

Biological Product Deviation Reporting (BPDR) Product Deviation Codes

[Blood BPD Codes](#) | [Non-Blood BPD Codes](#) | [HCT / P 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," (www.fda.gov/CBER/gdlns/devbld.htm) to determine if you must report an event. The list includes deviations from regulations, standards, and standard operating procedures (SOPs) that may affect the safety, purity, or potency of a product. These codes may not apply to all establishments because they include deviations and unexpected events related to SOPs implemented at individual establishments and may not be an industry standard or a procedure at your facility. The use of BPD Codes will assist the FDA in analyzing the data submitted and streamline the trend analysis.

Changes made on October 22, 2007 are identified with a dagger (†).

The donor suitability regulation for whole blood {640.3(c)(6)} and source plasma {640.63(c)(9)} requires that a donor should be in good health as indicated in part by "freedom from any disease transmissible by blood transfusion, insofar as can be determined by history and examinations". FDA has not issued a regulation or guidance that interprets this provision to include cancer. Most blood and plasma establishments have implemented procedures for deferring a donor who has active cancer, but the procedures vary regarding history of cancer or post donation diagnosis of cancer. Following review by our Blood Safety Team, CBER determined that BPD reports are not required for distributed products collected from a donor who either had a history of cancer or was diagnosed with cancer after donating; we found no evidence that the safety, purity or potency of these products may be affected. The establishment's medical director should determine the suitability of a donor who has a history of cancer. The medical director can use discretion regarding the need to retrieve products or notify consignees. Therefore, we have deleted:

PD-12-38 Post Donation Information-Behavior/History-History of cancer

PD-13-09 Post Donation Information-Illness-Post donation diagnosis of cancer

DS-25-38 Donor Screening-Deferral screening not done-History of cancer

DS-28-38 Donor Screening-Incorrect ID used during deferral search, donor previously deferred due to history-History of cancer

DS-29-38 Donor Screening-Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked-History of cancer

DD-32-38 Donor Deferral-Donor missing or incorrectly identified on deferral list, donor was or should have been previously deferred due to history-History of cancer

DD-35-38 Donor Deferral- Donor incorrectly deleted from deferral list, donor previously deferred due to history-History of cancer

QC-91-38 QC & Distribution-Failure to quarantine unit due to medical history-History of cancer

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).

[Donor Suitability](#)

[PD](#) - Post Donation Information

[DS](#) - Donor Screening

[DD](#) - Donor Deferral

[BC](#) - Blood Collection

[CP](#) - Component Preparation

[Laboratory Testing](#)

[VT](#) - Viral Testing

[RT](#) - Routine Testing

[LA](#) - Labeling

[QC](#) - Quality Control and Distribution

[MI](#) - Miscellaneous

PD/DS/DD DONOR SUITABILITY (Back to top)

PD-**-** POST DONATION INFORMATION (Back to top)

PD-10-**-** Miscellaneous

PD-10-01 Other

PD-11-**-** Testing

†PD-11-01 Other *{information provided by donor or third party, includes true positive and false positive test results; use MI codes for confirmed positives if testing performed at your facility}*

PD-11-02 Tested reactive for Hepatitis B post donation

PD-11-03 Tested reactive for Hepatitis B prior to donation

PD-11-04 Tested reactive for Hepatitis C post donation

PD-11-05 Tested reactive for Hepatitis C prior to donation

PD-11-06 Tested reactive for HIV post donation

PD-11-07 Tested reactive for HIV prior to donation

PD-11-08 Tested reactive for HTLV post donation

PD-11-09 Tested reactive for HTLV prior to donation

PD-11-10 Tested reactive for sexually transmitted disease post donation

PD-11-11 Tested reactive for sexually transmitted disease prior to donation

PD-11-12 Tested reactive for hepatitis not specified, post donation

PD-11-13 Tested reactive for hepatitis not specified, prior to donation

PD-11-14 Tested reactive at another center, specific testing unknown

PD-11-15 Tested reactive for Hepatitis A post donation

PD-11-16 Tested reactive for Hepatitis A prior to donation

PD-11-17 Elevated ALT post donation

PD-11-18 Elevated ALT prior to donation

PD-12-**-** Behavior/History

†PD-12-01 Other *{includes: type of behavior or history unknown or not specified; unacceptable address; rape; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions}*

PD-12-02 History of hepatitis not specified

PD-12-03 History of jaundice

PD-12-04 History of Hepatitis B

PD-12-05 History of Hepatitis C

PD-12-06 Sexually transmitted disease

PD-12-07 Sex partner has or had a sexually transmitted disease

PD-12-08 Sex partner tested reactive for HIV

- PD-12-09 Sex partner tested reactive for HTLV
- PD-12-10 Sex partner tested reactive for HBV
- PD-12-11 Sex partner tested reactive for HCV
- PD-12-12 Sex partner tested reactive for hepatitis, not specified
- †PD-12-13 Sex partner unsuitable or engaged in high risk behavior *{includes: sex partner- received clotting factor; incarcerated; history of jaundice; deferred by another center or on national or state deferral list, tested reactive for a viral marker or history/behavior unknown or not specified}*
- 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 *{includes taking illegal drugs by needle, e.g., IM}*
- PD-12-17 Sex with IV drug user
- †PD-12-18 Non-IV-drug use *{includes taking illegal drugs by route other than needle}*
- PD-12-19 Sex partner used non-IV drugs
- PD-12-20 Donor lived in or immigrated from an HIV Group O risk area
- PD-12-21 Sex partner lived in or immigrated from an HIV Group O risk area
- PD-12-22 Exchanged sex for drugs or money
- PD-12-23 Sex partner exchanged sex for drugs or money
- PD-12-24 Donor received tattoo
- PD-12-25 Donor received ear piercing
- PD-12-26 Donor received body piercing
- PD-12-27 Donor received accidental needlestick
- PD-12-28 Donor received transfusion or clotting factors
- PD-12-29 Donor received tissue allograft or transplanted organ
- †PD-12-30 Donor was exposed to blood or body fluids *{includes: animal bite; human bite; occupational exposure; scarification; branding; exposure not specified}*
- PD-12-31 Donor had multiple blood or body fluid exposures, *{includes: tattoo and piercing; does not include multiple exposures of the same type, such as multiple tattoos}*
 - A - Tattoo and piercing
- PD-12-32 Non-sexual exposure to HIV
- PD-12-33 Non-sexual exposure to hepatitis, type not specified
- PD-12-34 Non-sexual exposure to Hepatitis B
- PD-12-35 Non-sexual exposure to Hepatitis C
- PD-12-36 Travel to malaria endemic area/history of malaria
- †PD-12-37 History of disease or surgery *{condition or disease existed prior to donation; does not include diseases affecting donor safety only, e.g., heart disease}*
- PD-12-40 Risk factors associated with Creutzfeldt-Jakob Disease - brain surgery
- 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 insulin or other bovine derived product
- PD-12-44 Received growth hormone
- PD-12-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, or Avodart
- PD-12-46 Received medication or antibiotics
- PD-12-47 Received vaccine or immune globulin
- PD-12-48 Exposure to a disease
- PD-12-49 Incarcerated
- PD-12-50 Resided in a rehabilitation center or psychiatric hospital
- PD-12-51 History of Hepatitis A
- PD-12-52 Exposure to Hepatitis A
- PD-12-53 Multiple high risk behaviors/contacts
- PD-12-54 Positive drug screen
- PD-12-55 Deferred by another center – reason unknown *{reason for deferral unknown or not provided by the other center – use more specific PD code if reason known}*
- †PD-12-56 Travel to leishmania risk area *{e.g., Baghdad, Tikrit, Ramadi}*

