** Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented for *{includes discrepancies in testing due to weak reactions; QC not performed or unacceptable; expired reagents used; use QC92** if testing positive; use QC9406 if reagents used on automated instrument were expired or QC was not performed}*
†RT-61-01 Other
RT-61-04 ABO and/or Rh
RT-61-05 Antibody screening or identification
RT-61-06 Antigen typing
RT-61-07 Platelet count
RT-61-08 Compatibility *{includes electronic or immediate spin crossmatch performed instead of full crossmatch, when required}*
RT-61-09 ABO, Rh, and antibody screen
RT-61-10 ABO, Rh, antibody screen, and compatibility
RT-61-11 Antibody screen and compatibility

RT-62-** Sample identification
RT-62-01 Other
RT-62-02 Incorrect sample tested
RT-62-03 Sample used for testing was incorrectly or incompletely labeled
RT-62-04 Unsuitable sample used for testing (e.g., too old)

**LA-**-** LABELING**
LA-80-** Miscellaneous
LA-80-01 Other

†LA-81-** Labels applied to blood unit incorrect or missing information
LA-81-01 Other *{includes units collected from a paid donor labeled as collected from a volunteer donor}*
LA-81-02 ABO and/or Rh incorrect or missing
†LA-81-04 Product type or code incorrect or missing (e.g., RBC labeled as Whole Blood) *{reporting is not required if part or container identification was incorrect or missing; do not use LA8104 if there is a specific code available, e.g. use LA8113 if unit not labeled as leukoreduced}*
LA-81-06 Expiration date or time extended or missing
LA-81-08 Anticoagulant incorrect or missing (e.g., CPD vs ACD)
†LA-81-09 Donor/unit number incorrect or missing
LA-81-10 Combination of incorrect or missing information *{e.g., unit number and expiration date}*
†LA-81-11 Product volume or weight incorrect or missing
LA-81-12 Irradiation status incorrect or missing
LA-81-13 Leukoreduction status incorrect or missing
LA-81-14 Irradiation and leukoreduction status incorrect or missing
LA-81-15 CMV status incorrect or missing
LA-81-16 Machine-readable bar code incorrect or missing *{Lot number, product code, or ABO and Rh of the donor}*

LA-81-17 Transfusion-transmitted infection testing status incorrect or missing *{e.g. HIV, HBV, HCV, ZIKV}*
†LA-81-18 Anticoagulant volume on Whole Blood unit incorrect or missing

LA-82-** Crossmatch tag, tie tag or transfusion record incorrect or missing information *{Use LA-82 if tag physically attached to the unit is incorrect or missing information, the transfusion record, accompanied with unit, is incorrect or missing information, or both the tag and transfusion record are incorrect or missing information}*
†LA-82-01 Other *{includes required information that's not identified in any other deviation code}*
LA-82-02 Unit ABO and/or Rh incorrect or missing
LA-82-03 Recipient ABO and/or Rh incorrect or missing
†LA-82-04 Product type or code incorrect or missing *{reporting is not required if part or container identification was incorrect or missing}*
LA-82-05 Expiration date or time extended or missing
†LA-82-06 Unit or pool number incorrect or missing *{reporting is not required if tag/transfusion record was switched between two units intended for the same patient}*
LA-82-07 Recipient identification incorrect or missing
LA-82-08 Antigen incorrect or missing
LA-82-09 Antibody incorrect or missing
LA-82-10 Platelet count incorrect or missing
†LA-82-12 Product volume or weight, incorrect or missing
LA-82-13 CMV status incorrect or missing
LA-82-14 Irradiation status incorrect or missing
LA-82-15 Leukoreduced status incorrect or missing
LA-82-17 Compatibility information incorrect or missing
LA-82-19 Combination of incorrect or missing information *{e.g., unit number and expiration date}*
LA-82-20 Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit *{e.g., intended for different patient}*
†LA-82-21 Anticoagulant volume on Whole Blood unit incorrect or missing

