Biological Product Deviation Reporting and HCT/P Deviation Reporting - 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 FY2020**

For FY2020, we modified codes to clarify specific events that are reportable. We deleted codes for events in which reporting is no longer required.

2. **Summary of FY2020 Revisions**

An overview of the changes that were made to the BPD codes for FY2020 is provided below. Refer to each section below for the complete list of BPD codes.

A. **The following codes were modified to clarify or limit reporting to events that may affect the safety, purity, or potency of the product**

- DS-21-04 Donor Screening; Donor did not meet eligibility criteria; Medical history interview or physical assessment not performed or inadequate
- CP-53-04 Component Preparation; Component prepared from a unit that was; Stored at an...
unacceptable or undocumented temperature

- LA-81-11 Labeling; Labels applied to blood unit incorrect or missing information; Product volume incorrect or missing
- LA-82-12 Labeling; Crossmatch tag, tie tag or transfusion record incorrect or missing information; Product volume incorrect or missing
- QC-92-** Quality Control and Distribution; Product identified as unsuitable due to positive testing, event discovered subsequent to distribution \(\text{Use RT61** or VT71** if testing was performed incorrectly, not performed, incompletely performed, or not documented; use QC9418 if the event was discovered prior to distribution and the product was not quarantined}\)
- QC-96-04 No documentation that product was stored at appropriate temperature
- QC-96-08 Quality Control and Distribution; Shipping and storage; Product was reissued without a record of proper temperature maintenance

B. The following code has been deleted:

- QC-96-05 Quality Control and Distribution; Shipping and storage; Temperature not recorded or unacceptable upon return, unit redistributed

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

- RT-61-04 Routine Testing; ABO and/or Rh \(\text{includes failure to perform patient recheck/retyping}\)
- QC-97-07 QC and Distribution; Product released prior to obtaining current sample for ABO/Rh, antibody screen and or compatibility testing \(\text{includes crossmatch sample expired; patient left facility and a new sample was required when the patient returned}\)
- The following changes apply to the BPD codes under Post Donation Information (PD), Donor Screening (DS), Donor Deferral (DD) and Quality Control and Distribution (QC):
  - **-**-29 Donor received xenotransplantation product (specify product) \(\text{does not include human tissue products}\)
  - **-**-46 Received antibiotics or medication which may adversely affect the product (specify medication) \(\text{e.g., platelet inhibitor drugs; drugs with teratogenic effect; does not include anticoagulant therapy}\)

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, 2019 (the beginning of FY2020) are identified with a dagger (†).

The changes to the deviation codes for FY2020 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) \{does not include human tissue products\}
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; does not include anticoagulant therapy\}
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 PD12** 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 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-27-09 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) (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-28-43 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; 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-29-43 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; 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-31-09 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) {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-32-43 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; 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-71-20 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 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, 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 LA82 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}
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-91-43 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; 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 if the event was discovered prior to distribution and the product was not quarantined}
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 leukoreduction 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., 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 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 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 {includes crossmatch sample expired; patient left facility and a new sample was required}
   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 QC99** 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

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 FY2020

For FY2020, we modified QC-64-04 to include “container”.

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, 2019 (the beginning of FY2020) are identified with a dagger (†).

The changes to the deviation codes for FY2020 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
  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/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 FY2020

No changes to the HCT/P Deviation Codes were made for FY2020.

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

??-??-?? DO NOT KNOW
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))
Equity-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

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

Equity-99 Miscellaneous
  EQ-99-01 Other

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

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

Supply-99 Miscellaneous
  SR-99-01 Other

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

Recovery-99 Miscellaneous
  RE-99-01 Other

Processing and Process Controls (21 CFR 1271.220)
Processing-01
  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

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

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

Processing-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

Processing-99 Miscellaneous
  PC-99-01 Other

Labeling Controls (21 CFR 1271.250(a) and (b))
Labeling-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

Last Updated: 10/1/2019