†PD-12-57 Travel to leishmania and malarial endemic area {e.g., Afghanistan, Iraq (except Baghdad, Tikrit, Ramadi)}

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 post donation reaction (e.g., infection) at phlebotomy site; Babesiosis; West Nile Virus, Chagas}

PD-13-02 Post donation diagnosis or symptoms of Hepatitis B

PD-13-03 Post donation diagnosis or symptoms of Hepatitis C

PD-13-04 Post donation diagnosis or symptoms of HIV

PD-13-05 Post donation diagnosis or symptoms of HTLV

PD-13-06 Post donation diagnosis or symptoms of sexually transmitted disease

PD-13-07 Post donation diagnosis or symptoms of hepatitis, not specified

PD-13-08 Post donation diagnosis or symptoms of Hepatitis A

†PD-13-10 Post donation diagnosis or possible diagnosis of Creutzfeldt-Jakob Disease {includes variant CJD}

PD-14-** Not specifically related to high risk behavior, unsuitable history, or post donation illness

PD-14-01 Other {does not include reports of post donation illness – use PD13** codes; includes anything not included in PD12**}

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 (Back to top)

DS-20-** Miscellaneous

DS-20-01 Other

DS-21-** Donor did not meet acceptance criteria

DS-21-01 Other {includes inappropriate acceptance of donor with unacceptable address}

DS-21-02 Hemoglobin or Hematocrit unacceptable, not documented, or testing performed incorrectly {includes use of expired reagents for hemoglobin or hematocrit}

DS-21-03 Temperature unacceptable or not documented

DS-21-04 Medical review or physical not performed or inadequate

DS-21-05 Platelet count, no documented platelet count for product

DS-21-06 Unexplained weight loss

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: abbreviated questionnaire used instead of full-length questionnaire; response to educational material/AIDS questions not documented}

DS-22-04 Arm inspection

DS-22-05 Donor signature missing

DS-22-06 Confidential Unit Exclusion (CUE) procedure not performed in accordance with specifications

DS-22-07 Donor confidentiality compromised

†DS-23-** Deferral screening not done or incorrectly performed

†DS-23-01 Donor not previously deferred {use DS2301 when the deferral file is not checked during donor screening process or the deferral file check was incorrectly performed (e.g., all search criteria not used) and the donor was not previously deferred}

†DS-24-** Deferral screening not done or incorrectly performed, donor previously deferred due to testing: *{use DS24** when the deferral file is not checked during donor screening process or the deferral file check was incorrectly performed (e.g., all search criteria not used) and the donor was previously deferred due to testing}*

- DS-24-01 Other
- DS-24-02 HIV reactive
- DS-24-03 HBsAg reactive
- DS-24-04 Anti-HBc reactive
- DS-24-05 Anti-HCV reactive
- DS-24-06 Anti-HTLV reactive
- DS-24-07 ALT elevated
- DS-24-08 Syphilis reactive

†DS-25-** Deferral screening not done or incorrectly performed, donor previously deferred due to history *{use DS25** when the deferral file is not checked during donor screening process or the deferral file check was incorrectly performed (e.g., all search criteria not used) and the donor was previously deferred due to history}*

†DS-25-01 Other *{includes: type of behavior or history unknown or not specified; unacceptable address; rape; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions}*

- DS-25-02 History of hepatitis, not specified
- DS-25-03 History of jaundice
- DS-25-04 History of Hepatitis B
- DS-25-05 History of Hepatitis C
- DS-25-06 Sexually transmitted disease
- DS-25-07 Sex partner has or had a sexually transmitted disease
- DS-25-08 Sex partner tested reactive for HIV
- DS-25-09 Sex partner tested reactive for HTLV
- DS-25-10 Sex partner tested reactive for HBV
- DS-25-11 Sex partner tested reactive for HCV
- DS-25-12 Sex partner tested reactive for hepatitis, not specified

†DS-25-13 Sex partner unsuitable or engaged in high risk behavior *{includes: sex partner- received clotting factor; incarcerated; history of jaundice; deferred by another center or on national or state deferral list, tested reactive for a viral marker or history/behavior unknown or not specified}*

- DS-25-14 Male donor had sex with another man
- DS-25-15 Female had sex with a man who had sex with another man

†DS-25-16 IV drug use *{includes taking illegal drugs by needle, e.g., IM}*

DS-25-17 Sex with IV drug user

†DS-25-18 Non-IV-drug use *{includes taking illegal drugs by route other than needle}*

DS-25-19 Sex partner used non-IV drugs

DS-25-20 Donor lived in or immigrated from an HIV Group O risk area

DS-25-21 Sex partner lived in or immigrated from an HIV Group O risk area

DS-25-22 Exchanged sex for drugs or money

DS-25-23 Sex partner exchanged sex for drugs or money

DS-25-24 Donor received tattoo

DS-25-25 Donor received ear piercing

DS-25-26 Donor received body piercing

DS-25-27 Donor received accidental needlestick

DS-25-28 Donor received transfusion or clotting factors

DS-25-29 Donor received tissue allograft or transplanted organ

†DS-25-30 Donor was exposed to blood or body fluids *{includes: animal bite; human bite; occupational exposure; scarification; branding; exposure not specified}*

DS-25-31 Donor had multiple blood or body fluid exposures, *{includes: tattoo and piercing; does not include multiple exposures of the same type, such as multiple tattoos}*

DS-25-32 Non-sexual exposure to HIV

DS-25-33 Non-sexual exposure to hepatitis, type not specified

DS-25-34 Non-sexual exposure to Hepatitis B

DS-25-35 Non-sexual exposure to Hepatitis C

DS-25-36 Travel to malaria endemic area/history of malaria

†DS-25-37 History of disease or surgery *{condition or disease existed prior to donation; does not include diseases affecting donor safety only, e.g., heart disease}*

