# Biological Product Deviation Reporting (BPDR)

## Product Deviation Codes

(Updated 9/28/2004)

Blood BPD Codes **OR** Non-Blood BPD Codes

**Blood BPD Codes:**

The following list of Biological Product Deviation (BPD) Codes should be used as a tool for assigning a specific code to a reportable event when submitting the report to FDA. This list should not be used solely for the purpose of determining if an event is reportable. You should have a process consistent with the draft guidance document, "Biological Product Deviation Reporting for Blood and Plasma Establishments," to determine which events are reportable. The list includes deviations from regulations, standards, and standard operating procedures (SOPs) that may affect the safety, purity, or potency of a product. The list of codes was developed based on the error and accident reports previously submitted to FDA. These events 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 process.

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

PD-**-** POST DONATION INFORMATION

PD-10-** Miscellaneous
PD-10-01 Other

PD-11-** Testing
PD-11-01 Other
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-11-05Tested reactive for Hepatitis C prior to donation
PD-11-06Tested reactive for HIV post donation

PD-11-07 Tested reactive for HIV prior to donation
PD-11-08 Tested reactive for HTLV I/II post donation
PD-11-09 Tested reactive for HTLV I/II prior to donation
PD-11-10 Tested reactive for sexually transmitted disease post donation
PD-11-11Tested 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
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 I/II
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 engaged in high risk behavior or unsuitable
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
PD-12-17 Sex with IV drug user
PD-12-18 Non-IV-drug use
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
PD-12-31 Donor had multiple blood or body fluid exposures, e.g., 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
PD-12-38 History of cancer
PD-12-39 History of Creutzfeldt-Jakob 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
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

PD-13-** Illness
PD-13-01 Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer or cold/flu related)
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 I/II
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-13-09 Post donation diagnosis of cancer

PD-14-** Not specifically related to high risk behavior, unsuitable history, or post donation illness
PD-14-01 Other
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
DS-21-02 Hemoglobin or Hematocrit unacceptable, not documented, or testing performed incorrectly
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
DS-22-02 Donor identification
DS-22-03 Donor history questions
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
DS-23-01 Donor not previously deferred

DS-24-** Deferral screening not done, donor 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-I reactive
- DS-24-07 ALT elevated
- DS-24-08 Syphilis reactive

DS-25-** Deferral screening not done, donor previously deferred due to history
- DS-25-01 Other
- 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 I/II
- 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 engaged in high risk behavior or unsuitable
- 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
- DS-25-17 Sex with IV drug user
- DS-25-18 Non-IV-drug use
- 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
- DS-25-31 Donor had multiple blood or body fluid exposures, e.g., tattoo and piercing
- 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
- DS-25-38 History of cancer
- DS-25-39 History of Creutzfeldt-Jakob 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
- DS-25-44 Received growth hormone

DS-25-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, 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-26-** Incorrect ID used during deferral search
DS-26-01 donor not previously deferred

DS-27-** Incorrect ID used during deferral search, donor 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
DS-28-01 Other
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 I/II
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 engaged in high risk behavior or unsuitable
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
DS-28-17 Sex with IV drug user
DS-28-18 Non-IV-drug use
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

DS-28-31 Donor had multiple blood or body fluid exposures, e.g., tattoo and piercing
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
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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
DS-28-44 Received growth hormone
DS-28-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, 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-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
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 I/II
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 for hepatitis, not specified
DS-29-13 Sex partner engaged in high risk behavior or unsuitable
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DS-29-19 Sex partner used non-IV drugs
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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
DS-29-31 Donor had multiple blood or body fluid exposures, e.g., tattoo and piercing
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
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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

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:
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-I 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:
DD-32-01 Other
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 I/II
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 engaged in high risk behavior or unsuitable
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
DD-32-17 Sex with IV drug user
DD-32-18 Non-IV-drug use
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
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DD-32-23 Sex partner exchanged sex for drugs or money
DD-32-24 Donor received tattoo
DD-32-25 Donor received ear piercing
DD-32-26 Donor received body piercing
DD-32-27 Donor received accidental needlestick
DD-32-28 Donor received transfusion or clotting factors
DD-32-29 Donor received tissue allograft or transplanted organ
DD-32-30 Donor was exposed to blood or body fluids
DD-32-31 Donor had multiple blood or body fluid exposures, e.g., tattoo and piercing
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
DD-32-35 Non-sexual exposure to Hepatitis C
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DD-32-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, Avodart
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

DD-34-** Donor incorrectly deleted from deferral list or donor not reentered properly, donor previously deferred due to testing:
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-I 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:

DD-35-01 Other
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 I/II
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 engaged in high risk behavior or unsuitable
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
DD-35-17 Sex with IV drug user
DD-35-18 Non-IV-drug use
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
DD-35-31 Donor had multiple blood or body fluid exposures, e.g., tattoo and piercing
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
DD-35-38 History of cancer
DD-35-39 History of Creutzfeldt-Jakob Disease
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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
DD-35-44 Received growth hormone
DD-35-45 Received finasteride (Proscar or Propecia), Tegison, Accutane, 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

BC-**-** BLOOD COLLECTION

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

BC-41-** Sterility compromised
BC-41-01 Other
BC-41-02 Bacterial contamination (identify organism if possible)
BC-41-03 Air contamination
BC-41-04 Arm prep not performed or performed inappropriately

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
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
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-44-** Apheresis collection device
BC-44-01 Other
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 (identify organism if possible)
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
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 or platelet count not performed on

