HCT/P 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.

DE--** Donor Eligibility** (21 CFR 1271.50)
DE-02-** Ineligible donor accepted [except as provided in §1271.65(b)]
DE-02-01 Risk factors for, or clinical evidence of infection due to relevant communicable disease agents and diseases according to §1271.75(a)(1)
A - Final autopsy results received post distribution
B - Positive tissue recovery culture
DE-02-02 Xenotransplant recipient accepted as donor
DE-02-04 Donor tested reactive for relevant communicable disease

DE-03-** Donor eligibility determination
DE-03-01 Not determined by a responsible person, as defined in §1271.3(t)

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

DS--** Donor Screening** (21 CFR 1271.75)
DS-02-** Donor screening not performed [except as provided in §1271.60(d)] or performed incorrectly in the:
DS-02-01 Donor medical history interview
DS-02-02 Physical assessment of a cadaveric donor or physical examination of a living donor
DS-02-03 Medical record review
DS-02-04 Evaluation of communicable disease risks associated with xenotransplant
DS-02-05 Abbreviated donor screening inappropriately used or not performed
DS-02-06 Donor of viable, leukocyte-rich HCT/Ps not properly evaluated for evidence of infection due to HTLV

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

DT--** Donor Testing** (21 CFR 1271.80 and 1271.85
DT-01-** Testing not performed or documented when required, for:
DT-01-01 Human immunodeficiency virus
DT-01-03 Hepatitis B virus
DT-01-04 Hepatitis C virus
DT-01-05 Treponema pallidum
DT-01-06 Human T-lymphotropic virus

DT-01-08 Cytomegalovirus
DT-01-11 Multiple tests
A - HIV/HCV NAT

DT-02-** Testing incorrectly performed when required, for:
DT-02-01 Human immunodeficiency virus
DT-02-03 Hepatitis B virus
DT-02-04 Hepatitis C virus
DT-02-05 Treponema pallidum
DT-02-06 Human T-lymphotropic virus
DT-02-08 Cytomegalovirus
DT-02-11 Multiple tests

DT-03-** Unacceptable specimen tested
DT-03-01 Specimen collected more than 7 days before or after recovery (except for peripheral blood stem/progenitor cells)
DT-03-02 Specimen collected from donor 1 month of age or younger, instead of from birth mother
DT-03-03 Specimen collected from a peripheral blood stem cell donor more than 30 days before recovery
DT-03-04 Specimen storage conditions not met
DT-03-05 Specimen did not meet requirements in test kit package insert
A - Filtered specimen
B - Specimen collected in expired tube
C - Outdated specimen
DT-03-06 Donor incorrectly evaluated for plasma dilution
DT-03-07 Donor not evaluated or evaluation not documented for plasma dilution

DT-04-** Inappropriate test or test laboratory used
DT-04-01 Required test used was not licensed, approved, or cleared
A - HIV/HCV NAT performed on pooled samples instead of individual samples
DT-04-02 Required tests approved for cadaveric specimens not used when available
DT-04-03 Laboratory performing tests not CLIA certified (or equivalent for CMS)
DT-04-04 Laboratory performing tests not FDA approved

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

FA --** Facilities** (21 CFR 1271.190(a) and (b))
FA-01-** Design
FA-01-01 Facility not suitable in size, construction, and/or location
FA-01-02 Inadequate lighting, ventilation, plumbing, drainage and/or access to sinks and toilets

FA-02-** Cleaning and sanitization
FA-02-01 Facility not maintained in a clean, sanitary, and orderly manner

FA-02-02 Sewage, trash, and other refuse not disposed of in a timely, safe, and sanitary manner

FA-99-** Miscellaneous
FA-99-01 Other

EC--** Environmental Control** (21 CFR 1271.195(a))
EC-01-** Environmental controls, when required, not performed or documented for
EC-01-01 Temperature controls
EC-01-02 Humidity controls
EC-01-03 Ventilation and air filtration
EC-01-04 Cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations
EC-01-05 Maintenance of equipment used to control conditions necessary for aseptic processing operations

EC-02-** Environmental controls, when required, incorrectly performed for
EC-02-01 Temperature controls
EC-02-02 Humidity controls
EC-02-03 Ventilation and air filtration
EC-02-04 Cleaning and disinfecting of rooms and equipment to ensure aseptic processing operations
EC-02-05 Maintenance of equipment used to control conditions necessary for aseptic processing operations

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

EQ--** Equipment** (21 CFR 1271.200(a))
EQ-01-** Design
EQ-01-01 Equipment is not of an appropriate design for its use, and/or suitably located
EQ-01-02 Equipment not capable of producing valid results

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

EQ-99-** Miscellaneous
EQ-99-01 Other

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

SR-02-** Reagent unsuitable

SR-02-01 Not sterile, where appropriate

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

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

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

PC--** Processing and Process Controls** (21 CFR 1271.220)
PC-01-** Processing
PC-01-01 HCT/P contaminated, potentially contaminated, or cross-contaminated during processing
A - Candida glabrata
B - E. coli, Group D Enterococcus, Klebsiella oxytoca
C - Group D Enterococcus
D - Propionibacterium acnes
E - Staphylococcus coagulase negative
F - Clostridium perfringes
G - Propionibacterium species
H - Enterococcus species
I - E. coli
PC-01-02 HCT/Ps from two or more donors were pooled during manufacturing

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

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

PC-04-** Processing of Dura mater
PC-04-01 Available published validated process that reduces the risk of transmissible spongiform encephalopathy not used
PC-04-02 Available published validated process that reduces the risk of transmissible spongiform encephalopathy used, but not verified

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

LC--** Labeling Controls** (21 CFR 1271.250(a) and (b))
LC-01-** Procedures to control labeling of HCT/Ps

LC-01-01 Not established or maintained
LC-01-02 Did not prevent mix-ups
LC-01-03 Did not allow proper identification

LC-02-** Verification procedures not performed for:
LC-02-01 Accuracy, legibility, or integrity

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

ST--** Storage** (21 CFR 1271.260(a) through (d))
ST-01-** Storage area and stock room not controlled to prevent mix-ups pertaining to the following items:
ST-01-01 HCT/Ps
ST-01-02 Supplies
ST-01-03 Reagents

ST-02-** Storage area and stock room not controlled to prevent contamination or cross-contamination pertaining to the following items:
ST-02-01 HCT/Ps
ST-02-02 Supplies
ST-02-03 Reagents

ST-03-** Storage temperature
ST-03-01 Not appropriate

ST-04-** Expiration date, where appropriate
ST-04-01 Incorrect or missing

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

SD--** Receipt, Pre-distribution Shipment, and Distribution** (21 CFR 1271.265(a) through (d))
SD-01-** Quarantined HCT/Ps
SD-01-01 Shipped without quarantine identification

SD-02-** Inappropriate distribution
SD-02-01 Distributed without review of required records
SD-02-02 Distributed without sign-off by a responsible person
SD-02-03 Quarantined HCT/P that was determined ineligible for release
SD-02-04 Contaminated or potentially contaminated HCT/P
A - Staphylococcus aureus
B - Staphylococcus epidermidis
C - Staphylococcus coagulase negative
D - Propionibacterium acnes

E - Propionibacterium species
F - Bacillus species
SD-02-05 Release criteria related to expiration date of product not met

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

SD-04-** Receipt of incoming HCT/P
SD-04-01 Not evaluated for the presence and significance of microorganisms and inspected for damage and contamination

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