DS-25-40 Risk factors associated with Creutzfeldt-Jakob Disease - brain surgery

DS-25-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history

DS-25-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel

DS-25-43 Risk factors associated with Creutzfeldt-Jakob Disease - received insulin or other bovine derived product

DS-25-44 Received growth hormone

DS-25-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, or Avodart

DS-25-46 Received medication or antibiotics

DS-25-47 Received vaccine or immune globulin

DS-25-48 Exposure to a disease

DS-25-49 Incarcerated

DS-25-50 Resided in a rehabilitation center or psychiatric hospital

DS-25-51 History of Hepatitis A

DS-25-52 Exposure to Hepatitis A

DS-25-53 Multiple high risk behaviors/contacts

DS-25-54 Positive drug screen

DS-25-55 Deferred by another center – reason unknown

†DS-25-56 Travel to leishmania risk area *{e.g., Baghdad, Tikrit, Ramadi}*

†DS-25-57 Travel to leishmania and malarial endemic area *{e.g., Afghanistan, Iraq (except Baghdad, Tikrit, Ramadi)}*

DS-26-** Incorrect ID used during deferral search

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

DS-27-** Incorrect ID used during deferral search, donor previously deferred due to testing *{use DS27** when the deferral file is checked using incorrect donor identification information and the donor was previously deferred due to testing}*

DS-27-01 Other

DS-27-02 HIV reactive

DS-27-03 HBsAg reactive

DS-27-04 Anti-HBc reactive

DS-27-05 Anti-HCV reactive

DS-27-06 Anti-HTLV-I reactive

DS-27-07 ALT elevated

DS-27-08 Syphilis reactive

DS-28-** Incorrect ID used during deferral search, donor previously deferred due to history *{use DS28** when the deferral file is checked using incorrect donor identification information 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; rape; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions}*

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 Sexually transmitted disease

DS-28-07 Sex partner has or had a sexually transmitted disease

DS-28-08 Sex partner tested reactive for HIV

- DS-28-09 Sex partner tested reactive for HTLV
- DS-28-10 Sex partner tested reactive for HBV
- DS-28-11 Sex partner tested reactive for HCV
- DS-28-12 Sex partner tested reactive for hepatitis, not specified
- †DS-28-13 Sex partner unsuitable or engaged in high risk behavior *{includes: sex partner- received clotting factor; incarcerated; history of jaundice; deferred by another center or on national or state deferral list, tested reactive for a viral marker or history/behavior unknown or not specified}*
- 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 *{includes taking illegal drugs by needle, e.g., IM}*
- DS-28-17 Sex with IV drug user
- †DS-28-18 Non-IV-drug use *{includes taking illegal drugs by route other than needle}*
- DS-28-19 Sex partner used non-IV drugs
- DS-28-20 Donor lived in or immigrated from an HIV Group O risk area
- DS-28-21 Sex partner lived in or immigrated from an HIV Group O risk area
- DS-28-22 Exchanged sex for drugs or money
- DS-28-23 Sex partner exchanged sex for drugs or money
- DS-28-24 Donor received tattoo
- DS-28-25 Donor received ear piercing
- DS-28-26 Donor received body piercing
- DS-28-27 Donor received accidental needlestick
- DS-28-28 Donor received transfusion or clotting factors
- DS-28-29 Donor received tissue allograft or transplanted organ
- †DS-28-30 Donor was exposed to blood or body fluids *{includes: animal bite; human bite; occupational exposure; scarification; branding; exposure not specified}*
- DS-28-31 Donor had multiple blood or body fluid exposures *{includes: tattoo and piercing; does not include multiple exposures of the same type, such as multiple tattoos}*
- DS-28-32 Non-sexual exposure to HIV
- DS-28-33 Non-sexual exposure to hepatitis, type not specified
- DS-28-34 Non-sexual exposure to Hepatitis B
- DS-28-35 Non-sexual exposure to Hepatitis C
- DS-28-36 Travel to malaria endemic area/history of malaria
- †DS-28-37 History of disease or surgery *{condition or disease existed prior to donation; does not include diseases affecting donor safety only, e.g., heart disease}*
- DS-28-40 Risk factors associated with Creutzfeldt-Jakob Disease - brain surgery
- 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 insulin or other bovine derived product
- DS-28-44 Received growth hormone
- DS-28-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, or Avodart
- DS-28-46 Received medication or antibiotics
- DS-28-47 Received vaccine or immune globulin
- DS-28-48 Exposure to a disease
- DS-28-49 Incarcerated
- DS-28-50 Resided in a rehabilitation center or psychiatric hospital
- DS-28-51 History of Hepatitis A
- DS-28-52 Exposure to Hepatitis A
- DS-28-53 Multiple high risk behaviors/contacts
- DS-28-54 Positive drug screen
- DS-28-55 Deferred by another center – reason unknown
- †DS-28-56 Travel to leishmania risk area *{e.g., Baghdad, Tikrit, Ramadi}*
- †DS-28-57 Travel to leishmania and malarial endemic area *{e.g., Afghanistan, Iraq (except Baghdad, Tikrit, Ramadi)}*

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; rape; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions; response to educational material/AIDS questions unacceptable}*

DS-29-02 History of hepatitis, not specified

DS-29-03 History of jaundice

DS-29-04 History of Hepatitis B

DS-29-05 History of Hepatitis C

DS-29-06 Sexually transmitted disease

DS-29-07 Sex partner has or had a sexually transmitted disease

DS-29-08 Sex partner tested reactive for HIV

DS-29-09 Sex partner tested reactive for HTLV

DS-29-10 Sex partner tested reactive for HBV

DS-29-11 Sex partner tested reactive for HCV

DS-29-12 Sex partner tested reactive positive for hepatitis, not specified

†DS-29-13 Sex partner unsuitable or engaged in high risk behavior *{includes: sex partner- received clotting factor; incarcerated; history of jaundice; deferred by another center or on national or state deferral list, tested reactive for a viral marker or history/behavior unknown or not specified}*

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 *{includes taking illegal drugs by needle, e.g., IM}*

DS-29-17 Sex with IV drug user

†DS-29-18 Non-IV-drug use *{includes taking illegal drugs by route other than needle}*

DS-29-19 Sex partner used non-IV drugs

DS-29-20 Donor lived in or immigrated from an HIV Group O risk area

DS-29-21 Sex partner lived in or immigrated from an HIV Group O risk area

DS-29-22 Exchanged sex for drugs or money

DS-29-23 Sex partner exchanged sex for drugs or money

DS-29-24 Donor received tattoo

DS-29-25 Donor received ear piercing

DS-29-26 Donor received body piercing

DS-29-27 Donor received accidental needlestick

DS-29-28 Donor received transfusion or clotting factors

DS-29-29 Donor received tissue allograft or transplanted organ

†DS-29-30 Donor was exposed to blood or body fluids *{includes: animal bite; human bite; occupational exposure; scarification; branding; exposure not specified}*

