Change Notes

2004 Revision 4 - Infectious Disease Markers

Public ID: 3875656 Version: 1.0

Notes:

These change notes are based on a comparison with Form Builder report 2920158v1.0
2004 Revision 2 - Infectious Disease Markers

- These change notes do not list changes to module public IDs. The module public IDs for all modules have changed. Please refer to the AGNIS Metadata Tool output or the Excel spreadsheet downloaded from the caDSR's Form Builder application for more detailed information
- The "Major" changes section of the notes includes those changes which are most likely to impact database mapping applications. They include changes such as the addition or removal of CDEs
- The "Minor" changes section of the notes includes those changes which are least likely to impact database mapping applications. They include changes such as modifications to question or instruction texts.

Module: Registry Use Only:

Minor:

- Question text change for CDE 2527889v1.0 (Clinical Data Form Sequence Number)
    - Old: Sequence number:
    - New: Sequence Number:

- Question text change for CDE 2866943v1.0 (Clinical Data Form Received Date)

    - Old: Date received:
    - New: Date Received:

2004 Revision 2 Modules removed:

Major: Module & all CDEs removed

Module: Key Field

Module: Source Information

Module: Hepatitis B Virus (HBV)

Module: Hepatitis C Virus (HCV)

Module: Human T-Lymphotropic Virus

Module: Human Immunodeficiency Virus (HIV)

Module: Syphilis

Module: Cytomegalovirus (CMV)

Module: West Nile Virus (WNV)

Module: Other Infectious Disease Marker

Module: Key Fields:

Major:

- New Module

- Added the following CDEs:
    - 2527895v2.0 (Hematopoietic Cell Transplantation Recipient Institution::Center for International Blood and Marrow Transplant Research Facility Number)
    - 2527897v2.0 (Hematopoietic Cell Transplantation Recipient Identification Number)
    - 2866938v2.0 (Hematopoietic Cell Transplantation Occurrence Date)
    - 2730901v2.0 (Hematopoietic Cell Graft Source Name)

- Added the following permissible values for the following CDE 2730901v2.0 (Hematopoietic Cell Graft Source Name)
    - 2730898v1.0 (Allogeneic, unrelated)
    - 2730899v1.0 (Allogeneic, related)

Minor:

- Added the instruction text for CDE 2730901v2.0 (Hematopoietic Cell Graft Source Name)
    - Check only one

Module: Key Fields - Product Type:

Major:

- New Module
- Added repetition count:
  - New: 3

- Added the following CDEs:

  - 2730912v2.0 (Hematopoietic Cell Graft Type Name)
  - 3567334v1.0 (Hematopoietic Cell Graft Type Indicator)
  - 2527917v2.0 (Hematopoietic Cell Graft Other Type Specify)

- Added the following permissible values for CDE 2730912v2.0 (Hematopoietic Cell Graft Type Name)
  - 2581613v1.0 (Bone marrow)
  - 2581240v1.0 (PBSC)
  - 3809647v1.0 (Single cord blood unit)
  - 3870223v1.0 (Other product)

- Added the following permissible values for the following CDE 3567334v1.0 (Hematopoietic Cell Graft Type Indicator)
  - 2567168v1.0 (Yes)

Minor:

- Added module instruction text:
  - New: Normalized curation. Equivalent to key field Product Type on the PDF version of the form. Please repeat this module for each permissible value listed in CDE 2730912.

- Added question instruction text for CDE 2527917v2.0 ((Hematopoietic Cell Graft Other Type Specify)
  - New: Answer only if the response to CDE 2730912 is "Other product."

