**Immunization Test Tool Release Notes for Version 1.9.13 December 16, 2020**

**Data**

| **Test Case / Message Profile** | **Issue** | | **Resolution** |
| --- | --- | --- | --- |
| For Z22 messages | Per the CDC, the following **Unit of Sale NDCs** have been added:   * 80777-0273-99 for Moderna COVID-19 Vaccine; CARTON, 10 MULTI-DOSE VIALS * 59267-1000-02 for Pfizer COVID-19 Vaccine; CARTON, 195 MULTI-DOSE VIALS * 63361-0243-15 for VAXELIS * 50090-5147-00 for Shingrix | | Updates have been made to the **NDC Unit of Sale Value Set** in the Immunization Test Suite; added:   * **Code**: 80777-0273-99 * **Code System**: NDC * **Description**: Moderna COVID-19 Vaccine; CARTON, 10 MULTI-DOSE VIALS * **Code**: 59267-1000-02 * **Code System**: NDC * **Description**: Pfizer COVID-19 Vaccine; CARTON, 195 MULTI-DOSE VIALS * **Code**: 63361-0243-15 * **Code System**: NDC * **Description**: VAXELIS * **Code**: 50090-5147-00 * **Code System**: NDC * **Description**: Shingrix |
| For Z22 messages | Per the CDC, the following **Unit of Use NDCs** have been added:   * 80777-0273-10 for Moderna COVID-19 Vaccine; MULTI-DOSE VIAL, 10 DOSES * 59267-1000-01 for Pfizer COVID-19 Vaccine; MULTI-DOSE VIAL, 5 DOSES * 63361-0243-88 for VAXELIS * 58160-0828-01 for Shingrix | | Updates have been made to the **NDC Unit of Use Value Set** in the Immunization Test Suite; added:   * **Code**: 80777-0273-10 * **Code System**: NDC * **Description**: Moderna COVID-19 Vaccine; MULTI-DOSE VIAL, 10 DOSES * **Code**: 59267-1000-01 * **Code System**: NDC * **Description**: Pfizer COVID-19 Vaccine; MULTI-DOSE VIAL, 5 DOSES * **Code**: 63361-0243-88 * **Code System**: NDC * **Description**: VAXELIS * **Code**: 58160-0828-01 * **Code System**: NDC * **Description**: Shingrix or zoster vaccine subunit\*   \*see Known Issues document 1.9.13 for additional information |
| For Z22, Z32, and Z42 messages | Per the CDC, the following CVX codes have been added:   * CVX code 207, “COVID-19, mRNA, LNP-S, PF, 100 mcg/ 0.5 mL dose” * CVX code 208, “COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose” * CVX code 213, “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” | | Updates have been made to the **CVX Value Set** in the Immunization Test Suite; added:   * **Code**: 207 * **Code System**: CVX * **Description**: COVID-19, mRNA, LNP-S, PF, 100 mcg/ 0.5 mL dose * **Code**: 208 * **Code System**: CVX * **Description**: COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose * **Code**: 213\* * **Code System**: CVX * **Description**: SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED   \*see Known Issues document 1.9.13 for additional information |
| For Z22, Z32, and Z42 messages | Per the CDC, the following CVX codes have been added that require an EUA Recipient/Caregiver Fact Sheet be given to the recipient of a COVID-19 vaccine, and these CVX codes must be included in the PHVS\_VISVaccines\_IIS Value Set:   * CVX code 207, “COVID-19, mRNA, LNP-S, PF, 100 mcg/ 0.5 mL dose” * CVX code 208, “COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose” | | Updates have been made to the **PHVS\_VISVaccines\_IIS Value Set** in the Immunization Test Suite; added:   * **Code**: 207 * **Code System**: CVX * **Description**: COVID-19, mRNA, LNP-S, PF, 100 mcg/ 0.5 mL dose * **Code**: 208 * **Code System**: CVX * **Description**: COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose |
| For Z22, Z32, and Z42 messages | Per the CDC, the following MVX codes have been added:   * MOD for Moderna US, Inc. * ASZ for AstraZeneca * JSN for Janssen | | Updates have been made to the M**VX Value Set** in the Immunization Test Suite; added:   * **Code**: MOD * **Code System**: MVX * **Description**: Moderna US, Inc. * **Code**: ASZ * **Code System**: MVX * **Description**: AstraZeneca * **Code**: JSN * **Code System**: MVX * **Description**: Janssen |
| For Z22, Z32, and Z42 messages | Per the CDC, the following VIS documents have been added (Note: these codes were developed in advance of potential EUA decision by FDA for each vaccine; the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS): | | 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** |
| COVID-19 Pfizer BioNTech Vaccine EUA Recipient-Caregiver Fact Sheet | 253088698300033211201201 |
| COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet | 253088698300034911201201 |
| Administration Group  Test Case: IZ-QR-2\_Query\_Adult  Test Step: IZ-QR-2.1\_Query\_Q11\_Z44  Test Step: IZ-QR-2.2\_Response\_K11\_Z42 | The Test Story Descriptions contain a typo for the patient’s name. “Stanley S. Clement” should be “Clement S. Stanley” | | The patient’s name in the Test Story Descriptions has been changed to “Clement S. Stanley” |
| For Z22, Z32, and Z42 messages | The following CVX codes are associated with VIS codes and were not included in the **PHVS\_VISVaccines\_IIS Value Set** in the Immunization Test Suite:   |  |  |  | | --- | --- | --- | | **Code** | **Code System** | **Description** | | 143 | CVX | Adenovirus types 4 and 7 | | 20 | CVX | DTaP | | 28 | CVX | DT (pediatric) | | 149 | CVX | influenza, live, intranasal, quadrivalent | | 205 | CVX | Influenza vaccine, quadrivalent, adjuvanted | | 155 | CVX | influenza, recombinant, injectable, preservative free | | 168 | CVX | influenza, trivalent, adjuvanted | | 185 | CVX | influenza, recombinant, quadrivalent, injectable, preservative free | | 186 | CVX | Influenza, injectable, MDCK, quadrivalent, preservative | | 166 | CVX | influenza, intradermal, quadrivalent, preservative free | | 197 | CVX | influenza, high-dose, quadrivalent | | 161 | CVX | Influenza, injectable, quadrivalent, preservative free, pediatric | | 150 | CVX | influenza, injectable, quadrivalent, preservative free | | 158 | CVX | influenza, injectable, quadrivalent | | 171 | CVX | Influenza, injectable, MDCK, preservative free, quadrivalent | | 153 | CVX | Influenza, injectable, MDCK, preservative free | | 134 | CVX | Japanese Encephalitis IM | | 33 | CVX | pneumococcal polysaccharide PPV23 | | 175 | CVX | Rabies - IM Diploid cell culture | | 176 | CVX | Rabies - IM fibroblast culture | | 35 | CVX | tetanus toxoid, adsorbed | | 142 | CVX | tetanus toxoid, not adsorbed | | 101 | CVX | typhoid, ViCPs | | 41 | CVX | typhoid, parenteral | | 25 | CVX | typhoid, oral | | 37 | CVX | yellow fever | | 183 | CVX | Yellow fever vaccine - alt | | 196 | CVX | Td, adsorbed, preservative free, adult use, Lf unspecified | | 165 | CVX | HPV9 | | 162 | CVX | meningococcal B, recombinant | | 163 | CVX | meningococcal B, OMV | | 174 | CVX | cholera, live attenuated | | | These CVX codes have been added to the **PHVS\_VISVaccines\_IIS Value Set** in the Immunization Test Suite |
| For Z22, Z32, and Z42 messages | The CVX code 24 is duplicated in the **PHVS\_VISVaccines\_IIS Value Set** in the Immunization Test Suite; and the Description for one instance is “Anthrax VIS” and for the other instance is “Anthrax Vaccine VIS”: | | One of the instanced of CVX code 24 has been deletd from **PHVS\_VISVaccines\_IIS Value Set** in the Immunization Test Suite; and the Description for the remaining instance has been changed to “anthrax”. |