DS-29-31 Donor had multiple blood or body fluid exposures *{includes: tattoo and piercing; does not include multiple exposures of the same type, such as multiple tattoos}*

DS-29-32 Non-sexual exposure to HIV

DS-29-33 Non-sexual exposure to hepatitis, type not specified

DS-29-34 Non-sexual exposure to Hepatitis B

DS-29-35 Non-sexual exposure to Hepatitis C

DS-29-36 Travel to malaria endemic area/history of malaria

†DS-29-37 History of disease or surgery *{condition or disease existed prior to donation; does not include diseases affecting donor safety only, e.g., heart disease}*

DS-29-40 Risk factors associated with Creutzfeldt-Jakob Disease - brain surgery

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 insulin or other bovine derived product

DS-29-44 Received growth hormone

DS-29-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, or Avodart
DS-29-46 Received medication or antibiotics
DS-29-47 Received vaccine or immune globulin
DS-29-48 Exposure to a disease
DS-29-49 Incarcerated
DS-29-50 Resided in a rehabilitation center or psychiatric hospital
DS-29-51 History of Hepatitis A
DS-29-52 Exposure to Hepatitis A
DS-29-53 Multiple high risk behaviors/contacts
DS-29-54 Positive drug screen
DS-29-55 Deferred by another center – reason unknown
†DS-29-56 Travel to leishmania risk area {e.g., Baghdad, Tikrit, Ramadi}
†DS-29-57 Travel to leishmania and malarial endemic area {e.g., Afghanistan, Iraq
(except Baghdad, Tikrit, Ramadi)}

DD-**-** DONOR DEFERRAL (Back to top)

DD-30-**-** Miscellaneous
DD-30-01 Other

DD-31-**-** Donor missing or incorrectly identified on deferral list, donor was or should have been previously deferred due to testing: {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}

DD-31-01 Other
DD-31-02 HIV reactive
DD-31-03 HBsAg reactive
DD-31-04 Anti-HBc reactive
DD-31-05 Anti-HCV reactive
DD-31-06 Anti-HTLV reactive
DD-31-07 ALT elevated
DD-31-08 Syphilis reactive

DD-32-**-** Donor missing 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}

†DD-32-01 Other {includes: type of behavior or history unknown or not specified; unacceptable address; rape; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions}

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 Sexually transmitted disease
DD-32-07 Sex partner has or had sexually transmitted disease
DD-32-08 Sex partner tested reactive for HIV
DD-32-09 Sex partner tested reactive for HTLV
DD-32-10 Sex partner tested reactive for HBV
DD-32-11 Sex partner tested reactive for HCV
DD-32-12 Sex partner tested reactive for hepatitis, not specified

†DD-32-13 Sex partner unsuitable or engaged in high risk behavior {includes: sex partner- received clotting factor; incarcerated; history of jaundice; deferred by another center or on national or state deferral list, tested reactive for a viral marker or history/behavior unknown or not specified}

- 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 *{includes taking illegal drugs by needle, e.g., IM}*
- DD-32-17 Sex with IV drug user
- †DD-32-18 Non-IV-drug use *{includes taking illegal drugs by route other than needle}*
- DD-32-19 Sex partner used non-IV drugs
- DD-32-20 Donor lived in or immigrated from an HIV Group O risk area
- DD-32-21 Sex partner lived in or immigrated from an HIV Group O risk area
- DD-32-22 Exchanged sex for drugs or money
- DD-32-23 Sex partner exchanged sex for drugs or money
- DD-32-24 Donor received tattoo
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- DD-32-31 Donor had multiple blood or body fluid exposures *{includes: tattoo and piercing; does not include multiple exposures of the same type, such as multiple tattoos}*
- DD-32-32 Non-sexual exposure to HIV
- DD-32-33 Non-sexual exposure to hepatitis, type not specified
- DD-32-34 Non-sexual exposure to Hepatitis B
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- DD-32-49 Incarcerated
- DD-32-50 Resided in a rehabilitation center or psychiatric hospital
- DD-32-51 History of Hepatitis A
- DD-32-52 Exposure to Hepatitis A
- DD-32-53 Multiple high risk behaviors/contacts
- DD-32-54 Positive drug screen
- DD-32-55 Deferred by another center – reason unknown
- †DD-32-56 Travel to leishmania risk area *{e.g., Baghdad, Tikrit, Ramadi}*
- †DD-32-57 Travel to leishmania and malarial endemic area *{e.g., Afghanistan, Iraq (except Baghdad, Tikrit, Ramadi)}*

DD-34-** Donor incorrectly deleted from deferral list or donor not reentered properly, donor previously deferred due to testing: *{use DD34** if the donor was deferred due to testing at a previous donation and was either inappropriately removed from the deferral list or not reentered properly}*

- DD-34-01 Other
- DD-34-02 HIV reactive
- DD-34-03 HBsAg reactive

DD-34-04 Anti-HBc reactive
DD-34-05 Anti-HCV reactive
DD-34-06 Anti-HTLV reactive
DD-34-07 ALT elevated
DD-34-08 Syphilis reactive

DD-35-** Donor incorrectly deleted from deferral list, donor previously deferred due to history: *{use DD35** if the donor was deferred due to history at a previous donation and was inappropriately removed from the deferral list}*

†DD-35-01 Other *{includes: type of behavior or history unknown or not specified; unacceptable address; rape; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions}*

DD-35-02 History of hepatitis, not specified

DD-35-03 History of jaundice

DD-35-04 History of Hepatitis B

DD-35-05 History of Hepatitis C

DD-35-06 Sexually transmitted disease

DD-35-07 Sex partner has or had a sexually transmitted disease

DD-35-08 Sex partner tested reactive for HIV

DD-35-09 Sex partner tested reactive for HTLV

DD-35-10 Sex partner tested reactive for HBV

DD-35-11 Sex partner tested reactive for HCV

DD-35-12 Sex partner tested reactive for hepatitis, not specified

†DD-35-13 Sex partner unsuitable or engaged in high risk behavior *{includes: sex partner- received clotting factor; incarcerated; history of jaundice; deferred by another center or on national or state deferral list, tested reactive for a viral marker or history/behavior unknown or not specified}*

DD-35-14 Male donor had sex with another man

DD-35-15 Female had sex with a man who had sex with another man

†DD-35-16 IV drug use *{includes taking illegal drugs by needle, e.g., IM}*

DD-35-17 Sex with IV drug user

†DD-35-18 Non-IV-drug use *{includes taking illegal drugs by route other than needle}*