Platelet product
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
CP-52-10 Leukoreduction not performed in accordance with specifications
CP-52-11 Irradiation not performed in accordance with specifications
CP-52-12 Components not prepared within appropriate time frame after collection
CP-52-13 Additive solution not added, added incorrectly, 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
CP-52-16 Aliquot preparation not performed in accordance with specifications
CP-52-17 Sterile docking procedure not performed in accordance with specifications

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

VT/RT LABORATORY TESTING

VT-**-** VIRAL TESTING
VT-70-** Miscellaneous
VT-70-01 Other

VT-71-** Testing incorrectly performed, interpreted, or documented (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-I/II
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-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 incorrectly performed, interpreted, or documented for:
RT-61-01 Other
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
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

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
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)
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 Multiple labels incorrect or missing
LA-81-11 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-82-** Crossmatch tag or tie tag labels incorrect or missing information
LA-82-01 Other
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 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 Crossmatch tag missing or labeled with incorrect or missing information (e.g., compatibility results)
LA-82-18 Biohazard or test status incorrect or missing
LA-82-19 Multiple labels incorrect or missing

LA-83-** Transfusion record (crossmatch slip) incorrect or missing information
LA-83-01 Other
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 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 Transfusion record released with unit incorrect or labeled with incorrect or missing information (e.g., compatibility results)
LA-83-18 Biohazard or test status incorrect or missing
LA-83-19 Multiple labels incorrect or missing

QC-**-** QUALITY CONTROL and DISTRIBUTION

QC-90-** Miscellaneous
QC-90-01 Other

QC-91-** Failure to quarantine unit due to medical history:

QC-91-01 Other
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 I/II
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 engaged in high risk behavior or unsuitable
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
QC-91-17 Sex with IV drug user
QC-91-18 Non-IV-drug use
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
QC-91-31 Donor had multiple blood or body fluid exposures, e.g., tattoo and piercing
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
QC-91-38 History of cancer
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
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-92-** Required testing incomplete or positive for:
- QC-92-01 Other
- QC-92-02 HIV
- QC-92-03 HBsAg
- QC-92-04 Anti-HBc
- QC-92-05 Anti-HCV
- QC-92-06 Anti-HTLV-I
- QC-92-07 ALT
- QC-92-08 ABO (donor/unit or recipient)
- QC-92-09 Rh (donor/unit or recipient)
- 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 Nucleic Acid Test (NAT)
- QC-92-16 ABO and Rh (donor/unit or recipient)
- QC-92-17 ABO/Rh and antibody screen (donor/unit or recipient)

QC-93-** Required testing not performed or documented for:
- QC-93-01 Other
- QC-93-02 HIV
- QC-93-03 HBsAg
- QC-93-04 Anti-HBc
- QC-93-05 Anti-HCV
- QC-93-06 Anti-HTLV-I
- 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
- 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
- QC-94-02 Outdated product
- QC-94-03 Autologous unit not meeting homologous criteria
- QC-94-04 Product with unacceptable (e.g., positive), undocumented, or incomplete product QC
- QC-94-05 Product in which specification other than QC not met
- QC-94-06 Product in which instrument QC or validation was unacceptable, incomplete, or not documented
- QC-94-08 Product distributed prior to resolution of 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
- QC-94-13 Product identified as unsuitable due to a component preparation deviation or unexpected event
- QC-94-14 Product identified as unsuitable due to a labeling deviation or unexpected event
- QC-94-15 Product identified as unsuitable due to a donor screening deviation or unexpected event
- QC-94-16 Product identified as unsuitable due to a donor deferral deviation or unexpected event

QC-96-** Shipping and storage
QC-96-01 Other
QC-96-02 Shipped at incorrect 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 receipt, unit redistributed
QC-96-06 Shipment exceeded time allowed for shipping, unit redistributed
QC-96-07 Product not packed in accordance with specifications

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
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
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 as issued in the computer (computer documentation is final check of issue process)

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
MI-01-04 West Nile Virus

MI-02-** Lookback; subsequent unit tested confirmed positive for:
MI-02-01 Other
MI-02-02 HIV
MI-02-03 HBV
MI-02-04 HCV
MI-02-05 West Nile Virus

??-??-?? DO NOT KNOW

Non-Blood BPD Codes

The following list of Biological Product Deviation (BPD) Codes should be used as a tool for assigning a specific code to a reportable event when submitting the report to FDA. This list should not be used solely for the purpose of determining if an event is reportable. You should have a process consistent with the draft guidance document, "Biological Product Deviation Reporting for Manufacturers of Biological Products Other than Blood and Blood Components," to determine which events are reportable. The list includes deviations from regulations, standards, and standard operating procedures (SOPs) that may affect the safety, purity, or potency of a product. The list of codes was developed based on the error and accident reports previously submitted to FDA. These events 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 process.

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

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
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

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 procedures not performed according to specifications

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 qualified/calibrated
PC-22-05 Sanitization not performed or performed incorrectly
PC-22-06 Failed media fill

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

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

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

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

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

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

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

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

LA-**-** LABELING

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

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

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

QC-**-** QUALITY CONTROL AND DISTRIBUTION

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

QC-61-** Product distributed inappropriately
QC-61-01 Other
QC-61-02 Product distributed prior to completion of required testing
QC-61-03 Product distributed prior to CBER approval of a PAS
QC-61-04 Product distributed less than 30 days after submission of CBE-30 or prior to submission of CBE-30
QC-61-05 Product distributed prior to validation of process
QC-61-06 Outdated product distributed

QC-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

MI-**-** MISCELLANEOUS

MI-70-** Miscellaneous
MI-70-01 Other

??-??-?? DO NOT KNOW

Last Updated: 9/28/2004