Biological Product Deviation Reporting and HCT/P Deviation Reporting - Deviation Codes
(PDF version)

Blood BPD Codes | **Licensed Non-Blood BPD Codes** | **HCT/P Deviation Codes**

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 FY2022

For FY2022, we modified codes to clarify specific events that are reportable. We deleted codes for events in which reporting is no longer required.

In May 2021, we determined that Zika Virus is no longer a relevant transfusion-transmitted infection (Information for Blood Establishments Regarding FDA's Determination that Zika Virus is no Longer a Relevant Transfusion-Transmitted Infection, and Withdrawal of Guidance titled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components). Therefore, all codes related to Zika Virus have been deleted.

2. Summary of FY2022 Revisions

An overview of the changes that were made to the BPD codes for FY2022 is provided below. Refer to each section below for the complete list of BPD codes.

A. The following codes have been deleted:

- DS-27-** Deferral screening not done or incorrectly performed, including incorrect ID used during search, prior deferral due to testing for:
  - DS-27-09 ZIKV
- DD-31-** Donor missing, incorrectly deleted, or incorrectly identified on deferral list, donor was or should have been previously deferred due to testing for
  - DD-31-09 ZIKV
- VT-71-** Testing performed, interpreted or documented incorrectly; not performed; incompletely performed; or not documented for
  - VT-71-20 ZIKV
- QC-92-** Product identified as unsuitable due to positive testing; event discovered subsequent to distribution
  - QC-92-17 ZIKV
- QC-98-** Distribution of unit collected from a donor implicated in relevant transfusion-transmitted disease
  - 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
  - QC-99-09 Other *{multiple markers, ZIKV}*

B. The information within the parenthesis for the following BPD codes was modified to clarify reportable events:

- LA-82-20 Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit *{e.g., intended for different patient; **reporting is not required if tag/transfusion record was switched between two units intended for the same patient**}*

- QC-97-07 Product released prior to obtaining current sample for ABO, Rh, antibody screen and/or compatibility testing *{includes original sample was expired, patient left facility and new sample was required; **antibody screen/crossmatch expired**}*

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, 2021 (the beginning of FY2022) are identified with a dagger (†).

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

Donor Eligibility
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

DS/DD DONOR ELIGIBILITY

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 history interview or physical assessment 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-27-10 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) *{does not include human tissue}*
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-28-44 Received cadaveric pituitary growth hormone
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; does not include anticoagulant therapy}*
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) *{does not include human tissue products}*
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-29-44 Received cadaveric pituitary growth hormone
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; does not include anticoagulant therapy}*
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-31-10 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) *{does not include human tissue products}*
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-32-44 Received cadaveric pituitary growth hormone
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; does not include anticoagulant therapy}*
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 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-71-21 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 *(includes failure to perform patient recheck/retyping)*
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 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}*
- 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 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; reporting is not required if tag/transfusion record was switched between two units intended for the same 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) *{does not include human tissue products}*
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-91-44 Received cadaveric pituitary growth hormone
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; does not include anticoagulant therapy}*
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-** Product identified as unsuitable due to positive testing, event discovered subsequent to distribution *{Use RT61** or VT71** if testing was performed incorrectly, not performed, incompletely performed, or not documented; use QC9418, for events involving RTTI, if discovered prior to distribution but failed to quarantine product}*
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 the gram stain is negative, and no organism was identified}*
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}*

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 stored at appropriate temperature

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 was reissued without a record of proper temperature maintenance *{includes no record of inspection upon return}*

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 QC9405 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 *{includes original sample was expired, patient left facility and new sample was required; antibody screen/crossmatch expired}*

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, QC not performed or unacceptable; 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-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

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 FY2022

We modified the following codes:

- PC-22-07 In-process testing not performed or inadequate to include in-process controls, and testing performed incorrectly.
- QC-61-07 Product distributed prior to release by the quality control unit to include product released prior to record review

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, 2021 (the beginning of FY2022) are identified with a dagger (†).

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-22-07 In-process testing/controls not performed, performed incorrectly, or inadequate

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
- 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 a 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 record review or 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/container
QC-64-05 Improper orientation (e.g., sideways)

??-??-?? DO NOT KNOW

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 FY2022

No changes to the HCT/P Deviation Codes were made for FY2022.

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 Process 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
ST-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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