

HCT/P DEVIATION CODES
FY17

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

Attachment 6 – FY17: List of BPD Codes for 361 HCT/P Establishments

- 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 *{includes filtered specimen, specimen collected in an expired tube, outdated specimen}*
 - 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 *{includes HIV/HCV NAT performed on pooled samples instead of individual samples}*
 - 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

Attachment 6 – FY17: List of BPD Codes for 361 HCT/P Establishments

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*

J - *Staphylococcus aureus*

K - *Staphylococcus epidermidis*

L - *Bacillus species*

M - *Enterobacter cloacae*

N - *Klebsiella pneumonia*

O - Mixed gram negative and gram positive organism

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

Attachment 6 – FY17: List of BPD Codes for 361 HCT/P Establishments

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

ST-99-01 Other

SD--** Receipt, Pre-distribution Shipment, and Distribution** (21 CFR 1271.265(a) through (d))

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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 *{use this code if a positive culture result was known prior to distribution}*

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