**QC-**-** QUALITY CONTROL AND DISTRIBUTION**
QC-90-** Miscellaneous
QC-90-01 Other

QC-91-** Failure to quarantine unit due to medical history *{includes failure to quarantine after receiving post donation information, use the code specific to the post donation information}*
†QC-91-01 Other *{includes type of behavior or history unknown or not specified; unacceptable address; donor unreliable, for example mental status questionable}*
†QC-91-02 History of hepatitis, not specified, or tested reactive prior to donation
QC-91-03 History of jaundice
†QC-91-04 History of Hepatitis B, or tested reactive prior to donation
†QC-91-05 History of Hepatitis C, or tested reactive prior to donation
†QC-91-06 History of syphilis, or tested reactive prior to donation
QC-91-07 Intimate contact with risk for a relevant transfusion-transmitted infection - syphilis
QC-91-13 Non-specific intimate contact with risk for a relevant transfusion-transmitted infection *{includes contact with an individual who was deferred by another center, on a national deferral list, or tested reactive for an unknown viral marker}*
QC-91-14 Male donor had sex with another man
QC-91-15 Female had sex with a man who had sex with another man
QC-91-16 IV drug use not prescribed by a doctor *{includes taking illegal drugs by needle, e.g., IM}*
QC-91-17 Sex partner used IV drugs not prescribed by a doctor
QC-91-22 Exchanged sex for drugs or money
QC-91-23 Sex partner exchanged sex for drugs or money
QC-91-28 Donor received transfusion
QC-91-29 Donor received xenotransplantation product (specify product)

QC-91-36 Travel to or residence in a malaria endemic area/history of malaria
QC-91-37 History of disease *{donor was aware of condition or disease **prior** to donation; does not include diseases that do not affect the safety, purity, or potency of the product e.g., heart disease, hemochromatosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*
QC-91-39 History of Creutzfeldt-Jakob Disease
QC-91-40 Risk factors associated with Creutzfeldt-Jakob Disease - received dura mater transplant
QC-91-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history
QC-91-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel
†QC-91-43 Risk factors associated with Creutzfeldt-Jakob Disease - received bovine insulin
QC-91-44 Received growth hormone (derived from human pituitary glands)
QC-91-45 Received finasteride, etretinate, isotretinoin, dutasteride (specify medication) *{e.g., Proscar, Propecia, Tegison, Accutane, Avodart, Jalyn, or Absorica}*
QC-91-46 Received antibiotics or medication which may adversely affect the product (specify medication) *{e.g., platelet inhibitor drugs; drugs with teratogenic effect}*
QC-91-47 Received vaccine or immune globulin
QC-91-48 Exposure to a disease
QC-91-49 Incarcerated
QC-91-53 Multiple high risk behaviors/contacts
†QC-91-55 Donor deferred by another center due to history or tested reactive, specific history or testing unknown *{reason for deferral unknown or not provided by the other center – use more specific QC code if reason known}*
QC-91-56 Post donation illness
†QC-91-59 Risk factor associated with Chagas *{includes tested reactive prior to donation}*
QC-91-60 Donor received tattoo and/or piercing *{includes tattoo, any type of piercing or a combination of tattoo and/or piercing and any other type of potential blood exposure}*
QC-91-61 Donor was exposed to blood or body fluids other than tattoo or piercing *{includes accidental needlestick, animal bite; human bite; occupational exposure; scarification; branding; exposure not specified; multiple exposures, not including tattoo or piercing}*
QC-91-62 Intimate contact with risk for a relevant transfusion-transmitted infection - HIV
QC-91-63 Intimate contact with risk for a relevant transfusion-transmitted infection - HTLV
QC-91-64 Intimate contact with risk for a relevant transfusion-transmitted infection - HBV
QC-91-65 Intimate contact with risk for a relevant transfusion-transmitted infection - HCV
QC-91-66 Intimate contact with risk for a relevant transfusion-transmitted infection - hepatitis, not specified
QC-91-67 Intimate contact with risk for a relevant transfusion-transmitted infection – Other

QC-92-** Positive testing for *{Use RT61** or VT71** if testing was performed incorrectly, not performed, incompletely performed, or not documented}*
†QC-92-01 Other
QC-92-02 HIV
QC-92-03 HBV (HBsAg, HBV NAT)
QC-92-04 Anti-HBc
QC-92-05 HCV (Anti-HCV, HCV NAT)
QC-92-06 Anti-HTLV
QC-92-10 Antibody screen or identification (donor/unit or recipient)
QC-92-11 Antigen screen
QC-92-12 Syphilis
QC-92-13 All viral markers
QC-92-14 Compatibility
QC-92-15 Multiplex Nucleic Acid Test (NAT)
QC-92-16 Bacterial testing (identify organism if possible) *{reporting is not required if no organism was identified}*
QC-92-17 ZIKV
†QC-92-18 West Nile Virus
†QC-92-19 T. Cruzi (Chagas)

†QC-92-20 Babesia

QC-94-** Distribution of product that did not meet specifications

†QC-94-01 Other *{includes product distributed prior to required record review}*

QC-94-02 Outdated product

QC-94-04 Product QC unacceptable, not performed, not documented, or incomplete *{includes platelet count; product hematocrit/hemoglobin; RBC recovery; absolute red cell volume or product volume; WBC count; pH; product QC not performed during validation of the apheresis process}*

QC-94-05 Product in which specification, other than QC, was not met *{includes incorrect dose (e.g., single unit vs. pooled unit); age of product; appearance, foreign object or particulates}*

QC-94-06 Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented *{includes hemoglobin/hematocrit reagents; microhematocrit centrifuge; trip scale; collection device; incubator/heat block; waterbath; centrifuge; irradiator; hematology analyzer/cell counter; immunohematology instrument/analyzer; bacterial detection device}*

QC-94-08 Product distributed prior to resolution of discrepancy *{conflicting information that requires investigation which is not resolved prior to distribution, e.g., discrepant test results, ABO discrepancy, Whole Blood Number discrepancy; do not use QC9408 if more specific code applies, such as QC9412 through QC9418}*

QC-94-09 Product associated with product that contained clots or hemolysis *{use QC9409 if in-house component is discovered to be clotted or hemolyzed and associated component has already been distributed; use QC9412 if in-house component is discovered to be clotted or hemolyzed and associated product was not quarantined; use BC4305 (clotted) or BC4306 (hemolyzed) if consignee discovers component is clotted or hemolyzed and associated components were also distributed}*

†QC-94-12 Product identified as unsuitable due to a collection deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product; includes potential air contamination, arm preparation/inspection not performed or documented incorrectly, unit or associated unit was clotted or hemolyzed}*

QC-94-13 Product identified as unsuitable due to a component preparation deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product; includes lekoreduction or irradiation not performed in accordance with specifications; transport (from collection center) conditions unacceptable, not documented, or discrepant}*

QC-94-14 Product identified as unsuitable due to a labeling deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

†QC-94-15 Product identified as unsuitable due to a donor screening deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product; includes donor history question not answered or incomplete}*

QC-94-16 Product identified as unsuitable due to a donor deferral deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product}*

QC-94-17 Product identified as unsuitable due to a shipping or storage deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product; includes temperature excursions}*

QC-94-18 Product identified as unsuitable due to a transfusion-transmitted infection testing deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product; includes products released with positive or incomplete testing, e.g.,HBV, HCV, HIV, bacterial testing, ZIKV}*

QC-96-** Shipping and storage

QC-96-01 Other

QC-96-03 Product stored at incorrect temperature

QC-96-04 No documentation that product was shipped or stored at appropriate temperature

QC-96-05 Temperature not recorded or unacceptable upon return, unit redistributed

†QC-96-07 Product shipped at incorrect temperature *{includes shipment with incorrect or missing coolant, e.g., no ice in RBC shipment}*

QC-96-08 Product returned to blood center and reissued inappropriately *{includes no record of inspection upon return; use QC9605 if specific to temperature}*
QC-96-09 Visual inspection not performed or documented by blood center prior to distribution

QC-97-** Distribution procedure not performed in accordance with blood bank transfusion service's specifications

QC-97-01 Other
QC-97-02 Product not irradiated as required
QC-97-03 Product issued to wrong patient
QC-97-04 Improper product selected for patient *{e.g., FFP issued instead of RBC; use more specific codes, such as RT6106 if specific antigen typing is not performed; use QC0405 if incorrect dose (e.g., single unit vs. pooled unit) or incorrect age of product (e.g., not fresh) is issued}*
QC-97-05 Improper ABO or Rh type selected for patient
QC-97-06 Product not leukoreduced as required
QC-97-07 Product released prior to obtaining current sample for ABO, Rh, antibody screen and/or compatibility testing
QC-97-08 Product not CMV negative as required
QC-97-10 Filter not issued with product or incorrect filter issued
QC-97-11 Product not irradiated and leukoreduced as required
QC-97-12 Product not irradiated and CMV negative as required
†QC-97-13 Procedure for issuing not performed or documented in accordance with specifications*;* use QC9719 if the visual inspection was not performed *{includes request slip labeled with incorrect or missing patient identification; emergency release procedure not followed}*
QC-97-16 Product inspected and accepted upon receipt from blood center, subsequently discovered to be hemolyzed
QC-97-17 Product not washed as required
QC-97-18 Product returned and reissued inappropriately
†QC-97-19 Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer (computer documentation is final check of issue process)
QC-97-20 Product not volume reduced as required
†QC-97-21 Product not hemoglobin S negative or Sickle Cell protocol not met as required *{includes testing positive, not performed, performed incorrectly, product labeled incorrectly}*
†QC-97-22 Product not HLA matched as required *{includes testing positive, not performed, performed incorrectly, product labeled incorrectly}*

†QC-98-** Distribution of unit collected from a donor implicated in relevant transfusion-transmitted disease

†QC-98-01 Other
†QC-98-02 HIV
†QC-98-03 Hepatitis (specify type, if known)
†QC-98-04 West Nile Virus
†QC-98-05 Babesia
†QC-98-06 Chagas
†QC-98-07 Malaria
†QC-98-08 ZIKV

†QC-99-** Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease *{use QC-99** when confirmatory or additional supplemental testing is positive; if confirmatory or additional supplemental testing is not positive, a report is not required}*

†QC-99-01 Other *{multiple markers*}
†QC-99-02 HIV
†QC-99-03 HBV

†QC-99-04 HCV
†QC-99-05 West Nile Virus
†QC-99-06 HTLV
†QC-99-07 Babesia
†QC-99-08 Chagas
†QC-99-09 ZIKV

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**Licensed Non-Blood BPD Codes**:

Use the following list of Biological Product Deviation (BPD) Codes to assign a specific code to a reportable event when you submit the report to FDA. Use the guidance document, "Biological Product Deviation Reporting for Manufacturers of Biological Products Other than Blood and Blood Components," to determine if you must report an event. The list includes deviations from regulations, standards, and license application specifications that may affect the safety, purity, or potency of a product. These codes may not apply to all establishments. The use of BPD Codes will assist the FDA in analyzing the data submitted and streamline the trend analysis.

**1. Revisions to Licensed Non-Blood BPD Reporting Codes for FY2019**

For FY2019, we deleted the Miscellaneous category codes. The events previously captured using the code MI-70-02, Leaking vial/container; not confirmed or cause of leak cannot be determined, are now captured using the code PS-51-11 Container closure not secure or damaged, to include related events regardless of whether the event is confirmed to be associated with manufacturing.

**2. Licensed Non-Blood BPD Reporting Codes**

Please use the appropriate code(s) from the listing below to report a deviation or unexpected event that occurred in a licensed non-blood establishment.

Changes made on October 1, 2018 (the beginning of FY2019) are identified with a dagger (†).

The changes to the deviation codes for FY2019 are listed below.

**The following list is a summary of abbreviations used to identify each category of Licensed Non-Blood BPD codes:**

IM - Incoming Material Specifications
PC - Process Controls
TE - Testing
LA - Labeling
PS - Product Specifications
QC - Quality Control and Distribution

**IM-**-** INCOMING MATERIAL SPECIFICATIONS**
IM-10-** Miscellaneous
    IM-10-01 Other

IM-12-** Container
    IM-12-01 Specifications not met
    IM-12-02 Defective

IM-13-** Closures

IM-13-01 Specifications not met
IM-13-02 Defective

IM-14-** Source or raw material does not meet specifications or otherwise found to be unsuitable
IM-14-01 Other *{includes source material collected from donor who traveled to vCJD risk area or was diagnosed with CJD}*
IM-14-02 Contains precipitate/particle
IM-14-03 Contaminated with microorganism
IM-14-04 Contaminated with mold
IM-14-05 Impurities exceed specification
IM-14-06 Testing deviation
IM-14-07 Stored or shipped at incorrect temperature or lack of controlled temperature

**PC-**-** PROCESS CONTROLS**
PC-20-** Miscellaneous
PC-20-01 Other

PC-21-** Manufacturing or processing performed using incorrect parameters
PC-21-01 Other
PC-21-02 Incorrect temperature
PC-21-03 Filling not performed according to specifications
PC-21-04 Aseptic processing not performed according to procedures

PC-22-** Process/Procedure
PC-22-01 Other
PC-22-02 Interruption of process
PC-22-03 Environmental monitoring excursions; environmental monitoring not performed or performed incorrectly
PC-22-04 Equipment not performing properly
PC-22-05 Sanitization, cleaning or maintenance of equipment not performed or performed incorrectly
PC-22-06 Media fill failure or media fill performed incorrectly

PC-23-** Process Water - specification not met
PC-23-01 Other
PC-23-02 Water for injection
PC-23-03 Purified water

PC-24-** Bulk or intermediate material does not meet specifications or otherwise found to be unsuitable
PC-24-01 Other
PC-24-02 Contains precipitate/particle
PC-24-03 Contaminated with microorganism
PC-24-04 Contaminated with mold
PC-24-05 Impurities exceed specification
PC-24-06 Stored at incorrect temperature
PC-24-07 Stored for an excessive hold time

**TE-**-** TESTING**
TE-30-** Miscellaneous
TE-30-01 Other

TE-31-** Safety
TE-31-01 Performed incorrectly
TE-31-02 Not performed or not documented

TE-32-** Purity

TE-32-01 Performed incorrectly
TE-32-02 Not performed or not documented

TE-33-** Potency
TE-33-01 Performed incorrectly
TE-33-02 Not performed or not documented

TE-34-** Sterility
TE-34-01 Performed incorrectly
TE-34-02 Not performed or not documented

TE-35-** Identity
TE-35-01 Performed incorrectly
TE-35-02 Not performed or not documented

TE-36-** Stability
TE-36-01 Performed incorrectly
TE-36-02 Not performed or not documented

**LA-**-** LABELING**
LA-40-** Miscellaneous
LA-40-01 Other

LA-41-** Package insert
LA-41-01 Incorrect/illegible
LA-41-02 Missing
LA-41-03 Not current or approved

LA-42-** Product label
LA-42-01 Incorrect/illegible
A - Recipient identification
LA-42-02 Missing

LA-43-** Carton label
LA-43-01 Incorrect/illegible
LA-43-02 Missing

LA-44-** Expiration date
LA-44-01 Extended/illegible
LA-44-02 Missing

LA-45-** Lot number
LA-45-01 Incorrect/illegible
LA-45-02 Missing

LA-46-** Storage temperature
LA-46-01 Incorrect/illegible
LA-46-02 Missing

LA-47-** Administration route
LA-47-01 Incorrect/illegible
LA-47-02 Missing

LA-48-** Concentration or volume
LA-48-01 Incorrect/illegible
LA-48-02 Missing

LA-49-** Multiple information *{e.g., lot number and expiration date}*
- LA-49-01 Incorrect/illegible
- LA-49-02 Missing

**PS-**-** PRODUCT SPECIFICATIONS**

PS-50-** Miscellaneous
- PS-50-01 Other

PS-51-** Product specification not met
- PS-51-01 Other
- PS-51-02 Contains precipitate
- PS-51-03 Contaminated with microorganism
- PS-51-04 Contaminated with mold
- PS-51-05 Impurity levels
- PS-51-06 Moisture
- PS-51-07 Preservative content
- PS-51-08 Potency
- PS-51-09 Appearance *{includes: cloudy; hemolyzed; foreign object/particle, color}*
- PS-51-10 Fill volume
- †PS-51-11 Container closure not secure or damaged *{includes reports of complaints of leaking vials due to loose cap; missing stoppers; damaged or incomplete seals that may or may not be associated with manufacturing}*
- PS-51-12 Unexpected positive, negative, or weak reactions in testing

PS-52-**Component packaged with final product did not meet specifications
- PS-52-01 Other
- PS-52-02 Contains precipitate/particle
- PS-52-03 Contaminated with microorganism
- PS-52-04 Contaminated with mold
- PS-52-05 Fill volume
- PS-52-06 Broken/cracked vial

PS-53-** Stability testing failed
- PS-53-01 Other
- PS-53-02 Potency
- PS-53-03 Preservative
- PS-53-04 Container closure integrity
- PS-53-05 Chemical analysis/purity
- PS-53-06 Moisture
- PS-53-07 pH
- PS-53-08 Appearance

PS-54-** Administration set (packaged with product) incorrect or incomplete
- PS-54-01 Other
- PS-54-02 Incorrect or missing label
- PS-54-03 Defective
- PS-54-04 Expired

**QC-**-** QUALITY CONTROL AND DISTRIBUTION**

QC-60-** Miscellaneous
- QC-60-01 Other

QC-61-** Product distributed inappropriately
- QC-61-01 Other
- QC-61-02 Product distributed prior to completion of required testing

QC-61-03 Product distributed prior to CBER approval of a PAS
QC-61-04 Product distributed less than 30 days after submission of CBE-30 or prior to submission of CBE-30
QC-61-05 Product distributed prior to validation of process
QC-61-06 Outdated product distributed
QC-61-07 Product distributed prior to release by the quality control unit

QC-62-** Shipping and storage
QC-62-01 Other
QC-62-02 Product shipped at incorrect temperature
QC-62-03 Product stored at incorrect temperature
QC-62-04 No documentation product was shipped or stored at appropriate temperature

QC-63-** Product identified as unacceptable, and not quarantined
QC-63-01 Other

QC-64-** Packing
QC-64-01 Other
QC-64-02 Vial missing
QC-64-03 Packaged incorrectly
QC-64-04 Broken or cracked vial/syringe
QC-64-05 Improper orientation (e.g., sideways)

??-??-?? DO NOT KNOW

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**HCT/P Deviation Codes:**

Use the following list of Human Cells, Tissues and Cellular and Tissue-based Products (HCT/P) Deviation Codes to assign a specific code to a reportable event when you submit the report to FDA. Use the guidance document, "Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271" to determine if you must report an event. The list includes numerous codes for HCT/P deviations [see 21 CFR 1271.3(dd)] that may occur. However, an event is only required to be reported, if it relates to core Current Good Tissue Practices (CGTP) [see 21 CFR 1271.150(b)], involves a distributed HCT/P, and occurs in your facility or a facility that performs a manufacturing step for you under contract, agreement, or other arrangement [see 21 CFR 1271.350(b)(2)]. The use of the HCT/P Deviation Codes will assist the FDA in analyzing the data submitted and streamline the trend analysis.

**1. Revisions to HCT/P Deviation Reporting Codes for FY2019**

No changes to the HCT/P Deviation Codes were made for FY2019.

**2. HCT/P Deviation Reporting Codes**

Please use the appropriate code(s) from the listing below to report an HCT/P deviation.

**The following list is a summary of abbreviations used to identify each category of HCT/P Deviation Codes based on applicable core CGTP:**

DE - Donor Eligibility
DS - Donor Screening
DT - Donor Testing
FA - Facilities

EC - Environmental Control
EQ - Equipment
SR - Supplies and Reagents
RE - Recovery
PC - Processing and Processing Controls
LC - Labeling Controls
ST - Storage
SD - Receipt, Pre-Distribution, Shipment, and Distribution

**DE-**-** DONOR ELIGIBILITY** (21 CFR 1271.50)
DE-02-** Ineligible donor accepted [except as provided in §1271.65(b)]
DE-02-01 Risk factors for, or clinical evidence of infection due to relevant communicable disease agents and diseases according to §1271.75(a)(1)
DE-02-02 Xenotransplant recipient accepted as donor
DE-02-04 Donor tested reactive for relevant communicable disease

DE-03-** Donor eligibility determination
DE-03-01 Not determined by a responsible person, as defined in §1271.3(t)

DE-99-** Miscellaneous
DE-99-01 Other

**DS-**-** DONOR SCREENING** (21 CFR 1271.75)
DS-02-** Donor screening not performed [except as provided in §1271.60(d)] or performed incorrectly in the:
DS-02-01 Donor medical history interview
DS-02-02 Physical assessment of a cadaveric donor or physical examination of a living donor
DS-02-03 Medical record review
DS-02-04 Evaluation of communicable disease risks associated with xenotransplant
DS-02-05 Abbreviated donor screening inappropriately used or not performed
DS-02-06 Donor of viable, leukocyte-rich HCT/Ps not properly evaluated for evidence of infection due to HTLV

DS-99-** Miscellaneous
DS-99-01 Other

**DT-**-** DONOR TESTING** (21 CFR 1271.80 and 1271.85)
DT-01-** Testing not performed or documented when required, for:
DT-01-01 Human immunodeficiency virus
DT-01-03 Hepatitis B virus
DT-01-04 Hepatitis C virus
DT-01-05 Treponema pallidum
DT-01-06 Human T-lymphotropic virus
DT-01-08 Cytomegalovirus
DT-01-11 Multiple tests

DT-02-** Testing incorrectly performed when required, for:
DT-02-01 Human immunodeficiency virus
DT-02-03 Hepatitis B virus
DT-02-04 Hepatitis C virus
DT-02-05 Treponema pallidum
DT-02-06 Human T-lymphotropic virus
DT-02-08 Cytomegalovirus
DT-02-11 Multiple tests

DT-03-** Unacceptable specimen tested

DT-03-01 Specimen collected more than 7 days before or after recovery (except for peripheral blood stem/progenitor cells)
DT-03-02 Specimen collected from donor 1 month of age or younger, instead of from birth mother
DT-03-03 Specimen collected from a peripheral blood stem cell donor more than 30 days before recovery
DT-03-04 Specimen storage conditions not met
DT-03-05 Specimen did not meet requirements in test kit package insert *{includes filtered specimen, specimen collected in an expired tube, outdated specimen}*
DT-03-06 Donor incorrectly evaluated for plasma dilution
DT-03-07 Donor not evaluated or evaluation not documented for plasma dilution

DT-04-** Inappropriate test or test laboratory used
DT-04-01 Required test used was not licensed, approved, or cleared *{includes HIV/HCV NAT performed on pooled samples instead of individual samples}*
DT-04-02 Required tests approved for cadaveric specimens not used when available
DT-04-03 Laboratory performing tests not CLIA certified (or equivalent for CMS)
DT-04-04 Laboratory performing tests not FDA approved

DT-99-** Miscellaneous
DT-99-01 Other

**FA -**-** FACILITIES** (21 CFR 1271.190(a) and (b))
FA-01-** Design
FA-01-01 Facility not suitable in size, construction, and/or location
FA-01-02 Inadequate lighting, ventilation, plumbing, drainage and/or access to sinks and toilets

FA-02-** Cleaning and sanitization
FA-02-01 Facility not maintained in a clean, sanitary, and orderly manner
FA-02-02 Sewage, trash, and other refuse not disposed of in a timely, safe, and sanitary manner

FA-99-** Miscellaneous
FA-99-01 Other

**EC-**-** ENVIRONMENTAL CONTROL** (21 CFR 1271.195(a))
EC-01-** Environmental controls, when required, not performed or documented for
EC-01-01 Temperature controls
EC-01-02 Humidity controls
EC-01-03 Ventilation and air filtration
EC-01-04 Cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations
EC-01-05 Maintenance of equipment used to control conditions necessary for aseptic processing operations

EC-02-** Environmental controls, when required, incorrectly performed for
EC-02-01 Temperature controls
EC-02-02 Humidity controls
EC-02-03 Ventilation and air filtration
EC-02-04 Cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations
EC-02-05 Maintenance of equipment used to control conditions necessary for aseptic processing operations

EC-99-** Miscellaneous
EC-99-01 Other

**EQ-**-** EQUIPMENT** (21 CFR 1271.200(a))

EQ-01-** Design
EQ-01-01 Equipment is not of an appropriate design for its use, and/or suitably located
EQ-01-02 Equipment not capable of producing valid results

EQ-02-** Maintenance
EQ-02-01 Cleaning, sanitization, or maintenance of equipment not performed or documented in accordance with established schedules

EQ-99-** Miscellaneous
EQ-99-01 Other

**SR-**-** SUPPLIES AND REAGENTS** (21 CFR 1271.210(a) and (b))
SR-01-** Not verified to meet specifications for use
SR-01-01 Supplies
SR-01-02 Reagents

SR-02-** Reagent unsuitable
SR-02-01 Not sterile, where appropriate

SR-99-** Miscellaneous
SR-99-01 - Other

**RE-**-** - RECOVERY** (21 CFR 1271.215)
RE-01-** Manner of recovery
RE-01-01 HCT/P contaminated, potentially contaminated, or cross-contaminated during recovery

RE-99-** Miscellaneous
RE-99-01 Other

**PC-**-** PROCESSING AND PROCESS CONTROLS** (21 CFR 1271.220)
PC-01-** Processing
PC-01-01 HCT/P contaminated, potentially contaminated, or cross-contaminated during processing
PC-01-02 HCT/Ps from two or more donors were pooled during manufacturing

PC-02-** In-process controls
PC-02-01 Not followed
PC-02-02 Inadequate

PC-03-** In-process testing
PC-03-01 Sample not representative of the material to be evaluated

PC-04-** Processing of Dura mater
PC-04-01 Available published validated process that reduces the risk of transmissible spongiform encephalopathy not used
PC-04-02 Available published validated process that reduces the risk of transmissible spongiform encephalopathy used, but not verified
PC-99-** Miscellaneous
PC-99-01 Other

**LC-**-** LABELING CONTROLS** (21 CFR 1271.250(a) and (b))
LC-01-** Procedures to control labeling of HCT/Ps
LC-01-01 Not established or maintained
LC-01-02 Did not prevent mix-ups
LC-01-03 Did not allow proper identification

LC-02-** Verification procedures not performed for:
LC-02-01 Accuracy, legibility, or integrity

LC-99-** Miscellaneous
LC-99-01 Other

**ST-**-** STORAGE** (21 CFR 1271.260(a) through (d))
ST-01-** Storage area and stock room not controlled to prevent mix-ups pertaining to the following items:
ST-01-01 HCT/Ps
ST-01-02 Supplies
ST-01-03 Reagents

ST-02-** Storage area and stock room not controlled to prevent contamination or cross-contamination pertaining to the following items:
ST-02-01 HCT/Ps
ST-02-02 Supplies
ST-02-03 Reagents

ST-03-** Storage temperature
ST-03-01 Not appropriate

ST-04-** Expiration date, where appropriate
ST-04-01 Incorrect or missing
ST-99-** Miscellaneous
SR-99-01 Other

**SD-**-** RECEIPT, PRE-DISTRIBUTION SHIPMENT, AND DISTRIBUTION** (21 CFR 1271.265(a) through (d))
SD-01-** Quarantined HCT/Ps
SD-01-01 Shipped without quarantine identification

SD-02-** Inappropriate distribution
SD-02-01 Distributed without review of required records
SD-02-02 Distributed without sign-off by a responsible person
SD-02-03 Quarantined HCT/P that was determined ineligible for release
SD-02-04 Contaminated or potentially contaminated HCT/P
SD-02-05 Release criteria related to expiration date of product not met

SD-03-** Inappropriate shipping conditions
SD-03-01 Temperature
SD-03-02 Packaging
SD-03-03 Container construction

SD-04-** Receipt of incoming HCT/P
SD-04-01 Not evaluated for the presence and significance of microorganisms and inspected for damage and contamination

SD-99-** Miscellaneous
SD-99-01 Other

??-??-?? DO NOT KNOW

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Last Updated: 10/1/2018