Module: Donor / Cord Blood Unit Identification:

Major:

- New Module

- Added the following CDEs:

  - 2889035v2.0 (Negation Institution::National Marrow Donor Program Hematopoietic Cell Graft Tissue Donor Type Tissue Donor Type)
  - 3809537v1.0 (Hematopoietic Cell Graft Unrelated Tissue Donor Negation National Marrow Donor Program Identifier)
  - 3874258v1.0 (Hematopoietic Cell Graft Umbilical Cord Blood Type Negation National Marrow Donor Program Identifier)
  - 3809532v1.0 (Person Birth Date Known Unknown Indicator)
  - 3190237v1.0 (Person Birth Date)
  - 3809551v1.0 (Person Age Known Unknown Indicator)
  - 3809533v1.0 (Person Age Value)
  - 3809811v1.0 (Person Age Time Unit of Measure Text Name)
  - 3171628v2.0 (Person Sex Type)
  - 2693219v1.0 (Infection Disease Marker Laboratory Procedure Source Type)

- Added the following permissible values for CDE 2889035v2.0 (Negation Institution::National Marrow Donor Program Hematopoietic Cell Graft Tissue Donor Type Tissue Donor Type)
  - 2889023v1.0 (Related donor)
  - 2889025v1.0 (Non-NMDP unrelated donor)
  - 2889024v1.0 (Non-NMDP cord blood unit)

- Added the following permissible values for CDE 3809532v1.0 (Person Birth Date Known Unknown Indicator)
  - 2934435v1.0 (Known)
  - 2575365v1.0 (Unknown)

- Added the following permissible values for CDE 3809551v1.0 (Person Age Known Unknown Indicator)
  - 2934435v1.0 (Known)
  - 2575365v1.0 (Unknown)
- Added the following permissible values for CDE 3809811v1.0 (Person Age Time Unit of Measure Text Name)
  - 2569689v1.0 (Months)
  - 2670939v1.0 (Years)

- Added the following permissible values for CDE 2693219v1.0 (Infection Disease Marker Laboratory Procedure Source Type)
  - 3876436v1.0 (Donor IDM (bone marrow or PBSC))

- o 3876442v1.0 (Maternal IDM (cord blood))
- o 3876437v1.0 (Cord blood unit IDM)

<u>Minor</u>:

- Added question instruction text for CDE 3809537v1.0 (Hematopoietic Cell Graft Unrelated Tissue Donor Negation National Marrow Donor Program Identifier)
  - o New: Not applicable for related donor

- Added question instruction text for CDE 3874258v1.0 (Hematopoietic Cell Graft Umbilical Cord Blood Type Negation National Marrow Donor Program Identifier)
  - o <u>New</u>: Include related and autologous CBUs

- Added question instruction text for CDE 3809532v1.0 (Person Birth Date Known Unknown Indicator)
  - o <u>New</u>: Donor / infant

- Added question instruction text for CDE 3190237v1.0 (Person Birth Date)
  - o <u>New</u>: Donor / infant

- Added question instruction text for CDE 3809551v1.0 (Person Age Known Unknown Indicator)
  - o <u>New</u>: Donor / infant

- Added question instruction text for CDE 3809533v1.0 (Person Age Value)
  - o <u>New</u>: Donor / infant

- Added question instruction text for CDE 3171628v2.0 (Person Sex Type)
  - o <u>New</u>: Donor / infant

Module: Infectious Disease Marker - Hepatitis B Virus (HBV) - Part 1 of 2:

<u>Major</u>:

- New Module

- Added the following CDEs:

  - o 2693568v1.0 (Serological Hematology Hepatitis B Surface Antigen Test Laboratory Finding Result)

- o 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2693568v1.0 (Serological Hematology Hepatitis B Surface Antigen Test Laboratory Finding Result)
  - o 2707888v1.0 (Reactive)
  - o 2707884v1.0 (Non-reactive)
  - o 3104692v1.0 (Not done)

Minor:

- Added module instruction text:
  - o New: Report final test results

- Added question instruction text for CDE 2693568v1.0 (Serological Hematology Hepatitis B Surface Antigen Test Laboratory Finding Result)
  - o New: Hepatitis B surface antigen

Module: Infectious Disease Marker - Hepatitis B Virus (HBV) - Part 2 of 2:

Major:

- New Module

- Added the following CDEs:
  - o 2694945v1.0 (Serological Hematology Hepatitis B Virus Core Antibody Laboratory Finding Result)
  - o 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2694945v1.0 (Serological Hematology Hepatitis B Virus Core Antibody Laboratory Finding Result)
  - o 2707888v1.0 (Reactive)
  - o 2707884v1.0 (Non-reactive)
  - o 3104692v1.0 (Not done)

Minor:

- Added module instruction text:
  - o New: Report final test results

- Added question instruction text for CDE 2694945v1.0 (Serological Hematology Hepatitis B Virus Core Antibody Laboratory Finding Result)

o <u>New</u>: Hepatitis B core antibody

Module: Infectious Disease Marker - Hepatitis C Virus (HCV)

<u>Major</u>:

- New Module

- Added the following CDEs:
    o 2695021v1.0 (Serological Hematology Hepatitis C Antibody Test Laboratory Finding Result)
    o 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2695021v1.0 (Serological Hematology Hepatitis C Antibody Test Laboratory Finding Result)
    o 2707888v1.0 (Reactive)
    o 2707884v1.0 (Non-reactive)
    o 3104692v1.0 (Not done)

<u>Minor</u>:

- Added module instruction text:
    o <u>New</u>: Report final test results

- Added question instruction text for CDE 2695021v1.0 (Serological Hematology Hepatitis C Antibody Test Laboratory Finding Result)
    o <u>New</u>: Hepatitis C antibody

Module: Infectious Disease Marker - Human T-Lymphotropic Virus

<u>Major</u>:

- New Module

- Added the following CDEs:
    o 3883054v1.0 (HTLV-1 And/Or HTLV-2 Antibody Laboratory Procedure Performed Laboratory Finding Result)
    o 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3883054v1.0 (HTLV-1 And/Or HTLV-2 Antibody Laboratory Procedure Performed Laboratory Finding Result)
    o 2707888v1.0 (Reactive)
    o 2707884v1.0 (Non-reactive)

o   3104692v1.0 (Not done)

Minor:

- Added module instruction text:
    o   New: Report final test results

Module: Infectious Disease Marker - Human Immunodeficiency Virus (HIV) - Part 1 of 4

Major:

- New Module

- Added the following CDEs:
    o   2695029v1.0 (Laboratory Procedure HIV p24 Antigen Laboratory Finding Result)
    o   3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2695029v1.0 (Laboratory Procedure HIV p24 Antigen Laboratory Finding Result)
    o   2707888v1.0 (Reactive)
    o   2707884v1.0 (Non-reactive)
    o   3104692v1.0 (Not done)
    o   2707886v1.0 (Not reported)

Minor:

- Added module instruction text:
    o   New: Report final test results

Module: Infectious Disease Marker - Human Immunodeficiency Virus (HIV) - Part 2 of 4

Major:

- New Module

- Added the following CDEs:

- o 3883098v1.0 (HIV 1 And/Or HCV FDA Approval Nucleic Acid Amplification Test Performed Indicator)
  - o 2695060v2.0 (Nucleic Acid Amplification Test Human Immunodeficiency Virus 1 Laboratory Finding Result)
  - o 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3883098v1.0 (HIV 1 And/Or HCV FDA Approval Nucleic Acid Amplification Test Performed Indicator)
  - o 2567168v1.0 (Yes)
  - o 2567170v1.0 (No)

- Added the following permissible values for CDE 2695060v2.0 (Nucleic Acid Amplification Test Human Immunodeficiency Virus 1 Laboratory Finding Result)
  - o 2581523v1.0 (Positive)
  - o 2617835v1.0 (Negative)
  - o 2707886v1.0 (Not reported)

<u>Minor</u>:

- Added module instruction text:
  - o <u>New</u>: Report final test results

Module: Infectious Disease Marker - Human Immunodeficiency Virus (HIV) - Part 3 of 4

<u>Major</u>:

- New Module

- Added the following CDEs:
  - o 2695074v2.0 (Nucleic Acid Amplification Test Hepatitis C Virus Laboratory Finding Result)
  - o 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2695074v2.0 (Nucleic Acid Amplification Test Hepatitis C Virus Laboratory Finding Result)
  - o 2581523v1.0 (Positive)
  - o 2617835v1.0 (Negative)

<u>Minor</u>:

- Added module instruction text:
  - o <u>New</u>: Report final test results

Module: Infectious Disease Marker - Human Immunodeficiency Virus (HIV) - Part 4 of 4

<u>Major</u>:

- New Module

- Added the following CDEs:
    - 3883198v1.0 (Human Immunodeficiency Virus 1 And Human Immunodeficiency Virus 2 Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3883198v1.0 (Human Immunodeficiency Virus 1 And Human Immunodeficiency Virus 2 Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 2707888v1.0 (Reactive)
    - 2707884v1.0 (Non-reactive)
    - 3104692v1.0 (Not done)
    - 2707886v1.0 (Not reported)

<u>Minor</u>:

- Added module instruction text:
    - <u>New</u>: Report final test results

- Added question instruction text for CDE CDE 3883198v1.0 (Human Immunodeficiency Virus 1 And Human Immunodeficiency Virus 2 Antibody Laboratory Procedure Performed Laboratory Finding Result:
    - <u>New</u>: Antibodies to Human Immunodeficiency Viruses. Testing for both HIV antibodies is required. This testing may be performed as separate tests or done using a combined assay.

Module: Infectious Disease Marker - Syphilis

<u>Major</u>:

- New Module

- Added the following CDEs:
    - 2695088v1.0 (Serological Laboratory Procedure Syphilis Laboratory Finding Result)

- 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2695088v1.0 (Serological Laboratory Procedure Syphilis Laboratory Finding Result)
    - 2707888v1.0 (Reactive)
    - 2707884v1.0 (Non-reactive)
    - 3104692v1.0 (Not done)

Minor:

- Added module instruction text:
    - New: Report final test results

Module: Infectious Disease Marker - Cytomegalovirus (CMV)

Major:

- New Module

- Added the following CDEs:
    - 3880639v1.0 (Cytomegalovirus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3880639v1.0 (Cytomegalovirus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 2707888v1.0 (Reactive)
    - 2707884v1.0 (Non-reactive)
    - 3104692v1.0 (Not done)

Minor:

- Added module instruction text:
    - New: Report final test results

- Added question instruction text for CDE 3880639v1.0 (Cytomegalovirus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - New: IgG or Total

Module: Infectious Disease Marker - West Nile Virus (WNV)

Major:

- New Module

- Added the following CDEs:
    - 2695096v1.0 (Nucleic Acid Amplification Test West Nile Virus Laboratory Finding Result)
    - 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2695096v1.0 (Nucleic Acid Amplification Test West Nile Virus Laboratory Finding Result)
    - 2581523v1.0 (Positive)
    - 2617835v1.0 (Negative)
    - 3104692v1.0 (Not done)
    - 2581003v1.0 (Not applicable)

Minor:

- Added module instruction text:
    - New: Report final test results

Module: Infectious Disease Marker - Chagas

Major:

- New Module

- Added the following CDEs:
    - 3192228v1.0 (Chagas Disease Laboratory Procedure Laboratory Finding Result)
    - 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3192228v1.0 (Chagas Disease Laboratory Procedure Laboratory Finding Result)
    - 2581523v1.0 (Positive)
    - 2617835v1.0 (Negative)
    - 3104692v1.0 (Not done)

Minor:

- Added module instruction text:
    - New: Report final test results

Module: Infectious Disease Marker - Herpes simplex virus (HSV)

Major:

- New Module

- Added the following CDEs:
    - 3809558v1.0 (Herpes Simplex Virus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3809558v1.0 (Herpes Simplex Virus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 2581523v1.0 (Positive)
    - 2617835v1.0 (Negative)
    - 3104692v1.0 (Not done)

Minor:

- Added module instruction text:
    - New: Report final test results

- Added question instruction text for CDE 3809558v1.0 (Herpes Simplex Virus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - New: Herpes simplex virus antibody

Module: Infectious Disease Marker - Epstein-Barr virus (EBV)

Major:

- New Module

- Added the following CDEs:
    - 2873940v2.0 (Epstein-Barr Virus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 2873940v2.0 (Epstein-Barr Virus Antibody Laboratory Procedure Performed Laboratory Finding Result)
    - 2581523v1.0 (Positive)

- o   2617835v1.0 (Negative)
- o   2749725v1.0 (Inconclusive)
- o   3104692v1.0 (Not done)

Minor:

- Added module instruction text:
  - o   New: Report final test results

- Added question instruction text for CDE 2873940v2.0 (Epstein-Barr Virus Antibody Laboratory Procedure Performed Laboratory Finding Result)
  - o   New: Epstein-Barr virus antibody

Module: Infectious Disease Marker - Varicella zoster virus (VZV)

Major:

- New Module

- Added the following CDEs:
  - o   3809567v1.0 (Human Herpesvirus 3 Antibody Laboratory Procedure Performed Laboratory Finding Result)
  - o   3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3809567v1.0 (Human Herpesvirus 3 Antibody Laboratory Procedure Performed Laboratory Finding Result)
  - o   2581523v1.0 (Positive)
  - o   2617835v1.0 (Negative)
  - o   3104692v1.0 (Not done)

Minor:

- Added module instruction text:
  - o   New: Report final test results

- Added question instruction text for CDE 3809567v1.0 (Human Herpesvirus 3 Antibody Laboratory Procedure Performed Laboratory Finding Result)
  - o   New: Varicella zoster virus antibody

Module: Infectious Disease Marker - Toxoplasmosis

<u>Major:</u>

- New Module

- Added the following CDEs:
    - 3809568v1.0 (Toxoplasmosis Laboratory Procedure Performed Laboratory Finding Result)
    - 3006893v1.0 (Sample Collection Date)

- Added the following permissible values for CDE 3809568v1.0 (Toxoplasmosis Laboratory Procedure Performed Laboratory Finding Result)
    - 2581523v1.0 (Positive)
    - 2617835v1.0 (Negative)
    - 3104692v1.0 (Not done)

<u>Minor:</u>

- Added module instruction text:
    - <u>New</u>: Report final test results

Module: Infectious Disease Marker - Other Infectious Disease Marker - Part 1 of 2

<u>Major:</u>

- New Module

- Added the following CDEs:
    - 3575391v1.0 (Laboratory Procedure Other Infectious Disease Marker Indicator)

- Added the following permissible values for CDE 3575391v1.0 (Laboratory Procedure Other Infectious Disease Marker Indicator)
    - 2567168v1.0 (Yes)
    - 2567170v1.0 (No)

Module: Infectious Disease Marker - Other Infectious Disease Marker - Part 2 of 2

<u>Major:</u>

- New Module

- Added repetition count:
  - <u>New</u>: 9

- Added the following CDEs:
  - 3006893v1.0 (Sample Collection Date)
  - 2630451v1.0 (Laboratory Procedure Other Infectious Disease Marker Assessment Specify)
  - 2630453v1.0 (Laboratory Procedure Other Infectious Disease Marker Lab Result Specify)

<u>Minor</u>:

- Added module instruction text:
  - <u>New</u>: Report final test results

Module: Author Information

<u>Major</u>:

- Added the following CDEs:
  - 3771111v1.0 (Form Entry Date)

- Removed the following CDEs:
  - 2828513v1.0 (Contact Person Location Telephone Number)
  - 2828511v1.0 (Contact Person Location Fax Number)

<u>Minor</u>:

- Question instruction text change for CDE 2179591v2.0
  - <u>Old</u>: Last Name
  - <u>New</u>: Last Name: (colon added)

- Question instruction text change for CDE 2517550v1.0
  - <u>Old</u>: Email Address
  - <u>New</u>: E-mail address: