**Immunization Test Tool Release Notes for Version 2.0.6 March 17, 2022**

**Data**

| **Test Case / Message Profile** | **Issue** | **Resolution** |
| --- | --- | --- |
| For Z22 messages | Per the CDC, the following **Unit of Sale NDC**s have been added:   * 75052-0001-10 for PREHEVBRIO Hepatitis B Vaccine (Recombinant), HepB recombinant, 3-antigen, Al(OH)3 * 49281-0564-15 for QUADRACEL DTaP-IPV DTAP adsorbed and inactivated poliovirus vaccine * 00069-2025-10 for **Pfizer-BioNTech COVID-19 Vaccine COMIRNATY,** 30 mcg/0.3 mL for adult 16+ adult tris-sucrose formulation, GREY CAP * 00069-2025-25 for **Pfizer-BioNTech COVID-19 Vaccine COMIRNATY,** 30 mcg/0.3 mL for adult 16+ adult tris-sucrose formulation, GREY CAP * 80777-0275-99 **for Moderna COVID-19 Vaccine 50 mcg/0.50 mL for booster only**, adult 18+, DARK BLUE CAP | Updates have been made to the **NDC Unit of Sale Value Set** in the Immunization Test Suite  Added:   * **Code**: 75052-0001-10 * **Code System**: NDC * **Description**: PREHEVBRIO Hepatitis B Vaccine (Recombinant), HepB recombinant, 3-antigen, Al(OH)3, CARTON, 10 VIAL * **Code**: 49281-0564-15 * **Code System**: NDC * **Description**: QUADRACEL DTaP-IPV DTAP adsorbed and inactivated poliovirus vaccine, PACKAGE 10 SYRINGE * **Code**: 00069-2025-10 * **Code System**: NDC * **Description**: **Pfizer-BioNTech COVID-19 Vaccine COMIRNATY,** 30 mcg/0.3 mL for adult 16+ adult tris-sucrose formulation, GREY CAP, CARTON, 10 MULTI-DOSE VIALS * **Code**: 00069-2025-25 * **Code System**: NDC * **Description**: **Pfizer-BioNTech COVID-19 Vaccine COMIRNATY,** 30 mcg/0.3 mL for adult 16+ adult tris-sucrose formulation, GREY CAP, CARTON, 25 MULTI-DOSE VIALS * **Code**: 80777-0275-99 * **Code System**: NDC * **Description**: **Moderna COVID-19 Vaccine 50 mcg/0.50 mL for booster only**, adult 18+, DARK BLUE CAP, CARTON, 10 MULTI-DOSE VIAL 2.5 mL EACH |
| For Z22 messages | Per the CDC, the following **Unit of Use NDCs** have been added:   * 75052-0001-01 for PREHEVBRIO Hepatitis B Vaccine (Recombinant), HepB recombinant, 3-antigen, Al(OH)3 * 49281-0564-88 for QUADRACEL DTaP-IPV DTAP adsorbed and inactivated poliovirus vaccine * 00069-2025-01 for **Pfizer-BioNTech COVID-19 Vaccine COMIRNATY,** 30 mcg/0.3 mL for adult 16+ adult tris-sucrose formulation, GREY CAP * 80777-0275-05 **for Moderna COVID-19 Vaccine 50 mcg/0.50 mL for booster only**, adult 18+, DARK BLUE CAP | Updates have been made to the **NDC Unit of Use Value Set** in the Immunization Test Suite  Added:   * **Code**: 75052-0001-01 * **Code System**: NDC * **Description**: PREHEVBRIO Hepatitis B Vaccine (Recombinant), HepB recombinant, 3-antigen, Al(OH)3, VIAL, 1 mL * **Code**: 49281-0564-88 * **Code System**: NDC * **Description**: QUADRACEL DTaP-IPV DTAP adsorbed and inactivated poliovirus vaccine, SYRINGE, .5 mL * **Code**: 00069-2025-01 * **Code System**: NDC * **Description**: **Pfizer-BioNTech COVID-19 Vaccine COMIRNATY,** 30 mcg/0.3 mL for adult 16+ adult tris-sucrose formulation, GREY CAP, VIAL, 2 mL, MULTI-DOSE VIAL * **Code**: 80777-0275-05 * **Code System**: NDC * **Description**: **Moderna COVID-19 Vaccine 50 mcg/0.50 mL for booster only**, adult 18+, DARK BLUE CAP, VIAL, 2.5 mL, MULTI-DOSE VIAL |
| For Z22, Z32, and Z42 messages | Per the CDC, the following additions/modifications have been made to the **CVX** table:  Added:   * **CVX code 220** for Hepatitis B vaccine (recombinant), 3-antigen, Al(OH)3 adjuvanted * **CVX code 221** for **Moderna COVID-19 Vaccine** SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 50 mcg/0.5 mL dose   Modified Description:   * **CVX Code 207 description updated** to better differentiate that code from the new code 221; added **dose volumes**:   + “SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg or 50 mcg dose”   changed to   * + “SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg**/0.5mL** dose or 50 mcg**/0.25mL dose**” | Updates have been made to the **CVX** **Value Set** in the Immunization Test Suite  Added:   * **Code**: 220 * **Code System**: CVX * **Description**: Hepatitis B vaccine (recombinant), 3-antigen, Al(OH)3 adjuvanted * **Code**: 221 * **Code System**: CVX * **Description**: **Moderna,** SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 50 mcg/0.5 mL dose   Description Modified:   * **Code**: 207 * **Code System**: CVX * **Description**: Moderna, SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg/0.5mL dose or 50 mcg/0.25mL dose |
| For Z22, Z32, and Z42 messages | Per the CDC, the following CVX/VIS mapping additions have been made:   * **CVX Code 220** “Hepatitis B vaccine (recombinant), Al(OH)3 adjuvanted” has been mapped to the existing VIS barcode string 253088698300005911211015 for the current Hepatitis B Vaccine VIS | Update has been made to the **PHVS\_VISVaccines\_IIS** **Value Set** in the Immunization Test Suite  Added:   * **Code**: 220 * **Code System**: CVX * **Description**: Hepatitis B |
| For Z22, Z32, and Z42 messages | Per the CDC, the following addition has been made to the **MVX** table:  Added:   * **VBI** for “VBI Vaccines, Inc” | Update has been made to the **MVX** **Value Set** in the Immunization Test Suite  Added:   * **Code**: VBI * **Code System**: MVX * **Description**: VBI Vaccines, Inc |
| For Z22, Z32, and Z42 messages | MVX code “**BN**” for “Bavarian Nordic A/S” is missing from the **MVX value set** in the Immunization Test Suite. | Update has been made to the **MVX** **Value Set** in the Immunization Test Suite  Added:   * **Code**: BN * **Code System**: MVX * **Description**: Bavarian Nordic A/S |
| **COVID-19 Test Plan**  **Test Case**: IZ-COVID-19\_1\_Adult\_Admin\_Moderna  **Test Step**: IZ-1.1\_AA\_Send\_COVID-19\_Dose-1\_Moderna  **Test Step**: IZ-1.2\_AA\_Send\_COVID-19\_Dose-2\_Moderna | Per the CDC, the **CVX** **Description** for the **Moderna** vaccine with **CVX** code **207**– “SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg or 50 mcg dose” – has been modified to “SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg**/0.5mL** dose or 50 mcg**/0.25mL dose**”.  The example Test Messages provided for the Moderna vaccine Test Steps in the COVID-19 Test Plan include these data in the RXA segments:  RXA…^207^**COVID-19, mRNA, LNP-S, PF, 100 mcg/ 0.5 mL dose**^CVX|0.5|mL^mL^UCUM|… | In the example Test Messages provided for the Moderna vaccine Test Steps in the COVID-19 Test Plan, the relevant data in the RXA segments have been changed to  RXA…^207^ **SARS-COV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 100 mcg/0.5mL dose or 50 mcg/0.25mL dose**^CVX|0.5|mL^mL^UCUM|… |

|  |  |  |  |
| --- | --- | --- | --- |
| **Message Profile** | **Issue** | | **Resolution** |
| For Z22, Z32, Z42 messages | Per the CDC, the following VIS documents and VIS Codes have been added: | | The new VIS **Descriptions** and associated VIS **Codes** have been added to the **PHVS\_VISBarcodes\_IIS Value Set** in the Immunization Test Suite |
|  | **Document Type Description (New)** | **VIS Fully-encoded Test String** |
|  | Dengue Vaccine VIS | 253088698300046211211217 |  |
|  | Pneumococcal Conjugate Vaccine (PCV13\_PCV15\_PCV20) VIS | 253088698300049311220204 |  |
|  | Recombinant Zoster Vaccine VIS | 253088698300032511220204 |  |
|  |  |  |  |

**Specific Validation**

| **Issue** | **Resolution** |
| --- | --- |
| Cardinality for MSH-21 (Message Profile Identifier) is erroneously set to [1,1] (*meaning element must have exactly one occurrence*) for Z34, Z44, Z31, Z33, and Z42 Profiles.  **Note**: Cardinality for Profile Z33 is [1,1] in the Immunization Implementation Guide 1.5 but should be [1,\*]; Cardinality for Z34, Z44, Z31, and Z42 Profiles is [1,\*] in the Guide and is erroneous just in the Immunization Test Suite. | Cardinality for MSH-21 (Message Profile Identifier) for Z34, Z44, Z31, Z33, and Z42 Profiles in the Immunization Test Suite has been changed/corrected to [1,\*] (*meaning element must appear at least once and may repeat unlimited number of times in the message*). |
| The *Cardinality* for MSH-18 (Character Set) is **incorrect** in the **NIST** **Immunization Test Suite Profile Viewer** for the Z34, Z44, Z31, Z32,  Z33, and Z42 Profiles. *Usage* for these Profiles is Optional “O” in the Profile Viewer and is correct.  See the table below for the current MSH-18 Usage and Cardinality listed for each of the immunization message Profiles in:   * The HL7 v2.5.1 Implementation Guide r1.5 and associated Addendum * The Immunization Test Suite * The Consolidated IG (merging of the 2.5.1 IG r1.5 + Addendum) | After discussion with immunization SMEs, Cardinality for MSH-18 (Character Set) for Z34, Z44, Z31, Z32,  Z33, and Z42 Profiles in the **Immunization Test Suite Profile Viewer** has been **corrected** to [0,\*] (*meaning element may have none to many occurrences in the message*). |