**Specific Validation**

| **Issue** | **Resolution** |
| --- | --- |
| For VXU messages, the Conformance Statement IZ-24 states “If RXA-20 is valued 'CP' or 'PA' and the first occurrence of RXA-9.1 is valued '00' and RXA-5.1 is valued with a CVX code from table PHVS\_VISVaccines\_IIS…”; but the NIST Immunization Test Suite is only checking for the value of the RXA-5.1 code, regardless of the coding system (RXA-5.3).  Consequently, the NIST IZ testing tool is, under specific circumstances, issuing an error related to IZ-24 when it should not be. In such cases, the overall outcome of the message validation is still correct, but IZ-24 should not be listed as a failure. | A fix to IZ-24 has been made in the supporting XML profile, and the Context-**free** Validation in the NIST Immunization Test Suite now does not generate an error notification related to IZ-24 if RXA-5.3 is not “CVX”.  Note: For Context-**based** Validation in the NIST Immunization Test Suite, when RXA-9.1 is valued ‘00’ then RXA-5.3 must be “NDC” and RXA-5.1 must be valued with an NDC per the 2015 Edition ONC certification criteria requirements in [§170.315(f)(1)](https://www.healthit.gov/node/125556) [Transmission to immunization registries](https://www.healthit.gov/test-method/transmission-immunization-registries).  **Note**: The Known issues document has been updated with information about the IZ-24 error notification verbiage. |
| CVX code 213, “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” has been added to the CVX Value Set in the NIST Immunization Test Suite.  Per the CDC, the CVX code 213, “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED”, is never to be used in VXU messages to populate RXA-5.1 when RXA-9.1 is “00”. | A NIST Conformance Statement has been added to the NIST Immunization Test Suite that causes generation of the following error notification if the CVX code 213 is used in VXU messages to populate RXA-5.1 when RXA-9.1 is “00”:   * **NIST-02**: The value CVX code 213 “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” at location Field RXA-5 (Administered Code) is NOT RECOMMENDED by the CDC for newly administered (RXA-9.1 = “00”) COVID-19 vaccines. The CDC highly encourages sending a COVID-19 specified code; not doing so can affect ancillary systems and can negatively impact clinical outcomes.   **Note**: The Known issues document has been updated with information about the CVX code 213 and the error notification verbiage. |

**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**

| **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.) |