BLOOD AND SOURCE PLASMA
BIOLOGICAL PRODUCT DEVIATION CODES
FY16

CBER enters the fourth level detail code (e.g., A, B, C) into the database as standardized remarks to further describe some of the codes, in particular miscellaneous codes. These codes are not included on the BPD report form.

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

PD-11-** Testing *{information provided by donor or third party, includes true positive and false positive test results; use PD-13 for a reactive test obtained post donation*
PD-11-01 Other
PD-11-03 Tested reactive for Hepatitis B prior to donation
PD-11-05 Tested reactive for Hepatitis C prior to donation
PD-11-07 Tested reactive for HIV prior to donation
PD-11-09 Tested reactive for HTLV prior to donation
PD-11-11 Tested reactive for sexually transmitted disease prior to donation
PD-11-13 Tested reactive for hepatitis not specified or elevated liver enzymes, prior to donation
PD-11-14 Tested reactive at another center, specific testing unknown
PD-11-16 Tested reactive for Hepatitis A 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 Intimate contact with risk for a relevant transfusion-transmitted infection - sexually transmitted disease
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-12-18 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-12-28 Donor received transfusion
PD-12-29 Donor received tissue allograft or transplanted organ
PD-12-36 Travel to 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, hemochromotosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*

A - Babesia
B - West Nile Virus
C - Chagas
E - Fever/Diarrhea
F - Infection
G - Lyme disease
H - Mononucleosis/Epstein-Barr virus
I - Blood Disorder
J - Von Willebrand disease
K - Idiopathic Thrombocytopenic Purpura (ITP)/Thrombotic Thrombocytopenic purpura (TTP)
L – Unknown/not specified

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 (derived from human pituitary glands)
PD-12-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart, Jalyn, or Absorica
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}*
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-12-58 Risk factor associated with Chagas

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-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}*

A - Babesiosis
B - West Nile Virus
C - Non-specific symptoms - possible West Nile Virus
D - Reaction at phlebotomy site
E - Chagas
F - Fever/Diarrhea
G - Infection
H - Lyme disease
I - Mononucleosis/Epstein-Barr virus
J - Blood Disorder
K - Von Willebrand disease
L - Unknown/not specified

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 sexually transmitted disease, or reactive test for sexually transmitted disease

PD-13-07 Post donation diagnosis or symptoms of non-specific hepatitis, reactive test for non-specific hepatitis, or elevated liver enzymes

PD-13-08 Post donation diagnosis or symptoms of Hepatitis A, or reactive test for 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}*

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 acceptance criteria

DS-21-01 Other *{includes inappropriate acceptance of donor with unacceptable address or no proof of an acceptable 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; incorrect gender specific question asked}*

A - Abbreviated questionnaire used instead of full-length

B - Response to educational material/AIDS questions incorrect, not documented, or missing

C - Donor determined acceptable subsequent to distribution

D - Incorrect gender specific questions asked or incorrect answer (male answered "I am female")

E – Untrained staff/staff failed competency

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

DS-26-01 Donor not previously deferred

DS-27-** Deferral screening not done or incorrectly performed, including incorrect ID used during search, prior deferral due to testing for:
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-27-07 ALT
DS-27-08 Syphilis

DS-28-** Deferral screening not done or incorrectly performed, including incorrect ID used during search, prior deferral 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 Intimate contact with risk for a relevant transfusion-transmitted infection - sexually transmitted disease
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-28-18 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-28-28 Donor received transfusion
DS-28-29 Donor received tissue allograft or transplanted organ
DS-28-36 Travel to 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, hemochromotosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*

A - Babesia
B - West Nile Virus
C - Chagas
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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 (derived from human pituitary glands)
DS-28-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart, Jalyn, or Absorica
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 *{reason for deferral unknown or not provided by the other center*
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-28-58 Risk factor associated with Chagas
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-29-** Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked
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; residency/travel outside U.S., unacceptable, discrepant or missing response to gender specific or attention question}*
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 Intimate contact with risk for a relevant transfusion-transmitted infection - sexually transmitted disease
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}*
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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, hemochromotosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*
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DS-29-54 Positive drug screen
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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}*
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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

DD--** DONOR DEFERRAL**

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 for:

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-31-07 ALT
DD-31-08 Syphilis

DD-32-** Donor missing or incorrectly identified on deferral list, donor was or should have been previously deferred due to history

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 - Intimate contact with risk for a relevant transfusion-transmitted infection - sexually transmitted disease
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-32-18 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-32-28 Donor received transfusion
DD-32-29 Donor received tissue allograft or transplanted organ

DD-32-36 Travel to 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, hemochromotosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*

A - Babesia
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DD-32-40 Risk factors associated with Creutzfeldt-Jakob Disease - brain surgery

DD-32-41 Risk factors associated with Creutzfeldt-Jakob Disease - family history

DD-32-42 Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel

D-32-43 Risk factors associated with Creutzfeldt-Jakob Disease - received insulin or other bovine derived product