| **Issue** | **Resolution** |
| --- | --- |
| In the ONC 2015 Test Plan, Test Case **IZ-AD-1\_Admin\_Child**, Test Step **IZ-AD-1.1\_Send\_V04\_Z22**:  For the test message where a combo vaccine is used in an RXA segment, the validator does not check for the exact VIS code in the OBX segments associated with the Polio Vaccine VIS, the Haemophilus Influenzae type b (Hib) Vaccine VIS, and the DTaP (Diphtheria, Tetanus, Pertussis) Vaccine VIS. | The **Order Indifferent** function available in the **Test Case Authoring and Management Tool (TCAMT)** has been utilized to enable the validator to detect the exact VIS code that is to populate OBX-5.1 when OBX-3 = 69764-9^Document Type for the OBX segments associated with the Polio Vaccine VIS, the Haemophilus Influenzae type b (Hib) Vaccine VIS, and the DTaP (Diphtheria, Tetanus, Pertussis) Vaccine VIS. |
| In the ONC 2015 Test Plan, Test Case **IZ-AD-9\_Admin\_IIS-2Warnings**, Test Step **IZ-AD-9.1\_Send\_V04\_Z22**:  For the test message where a combo vaccine is used in an RXA segment, the validator does not check for the exact VIS code in the OBX segments associated with the Polio Vaccine VIS and the DTaP (Diphtheria, Tetanus, Pertussis) Vaccine VIS. | The **Order Indifferent** function available in the **Test Case Authoring and Management Tool (TCAMT)** has been utilized to enable the validator to detect the exact VIS code that is to populate OBX-5.1 when OBX-3 = 69764-9^Document Type for the OBX segments associated with the Polio Vaccine VIS and the DTaP (Diphtheria, Tetanus, Pertussis) Vaccine VIS. |

|  |  |
| --- | --- |
| The *Cardinality* for MSH-17 (Country Code), MSH-19 (Principal Language Of Message), and MSH-20 (Alternate Character Set Handling Scheme) is **incorrect** in the **NIST** **Immunization Test Suite Profile Viewer** for the Z31, Z33, Z42, and Z44 Profiles.  See the table below for the current MSH-17, 19, 20 Usage and Cardinality listed for each of the immunization message Profiles in the Immunization Test Suite: | The *Cardinality* for MSH-17 (Country Code), MSH-19 (Principal Language Of Message), and MSH-20 (Alternate Character Set Handling Scheme) for Z31, Z33, Z42, and Z44 Profiles in the **Immunization Test Suite Profile Viewer** has been **corrected** to [0,1] (*meaning element may have none to one occurrence in the message*).  See the table below for the updated MSH-17, 19, 20 Cardinality values. |

**User Interface**

| **Issue** | **Resolution** |
| --- | --- |
| None |  |

**Core Functionality**

| **Issue** | **Resolution** |
| --- | --- |
|  |  |

**Documentation**

| **Issue** | **Resolution** |
| --- | --- |
| None |  |

**SOAP Functionality**

| **Test Case** | **Issue** | **Resolution** |
| --- | --- | --- |
| None |  |  |

**Improvements/Features**

|  |
| --- |
| None |

**Issues for a Future Release**

**ONC 2015 Test Plan**

| **Test Case/if Applicable** | **Issue** |
| --- | --- |
| All Test Steps with a VXU message | In a VXU Context-based message where there are multiple OBX segments for each Order Group, if an OBX segment has OBX-3.1 populated with the 69764-9 LOINC code and has OBX-5.1 populated with an incorrect VIS ID, the Test Tool issues an Error notification that indicates   * in the **Path** information the VXU Order Group (e.g., “VXU\_V04.ORDER[1]”) within which the OBX with the error is contained and * in the **Line #** information the line number listed in the Message Content window for the ORC segment in that Order Group. * In the **Description** information that an Error has been found due to there being no OBX segment where OBX-3.1 is populated with the 69764-9 LOINC code and OBX-5.1 is populated with [an expected VIS ID] within in this Order Group.   The Path, Line #, and Description information may or may not be meaningful enough for a Tester to determine which OBX segment contains the VIS ID error.  The Tool will be modified to make the Error notification more specific and meaningful. |
| Context-free Data Quality Assurance (DQA) function | The DQA tab in the Context-free / VXU Z22 function has been removed in order to update the capability. The Tool will be modified with an updated version.  (Demonstration of how DQA is intended to function has been deleted from the updated Tool Tutorial.) |