DD-35-19 Sex partner used non-IV drugs

DD-35-20 Donor lived in or immigrated from an HIV Group O risk area

DD-35-21 Sex partner lived in or immigrated from an HIV Group O risk area

DD-35-22 Exchanged sex for drugs or money

DD-35-23 Sex partner exchanged sex for drugs or money

DD-35-24 Donor received tattoo

DD-35-25 Donor received ear piercing

DD-35-26 Donor received body piercing

DD-35-27 Donor received accidental needlestick

DD-35-28 Donor received transfusion or clotting factors

DD-35-29 Donor received tissue allograft or transplanted organ

†DD-35-30 Donor was exposed to blood or body fluids *{includes: animal bite; human bite; occupational exposure; scarification; branding; exposure not specified}*

DD-35-31 Donor had multiple blood or body fluid exposures *{includes: tattoo and piercing; does not include multiple exposures of the same type, such as multiple tattoos}*

DD-35-32 Non-sexual exposure to HIV

DD-35-33 Non-sexual exposure to hepatitis, type not specified

DD-35-34 Non-sexual exposure to Hepatitis B

DD-35-35 Non-sexual exposure to Hepatitis C

DD-35-36 Travel to malaria endemic area/history of malaria

†DD-35-37 History of disease or surgery *{condition or disease existed prior to donation; does not include diseases affecting donor safety only, e.g., heart disease}*

DD-35-40 Risk factors associated with Creutzfeldt-Jakob Disease - brain surgery

DD-35-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history

DD-35-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel
DD-35-43 Risk factors associated with Creutzfeldt-Jakob Disease - received insulin or other bovine derived product
DD-35-44 Received growth hormone
DD-35-45 Received finasteride, (Proscar or Propecia), Tegison, Accutane, or Avodart
DD-35-46 Received medication or antibiotics
DD-35-47 Received vaccine or immune globulin
DD-35-48 Exposure to a disease
DD-35-49 Incarcerated
DD-35-50 Resided in a rehabilitation center or psychiatric hospital
DD-35-51 History of Hepatitis A
DD-35-52 Exposure to Hepatitis A
DD-35-53 Multiple high risk behaviors/contacts
DD-35-54 Positive drug screen
DD-35-55 Deferred by another center – reason unknown
†DD-35-56 Travel to leishmania risk area {e.g., Baghdad, Tikrit, Ramadi}
†DD-35-57 Travel to leishmania and malarial endemic area {e.g., Afghanistan, Iraq (except Baghdad, Tikrit, Ramadi)}

BC-**-** BLOOD COLLECTION (Back to top)

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 product was prepared in an open system (e.g. pooled Platelets), use CP5102; if contamination was found during Bacterial Detection Testing (product QC), use QC9404}

BC-41-03 Air contamination {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-43-02 Collection time extended, discrepant, or not documented; not discovered prior to component preparation

BC-43-03 Overbleed; not discovered prior to component preparation

BC-43-04 Collection status not documented or discrepant

†BC-43-05 Product contained clots, 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 not required if hemolyzed product discovered after consignee accepted it into their inventory}

BC-43-07 Source Plasma from two different donors pooled into one pooling bottle
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 (Back to top)

CP-50-** Miscellaneous

CP-50-01 Other

CP-51-** Sterility compromised

CP-51-01 Other

CP-51-02 Bacterial contamination (identify organism if possible) *{use CP5102 if the contamination may be related to products prepared in an open system, e.g., pooled, washed, deglycerolized; if contamination is discovered during Bacterial Detection testing, use QC9404}*

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-52-03 Resting time requirements not met for Platelets

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 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 leukoreduced after 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 no documentation of weld inspection}*

CP-53-** Component prepared from Whole Blood unit that was
CP-53-01 Other
CP-53-02 Overweight
CP-53-03 Underweight
CP-53-04 Collected or stored at unacceptable or undocumented temperature
CP-53-05 A difficult collection or had an extended collection time

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 (Back to top)

VT-**-** VIRAL TESTING (Back to top)

VT-70-** Miscellaneous
VT-70-01 Other

†VT-71-** Testing performed, interpreted or documented incorrectly (includes QC not performed or unacceptable) for: *{use VT71** only if testing was performed, interpreted or documented incorrectly; use QC92** if testing is positive or use QC93** if testing is not performed, incompletely performed, or not documented}*

VT-71-01 HBsAg
VT-71-02 Anti-HIV-1
VT-71-03 Anti-HIV-2
VT-71-04 Anti-HIV-1/2
VT-71-05 HIV Antigen
VT-71-06 Syphilis
VT-71-07 Anti-HTLV
VT-71-08 Anti-HBc
VT-71-09 ALT
VT-71-10 Anti-HCV
VT-71-11 More than 1 test, e.g., all viral markers
VT-71-12 Cytomegalovirus
VT-71-13 HIV Nucleic Acid Test (NAT)
VT-71-14 HCV Nucleic Acid Test (NAT)
VT-71-15 HIV/HCV Nucleic Acid Test (NAT)
VT-71-16 HBV Nucleic Acid Test (NAT)
VT-71-17 West Nile Virus

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 (Back to top)

RT-60-** Miscellaneous
RT-60-01 Other

†RT-61-** Testing performed, interpreted, or documented incorrectly for: *{use RT61** only if testing was performed, interpreted or documented incorrectly; use QC92** if testing positive or use QC93** if testing is not performed incompletely performed or not documented}*

RT-61-01 Other *{includes: DAT; Hemoglobin S testing}*
RT-61-02 ABO

RT-61-03 Rh
RT-61-04 ABO & Rh
RT-61-05 Antibody screening or identification
RT-61-06 Antigen typing
RT-61-07 Platelet count
RT-61-08 Compatibility *{includes electronic or immediate spin crossmatch performed instead of full crossmatch, when required}*
RT-61-09 ABO, Rh, and antibody screen
RT-61-10 ABO, Rh, antibody screen, and compatibility
RT-61-11 Antibody screen and compatibility

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

RT-63-** Testing performed using reagents in which QC was unacceptable or not performed, or expired reagents were used

RT-63-01 Other
RT-63-02 ABO
RT-63-03 Rh
RT-63-04 ABO & Rh
RT-63-05 Antibody screening or identification
RT-63-06 Antigen typing
RT-63-07 Multiple testing *{includes all routine testing}*
RT-63-08 Coombs control cells

LA-**-** LABELING (Back to top)

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

LA-81-** Labels applied to blood unit or product 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
LA-81-03 ABO and/or Rh missing
LA-81-04 Product type or code incorrect (e.g., RBC labeled as Whole Blood) *{do not use LA8104 if there is a specific code available, e.g. use LA8113 if unit not labeled as leukoreduced}*
LA-81-05 Product type or code missing
LA-81-06 Extended expiration date or time
LA-81-07 Missing expiration date or time
LA-81-08 Anticoagulant incorrect or missing
LA-81-09 Donor number or lot number incorrect or missing
†LA-81-10 Combination of incorrect or missing information *{e.g., unit number and expiration date}*
†LA-81-11 Product or anticoagulant volume or weight incorrect or missing
LA-81-12 Irradiation status incorrect or missing
LA-81-13 Leukoreduction status incorrect or missing
LA-81-14 Irradiation and leukoreduction status incorrect or missing
LA-81-15 CMV status incorrect or missing
†LA-81-16 Machine-readable bar code incorrect or missing *{Lot number, product code, or ABO and Rh of the donor}*