DD-32-44 Received growth hormone (derived from human pituitary glands)

DD-32-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart, Jalyn, or Absorica

DD-32-46 Received medication or antibiotics

DD-32-47 Received vaccine or immune globulin

DD-32-48 Exposure to a disease

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 *{reason for deferral unknown or not provided by the other center}*

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-32-58 Risk factor associated with Chagas

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-34-** Donor incorrectly deleted from deferral list or donor not reentered properly, prior deferral due to testing for:

DD-34-01 Other

DD-34-02 HIV

DD-34-03 HBV

DD-34-04 Anti-HBc

DD-34-05 HCV

DD-34-06 Anti-HTLV

DD-34-07 ALT

DD-34-08 Syphilis

DD-35-** Donor incorrectly deleted from deferral list, prior deferral 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 Intimate contact with risk for a relevant transfusion-transmitted infection - sexually transmitted disease

DD-35-13 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-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 not prescribed by a doctor *{includes taking illegal drugs by needle, e.g., IM}*

DD-35-17 Sex partner used IV drugs not prescribed by a doctor

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
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DD-35-23 Sex partner exchanged sex for drugs or money
DD-35-28 Donor received transfusion
DD-35-29 Donor received tissue allograft or transplanted organ
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DD-35-37 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, hemochromotosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*

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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 *{reason for deferral unknown or not provided by the other center}*
DD-35-56 Travel to leishmania risk area *{e.g., Baghdad, Tikrit, Ramadi}*
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DD-35-58 Risk factor associated with Chagas
DD-35-59 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}*
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DD-35-61 Intimate contact with risk for a relevant transfusion-transmitted infection - HIV
DD-35-62 Intimate contact with risk for a relevant transfusion-transmitted infection - HTLV
DD-35-63 Intimate contact with risk for a relevant transfusion-transmitted infection - HBV
DD-35-64 Intimate contact with risk for a relevant transfusion-transmitted infection - HCV
DD-35-65 Intimate contact with risk for a relevant transfusion-transmitted infection - hepatitis, not specified

BC--** BLOOD COLLECTION**

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

BC-41-** Sterility compromised
BC-41-01 Other
BC-41-02 Bacterial contamination
A - Staphylococcus coagulase negative
B - Gram positive cocci
C - Staphylococcus epidermidis
D - Propionibacterium acnes
E - Staphylococcus aureus
F - Organism not identified or specified
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)
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 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
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**

CP-50-** Miscellaneous
CP-50-01 Other

CP-51-** Sterility compromised
CP-51-01 Other
CP-51-02 Bacterial contamination
A - Staphylococcus coagulase negative
CP-51-03 Air contamination
CP-51-04 Product integrity compromised during component preparation (e.g., leaking at sterile connection

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 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-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

VT--** VIRAL TESTING**

VT-70-** Miscellaneous

VT-70-01 Other

VT-71-** Testing performed, interpreted or documented incorrectly (includes QC not performed or unacceptable) for:

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/HBV Nucleic Acid Test (NAT)
VT-71-16 HBV Nucleic Acid Test (NAT)
VT-71-17 West Nile Virus
VT-71-18 T. Cruzi (Chagas)

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 for:
RT-61-01 Other *{includes DAT; Hemoglobin S testing}*
RT-61-04 ABO and/or Rh
RT-61-05 Antibody screening or identification
RT-61-06 Antigen typing
RT-61-07 Platelet count
RT-61-08 Compatibility *{includes electronic or immediate spin crossmatch performed instead of full crossmatch, when required}*
RT-61-09 ABO, Rh, and antibody screen
RT-61-10 ABO, Rh, antibody screen, and compatibility
RT-61-11 Antibody screen and compatibility

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

RT-63-** Testing performed using reagents in which QC was unacceptable, not performed, not documented, or expired reagents were used
RT-63-01 Other
RT-63-04 ABO and/or 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**

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 or missing
LA-81-04 Product type or code incorrect or missing (e.g., RBC labeled as Whole Blood)
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 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, tie tag or transfusion record 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 or code 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
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 tags or transfusion records 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, tie tag, or transfusion record missing or attached to incorrect unit *{e.g., intended for different patient}*

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}*
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 Intimate contact with risk for a relevant transfusion-transmitted infection - sexually transmitted disease
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 a 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-91-18 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-91-28 Donor received transfusion
QC-91-29 Donor received tissue allograft or transplanted organ
QC-91-36 Travel to 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, hemochromotosis, autoimmune disorders, such as Rheumatoid Arthritis, Lupus}*
A - Babesia

B - West Nile Virus
C - Chagas
E - Fever/Diarrhea
F - Infection
G - Lyme disease
H - Mononucleosis/Epstein-Barr virus
I - Blood Disorder
J - Von Willebrand disease
K - Idiopathic Thrombocytopenic Purpura (ITP) /Thrombotic Thrombocytopenic purpura (TTP)
L – Unknown/not specified