†LA-82-** Crossmatch tag or tie tag incorrect or missing information *{Use LA-82 if tag physically attached to the unit is incorrect or missing information, or both the tag and transfusion record are incorrect or missing information; Use LA-83 if transfusion record, accompanied with unit, is incorrect or missing information}*

LA-82-01 Other *{includes: Hemoglobin S; 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 incorrect or missing

LA-82-05 Expiration date or time extended or missing

LA-82-06 Unit, lot or pool number incorrect or missing

LA-82-07 Recipient identification incorrect or missing (specify if autologous unit)

LA-82-08 Antigen incorrect or missing

LA-82-09 Antibody incorrect or missing

LA-82-10 Platelet count incorrect or missing

LA-82-11 HLA type incorrect or missing

†LA-82-12 Product or anticoagulant volume or weight incorrect or missing

LA-82-13 CMV status incorrect or missing

LA-82-14 Irradiation status incorrect or missing

LA-82-15 Leukoreduced status incorrect or missing

LA-82-16 Crossmatch tag switched, both units intended for the same patient

†LA-82-17 Compatibility information incorrect or missing

LA-82-18 Biohazard or test status incorrect or missing *{includes autologous unit with a positive viral marker not labeled appropriately}*

†LA-82-19 Combination of incorrect or missing information *{e.g., unit number and expiration date}*

†LA-82-20 Crossmatch tag or tie tag missing or attached to incorrect unit *{e.g., intended for different patient}*

†LA-83-** Transfusion record incorrect or missing

information *{Use LA-83 if transfusion record, accompanied with unit, is incorrect or missing information; Use LA-82 if tag physically attached to the unit is incorrect or missing information or both the tag and transfusion record are incorrect or missing information}*

LA-83-01 Other *{includes incorrect dosage for Rh Immune Globulin or factor concentrates}*

LA-83-02 Unit ABO and/or Rh incorrect or missing

LA-83-03 Recipient ABO and/or Rh incorrect or missing

LA-83-04 Product type incorrect or missing

LA-83-05 Expiration date or time extended or missing

LA-83-06 Unit, lot or pool number incorrect or missing

LA-83-07 Recipient identification incorrect or missing (specify if autologous unit)

LA-83-08 Antigen incorrect or missing

LA-83-09 Antibody incorrect or missing

LA-83-10 Platelet count incorrect or missing

LA-83-11 HLA type incorrect or missing

†LA-83-12 Product or volume or weight incorrect or missing

LA-83-13 CMV status incorrect or missing

LA-83-14 Irradiation status incorrect or missing

LA-83-15 Leukoreduced status incorrect or missing

LA-83-16 Transfusion records switched, both units intended for the same patient

†LA-83-17 Compatibility information incorrect or missing

LA-83-18 Biohazard or test status incorrect or missing

†LA-83-19 Combination of incorrect or missing information *{e.g., unit number and expiration date}*

†LA-83-20 Transfusion record missing or attached to incorrect unit *{e.g., intended for different patient}*

QC-**-** QUALITY CONTROL and DISTRIBUTION (Back to top)

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; rape; donor unreliable, for example mental status questionable or donor unable to comprehend donor history questions}*

QC-91-02 History of hepatitis, not specified

QC-91-03 History of jaundice

QC-91-04 History of Hepatitis B

QC-91-05 History of Hepatitis C

QC-91-06 Sexually transmitted disease

QC-91-07 Sex partner has or had a sexually transmitted disease

QC-91-08 Sex partner tested reactive for HIV

QC-91-09 Sex partner tested reactive for HTLV

QC-91-10 Sex partner tested reactive for HBV

QC-91-11 Sex partner tested reactive for HCV

QC-91-12 Sex partner tested reactive for hepatitis, not specified

†QC-91-13 Sex partner unsuitable or engaged in high risk behavior *{includes: sex partner- received clotting factor; incarcerated; history of jaundice; deferred by another center or on national or state deferral list, tested reactive for a viral marker or history/behavior unknown or not specified}*

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 *{includes taking illegal drugs by needle, e.g., IM}*

QC-91-17 Sex with IV drug user

†QC-91-18 Non-IV-drug use *{includes taking illegal drugs by route other than needle}*

QC-91-19 Sex partner used non-IV drugs

QC-91-20 Donor lived in or immigrated from an HIV Group O risk area

QC-91-21 Sex partner lived in or immigrated from an HIV Group O risk area

QC-91-22 Exchanged sex for drugs or money

QC-91-23 Sex partner exchanged sex for drugs or money

QC-91-24 Donor received tattoo

QC-91-25 Donor received ear piercing

QC-91-26 Donor received body piercing

QC-91-27 Donor received accidental needlestick

QC-91-28 Donor received transfusion or clotting factors

QC-91-29 Donor received tissue allograft or transplanted organ

†QC-91-30 Donor was exposed to blood or body fluids *{includes: animal bite; human bite; occupational exposure; scarification; branding; exposure not specified}*

QC-91-31 Donor had multiple blood or body fluid exposures *{includes: tattoo and piercing; does not include multiple exposures of the same type, such as multiple tattoos}*

QC-91-32 Non-sexual exposure to HIV

QC-91-33 Non-sexual exposure to hepatitis, type not specified

QC-91-34 Non-sexual exposure to Hepatitis B

QC-91-35 Non-sexual exposure to Hepatitis C

QC-91-36 Travel to malaria endemic area/history of malaria

†QC-91-37 History of disease or surgery *{condition or disease existed prior to donation; does not include diseases affecting donor safety only, e.g., heart disease}*

QC-91-39 History of Creutzfeldt-Jakob Disease

QC-91-40 Risk factors associated with Creutzfeldt-Jakob Disease - brain surgery

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 insulin or other bovine derived product

QC-91-44 Received growth hormone

QC-91-45 Received finasteride, (Proscar or Propecia), Tegison, Accutane, or Avodart

QC-91-46 Received medication or antibiotics

QC-91-47 Received vaccine or immune globulin

QC-91-48 Exposure to a disease

QC-91-49 Incarcerated

QC-91-50 Resided in a rehabilitation center or psychiatric hospital

QC-91-51 History of Hepatitis A

QC-91-52 Exposure to Hepatitis A

QC-91-53 Multiple high risk behaviors/contacts

QC-91-54 Positive drug screen

QC-91-55 Deferred by another center

QC-91-56 Post donation illness

†QC-91-57 Travel to leishmania risk area *{e.g., Baghdad, Tikrit, Ramadi}*

†QC-91-58 Travel to leishmania and malarial endemic area *{e.g., Afghanistan, Iraq (except Baghdad, Tikrit, Ramadi)}*

†QC-92-** Positive testing for: *{Use RT61** if testing was performed incorrectly, use QC93** if testing was not performed, incompletely performed or not documented}*

†QC-92-01 Other *{includes: Hemoglobin S; drug screen; West Nile Virus; Parvovirus, Babsia; Chagas; DAT}*

†QC-92-02 HIV *{includes failure to quarantine a non-reactive unit collected from a donor who previously or subsequently tested positive}*

†QC-92-03 HBsAg *{includes failure to quarantine a non-reactive unit collected from a donor who previously or subsequently tested positive}*

†QC-92-04 Anti-HBc *{includes failure to quarantine a non-reactive unit collected from a donor who previously or subsequently tested positive}*

†QC-92-05 Anti-HCV *{includes failure to quarantine a non-reactive unit collected from a donor who previously or subsequently tested positive}*

†QC-92-06 Anti-HTLV *{includes failure to quarantine a non-reactive unit collected from a donor who previously or subsequently tested positive}*

†QC-92-07 ALT elevated *{includes failure to quarantine a unit with normal ALT collected from a donor who previously or subsequently had an elevated ALT}*

QC-92-10 Antibody screen or identification (donor/unit or recipient)

QC-92-11 Antigen screen

†QC-92-12 Syphilis *{includes failure to quarantine a non-reactive unit collected from a donor who previously or subsequently tested positive}*

QC-92-13 All viral markers

QC-92-14 Compatibility

QC-92-15 HIV/HCV Nucleic Acid Test (NAT)

†QC-93-** Testing not performed, incompletely performed or not documented for: *{use RT61** if testing was performed incorrectly, use QC92** if testing was positive}*

QC-93-01 Other *{includes: Hemoglobin S; drug screen; West Nile Virus; Parvovirus}*

QC-93-02 HIV

QC-93-03 HBsAg

QC-93-04 Anti-HBc

QC-93-05 Anti-HCV

QC-93-06 Anti-HTLV

QC-93-07 ALT

QC-93-08 ABO (donor/unit or recipient)

QC-93-09 Rh (donor/unit or recipient)

QC-93-10 Antibody screen or identification (donor/unit or recipient)

QC-93-11 Antigen screen *{use QC9311 if patient has history of positive antibody screen and unit is not screened for corresponding antigen}*

QC-93-12 Syphilis

QC-93-13 All viral markers

QC-93-14 Compatibility

QC-93-15 HIV/HCV Nucleic Acid Test (NAT)

QC-93-16 ABO and Rh (donor/unit or recipient)

QC-93-17 ABO/Rh and antibody screen (donor/unit or recipient)

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

QC-94-01 Other *{includes inappropriate release of Rh Immune Globulin; product distributed prior to required record review}*

QC-94-02 Outdated product

QC-94-03 Autologous unit not meeting homologous criteria

†QC-94-04 Product QC unacceptable (e.g., positive), not performed, not documented, or incomplete *{includes: platelet count; product hematocrit/hemoglobin; RBC recovery; absolute red cell volume or product volume; WBC count; pH (specify if used as a test for bacterial detection); bacterial detection testing; product QC not performed during validation of apheresis machine}*

†QC-94-05 Product in which specification other than QC not met *{includes incorrect dose; age of product; appearance}*

†QC-94-06 Product in which instrument QC 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}*

†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; do not use QC9408 if more specific code applies, such as QC9412 through QC9416}*

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; if consignee discovers component is clotted or hemolyzed and associated components were also distributed, use BC4305(clotted) or BC4306(hemolyzed)}*

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: collection time extended, discrepant, or not documented}*

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; includes: donor history question not answered or incomplete; abbreviated donor history questionnaire used instead of full-length}*

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-96-** Shipping and storage

QC-96-01 Other

†QC-96-02 Arrived at consignee at unacceptable temperature *{use this code if shipment was packed appropriately, but the temperature upon arrival was unacceptable}*

QC-96-03 Stored at incorrect temperature

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

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

QC-96-06 Shipment exceeded time allowed for shipping

QC-96-07 Product not packed in accordance with specifications

†QC-96-08 Product returned to blood center and reissued inappropriately *{includes no record of inspection upon return; if specific to temperature, use QC-96-05}*

†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 *{includes: product not Hemoglobin S negative as required}*

QC-97-02 Product not irradiated as required

QC-97-03 Product issued to wrong patient

QC-97-04 Improper product selected for patient

QC-97-05 Improper ABO or Rh type selected for patient

QC-97-06 Product not leukoreduced as required

QC-97-07 Product released prior to obtaining current sample for ABO, Rh, antibody screen and/or compatibility testing

QC-97-08 Product not CMV negative as required

QC-97-10 Filter not issued with product or incorrect filter issued

QC-97-11 Product not irradiated and leukoreduced as required

QC-97-12 Product not irradiated and CMV negative as required

QC-97-13 Procedure for issuing not performed or documented in accordance with specifications *{includes: request slip labeled with incorrect or missing patient identification; emergency release procedure not followed}*

QC-97-14 ABO and/or Rh retype of unit not performed or performed incorrectly

QC-97-15 Visual inspection not performed or documented

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 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

MI-**-** MISCELLANEOUS (Back to top)

MI-00-** Miscellaneous

MI-00-01 Other

MI-01-** Donor implicated in transfusion associated disease

MI-01-01 Other

MI-01-02 HIV

MI-01-03 Hepatitis

MI-01-04 West Nile Virus

MI-01-05 Babesia

†MI-01-06 Chagas

MI-02-** Lookback; subsequent unit tested confirmed positive for: *{use MI02** when confirmatory or additional supplemental testing is positive; if confirmatory or additional supplemental testing is not positive, a report is not required}*

MI-02-01 Other

MI-02-02 HIV

MI-02-03 HBV

MI-02-04 HCV

MI-02-05 West Nile Virus

MI-02-06 HTLV

†MI-02-07 Babesia

†MI-02-08 Chagas

??-??-?? DO NOT KNOW

Non-Blood BPD Codes (Back to top)

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," (www.fda.gov/CBER/gdlns/devnbld.htm) to determine if you must report an event. The list includes deviations from regulations, standards, and standard operating procedures (SOPs) that may affect the safety, purity, or potency of a product. These codes may not apply to all establishments because they include deviations and unexpected events related to SOPs implemented at individual establishments and may not be an industry standard or a procedure at your facility. The use of BPD Codes will assist the FDA in analyzing the data submitted and streamline the trend analysis.