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 (derived from human pituitary glands)
QC-91-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart, Jalyn, or Absorica
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 - reason unknown *{reason for deferral unknown or not provided by the other 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-91-59 Risk factor associated with Chagas
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-92-** Positive testing for
QC-92-01 Other
A - Hemoglobin S
B - Drug Screen
C - West Nile Virus
D - Parvovirus
E - Drug Screen and antibody screen
F - Babesia
G - Chagas
H - DAT
I - Fetal screen
J - HLA antibody
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-92-07 ALT elevated
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 HIV/HCV/HBV Nucleic Acid Test (NAT)

QC-93-** Testing not performed, incompletely performed or not documented for
QC-93-01 Other
A - Sickle Cell protocol
B - Drug screen
C - West Nile Virus
D - Parvovirus
E - Drug Screen and antibody screen
F - Babesia
G - Chagas
H - DAT
I - Fetal screen
J - HLA antibodies

QC-93-02 HIV
QC-93-03 HBV (HBsAg, HBV NAT)
QC-93-04 Anti-HBc
QC-93-05 HCV (anti-HCV, HCV NAT)
QC-93-06 Anti-HTLV
QC-93-07 ALT
QC-93-10 Antibody screen or identification (donor/unit or recipient)
QC-93-11 Antigen screen
QC-93-12 Syphilis
QC-93-13 All viral markers
QC-93-14 Compatibility
QC-93-15 HIV/HCV/HBV Nucleic Acid Test (NAT)
QC-93-16 ABO and/or 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
A - Platelet count
B - Hematocrit/Hemoglobin
C - RBC recovery
D - Volume
E - WBC count
F - pH
G - Bacterial detection testing
H - Product QC not performed during validation of apheresis machine
I - Multiple parameters
J - Factor VIII
QC-94-05 Product in which specification other than QC 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
A - Hemoglobin/Hematocrit reagents, Hematostat, Hemocue, mirohematocrit centrifuge
C - Trip scale
D - Collection device
E - Incubator/heat block
F - Centrifuge
G - Irradiator
H - Waterbath
I - Hematology analyzer/cell counter

J - pH meter
K - Sterile connecting device
L - Donor screening thermometer
M - Cell washer
N - Scale
O - Multiple instruments

QC-94-08 Product distributed prior to resolution of discrepancy *{conflicting information that requires investigation which is not resolved prior to distribution}*

A - Other
B - ABO/Rh discrepancy
C - Transfusion order/request and blood bank computer information discrepant
D - WBN discrepancy
E - Product released with quarantine tag
F - Sample tube discrepancy

QC-94-09 Product associated with product that contained clots or hemolysis

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}*

A - Collection time extended, discrepant or not documented
B - Potential air contamination
C - Arm preparation/inspection not performed or documented or performed incorrectly
D - Unacceptable unit weight
E - 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}*

A - Leukoreduction procedures not performed in accordance with specifications
B - Irradiation procedures not performed in accordance with specifications
C - Sterile docking procedures not performed in accordance with specifications
D - Transport 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; abbreviated donor history questionnaire used instead of full-length}*

A - Donor history question not answered, incomplete, or unacceptable
B - Abbreviated donor history questionnaire used instead of full-length
C - Hemoglobin/Hematocrit unacceptable, not documented, or discrepant
D - Donor temperature unacceptable, not documented, or discrepant
E - Incorrect gender-related questions
F - Arm inspection

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, shipping time out of specification}*

A - Product stored at unacceptable conditions

B - No documentation of acceptable storage or shipping temperatures

QC-94-18 Product identified as unsuitable due to a viral testing deviation or unexpected event *{event discovered prior to distribution, but failed to quarantine product; includes products released with positive or incomplete viral testing}*

QC-96-** Shipping and storage

QC-96-01 Other

QC-96-02 Arrived at consignee at unacceptable temperature

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 or no documentation that product was packed appropriately

QC-96-08 Product returned to blood center and reissued inappropriately *{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}*

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

QC-97-06 Product not leukoreduced as required

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

QC-97-08 Product not CMV negative as required

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

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

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

QC-97-13 Procedure for issuing not performed or documented in accordance with specifications*;* use QC9719 if product not issued in computer *{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, not documented, or inadequate

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
QC-97-21 Product not hemoglobin S negative as required

MI--** MISCELLANEOUS**

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
A - HBV
B - HCV
MI-01-04 West Nile Virus
MI-01-05 Babesia
MI-01-06 Chagas
MI-01-07 Malaria

MI-02-** Lookback; subsequent unit tested confirmed positive for
MI-02-01 Other *{multiple markers}*
A - HIV and HBV
B - HIV and HCV
C - HBV and HCV
MI-02-02 HIV
A - HIV-2
MI-02-03 HBV
A -Anti-HBc positive
MI-02-04 HCV
MI-02-05 West Nile Virus
MI-02-06 HTLV
MI-02-07 Babesia
MI-02-08 Chagas