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

IM-**-** INCOMING MATERIAL SPECIFICATIONS (Back to Non-Blood)

- 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}*

- IM-14-02 Contains precipitate
 - 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 (Back to Non-Blood)

- 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
- PC-22-04 Equipment not performing properly
- PC-22-05 Sanitization procedures 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 material does not meet specifications or otherwise found to be unsuitable
 - PC-24-01 Other
 - PC-24-02 Contains precipitate
 - 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 (Back to Non-Blood)

- 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 (Back to Non-Blood)

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

- LA-41-** Package insert
 - LA-41-01 Incorrect
 - LA-41-02 Missing

LA-41-03 Not current or approved

LA-42-** Product label

LA-42-01 Incorrect

LA-42-02 Missing

LA-43-** Carton label

LA-43-01 Incorrect

LA-43-02 Missing

LA-44-** Expiration date

LA-44-01 Extended

LA-44-02 Missing

LA-45-** Lot number

LA-45-01 Incorrect

LA-45-02 Missing

LA-46-** Storage temperature

LA-46-01 Incorrect

LA-46-02 Missing

LA-47-** Administration route

LA-47-01 Incorrect

LA-47-02 Missing

LA-48-** Concentration or volume

LA-48-01 Incorrect

LA-48-02 Missing

PS-**-** PRODUCT SPECIFICATIONS (Back to Non-Blood)

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}*

PS-51-10 Fill volume

PS-52-**Component packaged with final product did not meet specifications

PS-52-01 Other

PS-52-02 Contains precipitate

PS-52-03 Contaminated with microorganism

PS-52-04 Contaminated with mold

PS-52-05 Fill volume

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-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 Back to Non-Blood)
 - 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-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

- MI-**-** MISCELLANEOUS (Back to Non-Blood)
 - MI-70-** Miscellaneous
 - MI-70-01 Other

??-??-?? DO NOT KNOW

Deviation Codes for Human Cells, Tissues and Cellular and Tissue-based Products (HCT/P)

Use the following list of Deviation Codes for Human Cells, Tissues and Cellular and Tissue-based Products to assign a specific code to a reportable event when you submit the report to FDA. The list includes numerous HCT/P deviations [see 1271.3(dd)] that may occur. However, an event is only required to be reported [see 1271.350(b)(2)] if it relates to “core Current Good Tissue Practices” [see 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.

The use of the HCT/P deviation codes will assist the FDA in analyzing the data submitted and streamline the trend analysis.

DE - Donor Eligibility
DS - Donor Screening
DT - Donor Testing
EC - Environmental Control
SR - Supplies and Reagents
RE - Recovery
PC - Processing and Processing Controls
LC - Labeling Controls
ST - Storage
SD - Receipt, Pre-Distribution, Shipment, and Distribution

DE--** – Donor Eligibility**

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

DE-01-**- Not performed or documented [except as provided in 1271.90]
DE-01-01 - Donor screening not performed or documented
DE-01-02 - Donor testing not performed or documented
DE-01-03 - Donor screening and testing not performed or documented

DE-02-**- Ineligible donor accepted [except as provided in 1271.65(b)]
DE-02-01 - Risk factors, clinical evidence or physical evidence identified
DE-02-02 - Xenotransplant recipient accepted as donor
DE-02-03 - Abbreviated donor screening inappropriately used or not performed
DE-02-04 - Donor tested reactive for relevant communicable disease
DE-02-05 - Donor of viable, leukocyte-rich HCT/PS not properly evaluated for evidence of infection due to cytomegalovirus
DE-02-06 - Assessment to detect evidence of TSE not performed for dura mater donor
DE-02-07 - Donor incorrectly evaluated for plasma dilution
DE-02-08 - Donor not evaluated or evaluation not documented for plasma dilution

DS--** – Donor Screening**

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

DS-01-**- Donor screening not performed or documented in the:
DS-01-01 - Donor medical history interview
DS-01-02 - Physical assessment of a cadaveric donor or physical examination of a living donor
DS-01-03 - Medical record review
DS-01-04 - Evaluation of communicable disease risks associated with xenotransplant

DS-02-**- Donor screening performed incorrectly (incomplete or inaccurate) 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

DT--** – Donor Testing**

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

DT-01-**- Testing not performed or documented when required, for:

- DT-01-01 - Human immunodeficiency virus, type 1
- DT-01-02 - Human immunodeficiency virus, type 2
- DT-01-03 - Hepatitis B virus
- DT-01-04 - Hepatitis C virus
- DT-01-05 - Treponema pallidum
- DT-01-06 - Human T-lymphotropic virus, type I
- DT-01-07 - Human T-lymphotropic virus, type II
- DT-01-08 - Cytomegalovirus
- DT-01-11 – Multiple tests

DT-02-**- Testing incorrectly performed when required, for:

- DT-02-01 - Human immunodeficiency virus, type 1
- DT-02-02 - Human immunodeficiency virus, type 2
- DT-02-03 - Hepatitis B virus
- DT-02-04 - Hepatitis C virus
- DT-02-05 - Treponema pallidum
- DT-02-06 - Human T-lymphotropic virus, type I
- DT-02-07 - Human T-lymphotropic virus, type II
- 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
- 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-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

EC--** - Environmental Control**

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

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 controls
- EC-01-04 - Cleaning and disinfecting of rooms
- EC-01-05 - Maintenance of environmental monitoring and control equipment

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 controls
EC-02-04 - Cleaning and disinfecting of rooms
EC-02-05 - Maintenance of environmental monitoring and control equipment

SR--** - Supplies and Reagents**

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

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

RE--** - Recovery**

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

RE-01-**- Manner of recovery
RE-01-01 - HCT/P contaminated, potentially contaminated, or cross-contaminated during recovery

PC--** - Processing and Process Controls**

PC-99-**- Miscellaneous
PC-99-01 - Other

PC-01-**- Processing
PC-01-01 - HCT/P contaminated, potentially contaminated, or cross-contaminated during processing
PC-01-02 - HCT/Ps from more than one donor 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

LC--** - Labeling Controls**

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

LC-01-**- Controls for labeling
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-**- Label unacceptable
LC-02-01 - Inaccurate
LC-02-02 - Illegible

ST--** - Storage**

ST-99-**- Miscellaneous
SR-99-01 – Other

ST-01-**- Storage area not controlled to prevent mix-ups of:
ST-01-01 - HCT/Ps
ST-01-02 - Supplies
ST-01-03 - Reagents

ST-02-**- Storage area not controlled to prevent contamination or cross-contamination of:
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

SD--** - Receipt, Pre-distribution Shipment, and Distribution**

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

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

SD-04-**- Incoming HCT/P
SD-04-01 - Not evaluated and inspected for damage and contamination

??-??-?? DO NOT KNOW

Last Updated: 10/22/2007