Data Collection Form—Final Annotated

**Report of Verified Case of Tuberculosis (RVCT) – 10/29/2019**

# Administrative Information

1. **Date Reported:** 🞏🞏/🞏🞏/🞏🞏🞏🞏 [**77995-9**]

Red Text = Generic v2 Data Element

Black Text = TB & LTBI MMG Data Element

Purple Text = Value Set Codes

1. **Date Counted**
   1. MMWR Week: 🞏🞏 [**77991-8**]
   2. MMWR Year: 🞏🞏🞏🞏 [**77992-6**]
2. **State Case Number:**🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 [INV1107]
3. **Local Case Number:** 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 [INV1108]
4. **Case Already Counted by Another Reporting Area?** [INV1109]

\_\_\_ {PHC659} Yes, another U.S. reporting area (State case number from other area:  
 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏) [INV1110]

\_\_\_ {PHC660} Yes, another country (Specify country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) [INV1111]

\_\_\_ {N} No

**Country Options:** Choose from value set PHVS\_BirthCountry\_CDC

# Demographics and Initial Evaluation

1. **Reporting Address**
   1. City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [PID-11.3]
   2. Is the Patient’s Residence within City Limits? [INV1112]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

* 1. County: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [**PID-11.9**]

**County Options:** Choose from value set PHVS\_County\_FIPS\_6-4

* 1. ZIP Code: 🞏🞏🞏🞏🞏-🞏🞏🞏🞏 [**PID-11.5**]
  2. Census Tract (11-digit GEOID): 🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏 [PID-11.10]

1. **Date of Birth**: 🞏🞏/🞏🞏/🞏🞏🞏🞏 [**PID-7**]
2. **Sex at Birth** [**76689-9**]

\_\_\_ {M} Male

\_\_\_ {F} Female

If Female, Was Patient Pregnant at Time of Diagnostic Evaluation? [**77996-7**]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

\_\_\_ {U} Unknown

1. **Ethnicity** [**PID-22**]

\_\_\_ {2135-2} Hispanic or Latino

\_\_\_ {2186-5} Not Hispanic or Latino

\_\_\_ {UNK} Unknown

*NOTE: OTH is in the NND vocabulary; however, TB is not interested in that result*

1. **Race** [**PID-10**]

\_\_\_ {1002-5} American Indian or Alaska Native

\_\_\_ {2028-9} Asian (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) [DEM153]

\_\_\_ {2054-5} Black or African American

\_\_\_ {2076-8} Native Hawaiian or Other Pacific Islander (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) [DEM153]

\_\_\_ {2106-3} White

\_\_\_ {2131-1} Other Race (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) [**32624-9**]

\_\_\_ {UNK} Unknown

*NOTE: ASKU, NI, NASK, PHC1175 is in the NND vocabulary; however, TB is not interested in these results*

**Race Specify [DEM153] Options:** Choose from value set PHVS\_Race\_CDC; the TB program is specifically interested in Asian and Native Hawaiian or Other Pacific Islander details; however all are accepted.

1. **Nativity**
   1. Country of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [**78746-5**]

(If NOT United States, Date of First U.S. Arrival: 🞏🞏/🞏🞏/🞏🞏🞏🞏) [DEM2005]

* 1. Eligible for U.S. Citizenship/Nationality at Birth (regardless of country of birth)? [DEM2003]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

* 1. Countries of Birth for Primary Guardian(s) (pediatric [<15 years old] cases only)
     1. Guardian 1: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [INV1113]
     2. Guardian 2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [INV1113]

**Birth Country Specify Options:** Choose from value set PHVS\_BirthCountry\_CDC

1. **Country of Usual Residence**
   1. Country of Usual Residence: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [**77983-5**]
   2. If **NOT** U.S. Reporting Area, Has Been in United States for ≥90 days (inclusive of Report Date)? [INV1114]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

**Country Specify Options:** Choose from value set PHVS\_Country\_ISO\_3166-1

1. **Status at TB Diagnosis** [TB101]

\_\_\_ {438949009} Alive

\_\_\_ {419099009} Dead (Make sure to complete question 43)

1. **Initial Reason Evaluated for TB** [INV1116]

\_\_\_ {PHC681} Contact Investigation

\_\_\_ {360156006} Screening

\_\_\_ {PHC680} TB Symptoms

\_\_\_ {OTH} Other

\_\_\_ {UNK} Unknown

# Risk Factors

1. **Occupation and Industry**
   1. Has the patient *ever* worked as one of the following? (select all that apply) [INV1276]

\_\_\_ {223366009} Healthcare Worker

\_\_\_ {C0682244} Correctional Facility Employee

\_\_\_ {PHC2121} Migrant/Seasonal Worker

\_\_\_ {260413007} None of the above

\_\_\_ {UNK} Unknown

* 1. Patient’s Current Occupation(s) and Industry(ies)

|  |  |
| --- | --- |
| Occupation [85658-3] | Industry [85078-4] |
|  |  |
|  |  |
|  |  |

**Coded Occupation Options** [85659-1]**:** If completing choose from value set PHVS\_Occupation\_CDC\_Census2010

**Coded Industry Options** [85657-5]**:** If completing choose from value set PHVS\_Industry\_CDC\_Census2010

1. **Other Risk Factors**

|  |  |
| --- | --- |
| Risk Factor [INV1117] | Indicator [INV1118] |
| {PHC2098} Diabetic at Diagnostic Evaluation | {Y/N/UNK} |
| {PHC1876} Homeless in the Past 12 Months | {Y/N/UNK} |
| {32911000} Homeless Ever | {Y/N/UNK} |
| {257656006} Resident of Correctional Facility at Diagnostic Evaluation | {Y/N/UNK} |
| {PHC2099} Resident of Correctional Facility Ever | {Y/N/UNK} |
| {42665001} Resident of Long-Term Care Facility at Diagnostic Evaluation | {Y/N/UNK} |
| {226034001} Injecting Drug Use in the Past 12 Months | {Y/N/UNK} |
| {PHC1877} Noninjecting Drug Use in the Past 12 Months | {Y/N/UNK} |
| {86933000} Heavy Alcohol Use in the Past 12 Months | {Y/N/UNK} |
| {PHC690} TNF-α Antagonist Therapy | {Y/N/UNK} |
| {161663000} Post-Organ Transplantation | {Y/N/UNK} |
| {46177005} End Stage Renal Disease | {Y/N/UNK} |
| {PHC2236} Viral Hepatitis (B or C only) | {Y/N/UNK} |
| {PHC1878} Other Immunocompromise (other than HIV/AIDS) | {Y/N/UNK} |
| {OTH} Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | {Y/N/UNK} |

1. **If Resident of Correctional Facility at Diagnostic Evaluation, Type of Facility?** [INV1119]

\_\_\_ {PHC46} Federal Prison

\_\_\_ {PHC26} State Prison

\_\_\_ {PHC62} Local Jail

\_\_\_ {C0680668} Juvenile Correction Facility

\_\_\_ {OTH} Other Correctional Facility

\_\_\_ {UNK} Unknown

1. **If Resident of Long-Term Care Facility at Diagnostic Evaluation, Type of Facility?** [INV1120]

\_\_\_{C0028688} Nursing Home

\_\_\_{PHC221} Hospital-Based Facility

\_\_\_{C0035186} Residential Facility

\_\_\_{283Q00000X} Mental Health Residential Facility

\_\_\_{324500000X} Alcohol or Drug Treatment Facility

\_\_\_{OTH} Other Long-Term Care Facility

\_\_\_{UNK} Unknown

1. **Current Smoking Status at Diagnostic Evaluation** [72166-2]

\_\_\_ {449868002} Current everyday smoker

\_\_\_ {428041000124106} Current someday smoker

\_\_\_ {8517006} Former smoker

\_\_\_ {266919005} Never smoker

\_\_\_ {77176002} Smoker, current status unknown

\_\_\_ {266927001} Unknown if ever smoked

1. **Lived outside of the United States for >2 months (uninterrupted)?** [INV1121]

\_\_\_{Y} Yes

\_\_\_{N} No

\_\_\_{UNK} Unknown

# Diagnostic Testing (Non-DST)

1. **Tuberculin Skin Test and All Non-DST TB Laboratory Test Results**

*Please provide a response for each of the main test types (culture, smear, pathology/cytology, NAA, TST, IGRA, HIV, diabetes) If test was not done please indicate so. See list example in table.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Test Type  [INV290] | Specimen Source Site  [31208-2] | Date Collected/Placed  [68963-8] | Date Reported/Read  [82773-3] | Test Result (Qual.)  [INV291] | Test Result (Quant.)  [LAB628] | Test Result (Units of Measure)  [LAB115] |
| TST | Skin Structure | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | Positive | 15 | mm |
| IGRA [spec. type] | Blood | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |  |
| Smear | Sputum | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |  |
| Culture | Sputum | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |  |
| NAA | Sputum | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |  |
| HIV | Blood | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |  |
|  |  |  |  |  |  |  |

**Test Type Options:** {20431-3} Smear, {50595-8} Pathology, {10525-4} Cytology, {LAB673} NAA, {50941-4} Culture, {TB119} TST, {LAB671} IGRA-QFT, {LAB672} IGRA-TSpot, {71773-6} IGRA-Unknown, {LAB720} IGRA-Other, {55277-8} HIV, {24467-3} CD4 Count, {55454-3} Hemoglobin A1c, {76629-5} Fasting Blood Glucose, {LAB608} Other Test Type, and {LAB719} Pathology/Cytology

**Specimen Source Options:** Choose from value set PHVS\_MicroscopicExamCultureSite\_TB; examples: {39937001} Skin Structure, {87612001} Blood, {119334006} Sputum

**Test Result (Qualitative) Options:** {10828004} Positive, {260385009} Negative, {82334004} Indeterminate, {385660001} Not Done, {UNK} Unknown, {443390004} Refused, {PHC2092} Test Done Result Unknown, {410530007} Not Offered

**Test Result (Units of Measure) Options:** Choose from value set PHVS\_UnitofMeasure\_TB; examples: {mm} Millimeters of Induration (TST), {{cells}/uL} Cell Count (CD4), {%} Percentage (HGB-A1c), {mg/dL} Milligrams per deciliter (FBG)

1. **Chest Radiograph or Other Chest Imaging Study Results**

(Please provide a response for each of the main test types (plain chest radiograph, chest CT Scan) and if test was not done please indicate so. *See list example in table.*)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Type  [LAB677] | Date of Study  [LAB681] | Result  [LAB678] | Cavity?  [LAB679] | Miliary?  [LAB680] |
| Plain Chest X-Ray | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |  |
| CT Scan | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |  |
|  |  |  |  |  |

**Study Type Options:** {399208008} Plain Chest X-Ray, {169069000} CT Scan, {113091000} MRI, {82918005} PET, {OTH} Other

**Result Options:** {PHC1874} Not Consistent with TB, {PHC1873} Consistent with TB, {385660001} Not Done, {UNK} Unknown

**Cavity Options**: {Y} Yes, {N} No, {UNK} Unknown

**Miliary Options**: {Y} Yes, {N} No, {UNK} Unknown

# Clinical History and Findings

1. **Has the Patient been Previously Diagnosed with TB Disease or LTBI?** [161413004]

\_\_\_{Y} Yes

\_\_\_{N} No

\_\_\_{UNK} Unknown

**If YES, Complete Table Below**

(Provide only 1 response for LTBI, multiple responses for TB are allowed):

|  |  |  |  |
| --- | --- | --- | --- |
| Diagnosis Type [INV1135]  (TB Disease/LTBI) | Date of Diagnosis [82758-4] | Previous State Case No. [INV1136] | Completed Treatment? [INV1137]  (Yes/No/Unknown) |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |

**Diagnosis Type Options:** {56717001} TB Disease, {11999007} LTBI

**Completed Treatment Options**: {Y} Yes, {N} No, {UNK} Unknown

1. **Date of Illness Onset/Symptom Start Date:** 🞏🞏/🞏🞏/🞏🞏🞏🞏 [**11368-8**]
2. **Site of TB Disease** (select all that apply) [INV1133]

|  |  |
| --- | --- |
| **Primary Sites** | |
| \_\_\_ {39607008} Pulmonary (Lung)  \_\_\_ {3120008} Pleural  \_\_\_ {69831007} Lymphatic: Cervical  \_\_\_ {281778006} Lymphatic: Intrathoracic  \_\_\_ {281777001} Lymphatic: Axillary  \_\_\_ {PHC2} Lymphatic: Other  \_\_\_ {PHC3} Lymphatic: Unknown | \_\_\_ {110547006} Laryngeal  \_\_\_ {110522009} Bone and/or Joint  \_\_\_ {21514008} Genitourinary  \_\_\_ {1231004} Meningeal  \_\_\_ {83670000} Peritoneal  \_\_\_ {PHC5} Site Not Stated |
| **Additional Sites** | |
| \_\_\_ {23451007} Adrenal structure  \_\_\_ {362102006} All teeth, gums and supporting structures  \_\_\_ {53505006} Anal structure  \_\_\_ {66754008} Appendix structure  \_\_\_ {87612001} Blood  \_\_\_ {59820001} Blood vessel structure  \_\_\_ {14016003} Bone marrow structure  \_\_\_ {12738006} Brain structure  \_\_\_ {76752008} Breast structure  \_\_\_ {17401000} Cardiac valve structure  \_\_\_ {71854001} Colon structure  \_\_\_ {38848004} Duodenal structure  \_\_\_ {32849002} Esophageal structure  \_\_\_ {16014003} Extrahepatic duct structure  \_\_\_ {PHC4} Eye and ear appendages  \_\_\_ {C0230999} Fetus and embryo  \_\_\_ {28231008} Gallbladder structure  \_\_\_ {80891009} Heart structure  \_\_\_ {110611003} Jejunum and ileum  \_\_\_ {48477009} Lip structure  \_\_\_ {10200004} Liver structure  \_\_\_ {110708006} Middle ear and mastoid cells  \_\_\_ {123851003} Mouth region structure | \_\_\_ {71836000} Nasopharyngeal structure  \_\_\_ {45206002} Nasal structure  \_\_\_ {OTH} Other  \_\_\_ {15776009} Pancreatic structure  \_\_\_ {120228005} Paranasal sinus part (Accessory sinus)  \_\_\_ {76848001} Pericardial structure  \_\_\_ {54066008} Pharyngeal structure  \_\_\_ {56329008} Pituitary structure  \_\_\_ {110973009} Placenta, umbilical cord and implantation site  \_\_\_ {34402009} Rectum structure  \_\_\_ {385294005} Salivary gland structure  \_\_\_ {39937001} Skin structure  \_\_\_ {2748008} Spinal cord structure  \_\_\_ {78961009} Splenic structure  \_\_\_ {69695003} Stomach structure  \_\_\_ {25087005} Structure of nervous system  \_\_\_ {71966008} Subcutaneous tissue structure  \_\_\_ {9875009} Thymus gland structure  \_\_\_ {297261005} Thyroid and/or parathyroid structures  \_\_\_ {21974007} Tongue structure  \_\_\_ {303337002} Tonsil and adenoid structure  \_\_\_ {44567001} Tracheal structure |

# Epidemiologic Investigation

1. **Case Meets Binational Reporting Criteria?** [INV1274]

\_\_\_ {Y} Yes

If Yes, Which Criteria were Met? (Select All That Apply) [**77988-4**]

\_\_\_ {PHC1140} Exposure to Suspected Product from Canada or Mexico (e.g., dairy product for *M. bovis* case)

\_\_\_ {PHC1139} Has Case Contacts in or From Mexico or Canada

\_\_\_ {PHC1215} Potentially Exposed by a Resident of Mexico or Canada

\_\_\_ {PHC1137} Potentially Exposed while in Mexico or Canada

\_\_\_ {PHC1138} Resident of Canada or Mexico

\_\_\_ {PHC1141} Other Situations that May Require Binational Notification or Coordination of Response

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

1. **Case Identified During the Contact Investigation of Another Case?** [INV1122]

\_\_\_ {Y} Yes

If Yes, Evaluated for TB During that Contact Investigation? [INV1123]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

1. **Contact Investigation Conducted for This Case?** [INV1134]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

1. **Complete Table Below for All Known TB and LTBI Cases Epidemiologically Linked to this Case**(an unlimited number of rows may be entered):

|  |
| --- |
| State Case Number  [INV1124] |
| 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |
| 🞏🞏🞏🞏- 🞏🞏- 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |

# Initial Treatment Information

1. **Date Therapy Started:** 🞏🞏/🞏🞏/🞏🞏🞏🞏 [86948-7]
2. **Initial Drug Regimen**

| Drug Name [INV1143] | Used? [INV1144] |
| --- | --- |
| {6038} Isoniazid | {Y/N/UNK} |
| {9384} Rifampin | {Y/N/UNK} |
| {8987} Pyrazinamide | {Y/N/UNK} |
| {4110} Ethambutol | {Y/N/UNK} |
| {10109} Streptomycin | {Y/N/UNK} |
| {55672} Rifabutin | {Y/N/UNK} |
| {35617} Rifapentine | {Y/N/UNK} |
| {4127} Ethionamide | {Y/N/UNK} |
| {641} Amikacin | {Y/N/UNK} |
| {6099} Kanamycin | {Y/N/UNK} |
| {78903} Capreomycin | {Y/N/UNK} |
| {2551} Ciprofloxacin | {Y/N/UNK} |
| {82122} Levofloxacin | {Y/N/UNK} |
| {7623} Ofloxacin | {Y/N/UNK} |
| {139462} Moxifloxacin | {Y/N/UNK} |
| {3007} Cycloserine | {Y/N/UNK} |
| {7833} Para-Amino Salicylic Acid | {Y/N/UNK} |
| {190376} Linezolid | {Y/N/UNK} |
| {1364504} Bedaquiline | {Y/N/UNK} |
| {PHC1889} Delamanid | {Y/N/UNK} |
| {2592} Clofazimine | {Y/N/UNK} |
| {2198359} Pretomanid | {Y/N/UNK} |
| {OTH} Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | {Y/N/UNK} |

1. **If Initial Drug Regimen NOT RIPE/HRZE, Why Not?** [INV1139]

\_\_\_ {79899007} Drug contraindication/interaction

\_\_\_ {PHC1908} Drug susceptibility testing results already known  
\_\_\_ {PHC1909} Suspected drug resistance  
\_\_\_ {PHC1910} Drug shortage

\_\_\_ {OTH} Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

\_\_\_ {UNK} Unknown

# Genotyping and Drug Susceptibility Testing

1. **Isolate Submitted for Genotyping?** [INV1145]

\_\_\_ {Y} Yes (Accession Number:🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏🞏) [INV1146]

\_\_\_ {N} No

*NOTE: UNK is in the NND vocabulary; however, TB is not interested in that result*

1. **Was Phenotypic/Growth-Based Drug Susceptibility Testing Done?** [INV1147]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

**If YES, Provide Test Results:**

(For the initial susceptibility testing please send a response for each test type in the value set. Changes in susceptibility should be reported for each individual drug when change is identified.)

| Drug Name  [LABAST6] | Date Collected  [LABAST5] | Date Reported  [LABAST14] | Specimen Source  [LABAST3] | Result  [LABAST8] |
| --- | --- | --- | --- | --- |
| {18934-0} Isoniazid [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18974-6} Rifampin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18973-8} Pyrazinamide [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18921-7} Ethambutol [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18982-9} Streptomycin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {19149-4} Rifabutin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {76627-9} Rifapentine [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18922-5} Ethionamide [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18860-7} Amikacin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18935-7} Kanamycin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18872-2} Capreomycin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18906-8} Ciprofloxacin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {20629-2} Levofloxacin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18959-7} Ofloxacin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {31039-1} Moxifloxacin [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {LAB674} Other Quinolones [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {18914-2} Cycloserine [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {23629-9} Para-Amino Salicylic Acid [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {29258-1} Linezolid [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {LAB675} Bedaquiline [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {LAB676} Delamanid [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {23627-3} Clofazimine [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |
| {93850-6} Pretomanid [Susceptibility] | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  |

**Drug Name Options:** Choose from all the above drugs and {LAB608} Other (which is not required for the Susceptibilities)

**Specimen Source Options:** Choose from value set PHVS\_MicroscopicExamCultureSite\_TB; examples: {39937001} Skin Structure, {87612001} Blood, {119334006} Sputum

**Test Result (Qualitative) Options:** Choose from {30714006} Resistant, {131196009} Susceptible, {385660001} Not Done, {UNK} Unknown

**Test Method [LABAST7] Options:** This data element is optional but if used choose from value set PHVS\_SusceptibilityTestMethod\_TB

1. **Was Genotypic/Molecular Drug Susceptibility Testing Done?** [INV1148]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

**If YES, Provide Test Results:**

(Please report the full test results for the samples that have unique features, such as specimen type, test type, or mutation. There is no need to report test results that differ only by date or laboratory and where all other aspects are identical in regards to specimen type, test type, and/or the results of mutation.)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Gene Name  [48018-6] | Date Collected  [LAB682] | Date Reported  [LAB683] | Specimen Source Site  [LAB684] | Result  [LAB865] | NA Change  [LAB686] | AA Change  [LAB687] | INDEL  [LAB688] | Test Type  [LAB689] |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |
|  | 🞏🞏/🞏🞏/🞏🞏🞏🞏 | 🞏🞏/🞏🞏/🞏🞏🞏🞏 |  |  | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 | 🞏🞏🞏🞏🞏🞏🞏🞏🞏 |  |  |

**Gene Name Options:** Choose from value set PHVS\_GeneName\_TB; examples: {PHC1894} rpoB; {PHC1891} inhA

**Specimen Source Options:** Choose from value set PHVS\_MicroscopicExamCultureSite\_TB; examples: {39937001} Skin Structure, {87612001} Blood, {119334006} Sputum

**Result Options:** {260373001} Mutation Detected, {260415000} Mutation Not Detected, {UNK} Unknown

**Indel Options:** {PHC1904} Insertion, {246114006} Deletion, {PHC1905} Indel (not otherwise specified), {UNK} Unknown

**Test Type Options:** {PHC1906} Nonsequencing, {PHC1907} Sequencing, {OTH} Other, {UNK} Unknown

1. **Was the Patient Treated as an MDR TB Case (Regardless of DST Results)?** [INV1275]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

**If YES, complete MDR TB Supplemental Data Form**

# Case Outcome

1. **Sputum Culture Conversion Documented?** [INV1149]

\_\_\_ {Y} Yes (Date specimen collected for FIRST consistently negative sputum culture: 🞏🞏/🞏🞏/🞏🞏🞏🞏) [INV1150]

\_\_\_ {N} No

If No, Reason for Not Documenting Sputum Culture Conversion? [INV1151]

\_\_\_ {PHC1912} No Follow-up Sputum Despite Induction

\_\_\_ {PHC1913} No Follow-up Sputum and No Induction  
\_\_\_ {419099009} Died  
\_\_\_ {105480006} Patient Refused

\_\_\_ {399307001} Patient Lost to Follow-up

\_\_\_ {OTH} Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

\_\_\_ {UNK} Unknown

\_\_\_ {UNK} Unknown

1. **Moved During Therapy?** [TB279]

\_\_\_ {Y} Yes

If Yes, Moved to Where? (select all that apply) [INV1152]

\_\_\_ {PHC246} Out of State (Specify Destination: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) [INV1153]

\_\_\_ {PHC1911} Out of United States (Specify Destination: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) [INV1154]

Transnational Referral Made? [INV1155]

\_\_\_ {Y} Yes

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

\_\_\_ {N} No

\_\_\_ {UNK} Unknown

**State Destination Options:** Choose from value set PHVS\_NationalReportingJurisdiction\_NND

**Country Destination Options:** Choose from value set PHVS\_Country\_ISO\_3166-1

1. **Date Therapy Stopped:** 🞏🞏/🞏🞏/🞏🞏🞏🞏 [63939-3]
2. **Reason Therapy Stopped or Never Started?** [INV1140]

\_\_\_ {182992009} Completed Treatment

\_\_\_ {399307001} Lost

\_\_\_ {105480006} Patient Choice (Uncooperative or Refused)

\_\_\_ {281647001} Adverse Treatment Event

\_\_\_ {PHC72} Not TB

\_\_\_ {419099009} Died

\_\_\_ {418646009} Dying (treatment stopped because of imminent death, regardless of cause of death)

\_\_\_ {OTH} Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

\_\_\_ {UNK} Unknown

1. **Reason TB Disease Therapy Extended >12 Months, if applicable** (select all that apply) [INV1141]

\_\_\_ {PHC700} Inability to Use Rifampin (Resistance, Intolerance, etc.)

\_\_\_ {62014003} Adverse Drug Reaction

\_\_\_ {258143003} Nonadherence

\_\_\_ {76797004} Failure

\_\_\_ {PHC701} Clinically Indicated for Reasons Other than Above

\_\_\_ {OTH} Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

\_\_\_ {UNK} Unknown

1. **Treatment Administration** (select all that apply) [55753-8]

\_\_\_ {435891000124101} DOT (Directly Observed Therapy, in person)

\_\_\_ {PHC1881} EDOT (Electronic DOT, via video call or other electronic method)

\_\_\_ {225425006} Self-Administered

1. **Did the Patient Die (either before diagnosis or at any time while being followed by TB program)?** [INV1167]

\_\_\_\_ {Y} Yes (Date of Death: 🞏🞏/🞏🞏/🞏🞏🞏🞏) [**PID-29**]

Did TB or Complications of TB Treatment Contribute to Death? [**77978-5**]

\_\_\_ {Y} Yes

\_\_\_ {N} No  
\_\_\_ {UNK} Unknown

\_\_\_\_ {N} No

\_\_\_\_ {UNK} Unknown

**END OF RVCT**

|  |  |  |
| --- | --- | --- |
| MDR TB SUPPLEMENTAL SURVEILLANCE FORM  To be completed for all cases treated as MDR TB, regardless of DST results | | |
| 1. **History of treatment before current episode with second-line TB drugs for the treatment of TB disease (not LTBI)?** [INV1156] | | {Y} Yes  {N} No  {UNK} Unknown |
| **TREATMENT COURSE** | | |
| 1. **Date MDR TB therapy started  for current episode** [INV1157] | Month Day Year  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.** | |
| 1. **Drugs ever used for MDR TB treatment, from MDR start date (select one option for each drug)** | | |

|  |  |
| --- | --- |
| **Drug** [INV1158] | **Length of Time Administered** [INV1159]  (Not Used, <1 Month, ≥1 Month) |
| {6038}Isoniazid |  |
| {9384}Rifampin |  |
| {8987}Pyrazinamide |  |
| {4110}Ethambutol |  |
| {10109}Streptomycin\* |  |
| {55672}Rifabutin\* |  |
| {35617}Rifapentine\* |  |
| {4127}Ethionamide\* |  |
| {641}Amikacin\* |  |
| {6099}Kanamycin\* |  |
| {78903}Capreomycin\* |  |
| {2551}Ciprofloxacin\* |  |
| {82122}Levofloxacin\* |  |
| {7623}Ofloxacin\* |  |
| {139462}Moxifloxacin\* |  |
| {3007}Cycloserine\* |  |
| {7833}Para-Amino Salicylic Acid\* |  |
| {190376}Linezolid\* |  |
| {1364504}Bedaquiline\* |  |
| {PHC1889}Delamanid\* |  |
| {2592}Clofazimine\* |  |
| {2198359}Pretomanid\* |  |
| {OTH}Other (Specify: \_\_\_\_\_\_\_\_\_\_\_) |  |
| \* indicates second- or third-line medication for purpose of US surveillance  **Length of Time Administered Options:** {266710000} Not Used, {PHC1915} < 1 Month, {PHC2093} >= 1 Month | |

|  |  |
| --- | --- |
| 1. **Date injectable medication was stopped** [INV1160] | Month Day Year  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.**  **Primary Purpose: Case management. Data are used for evaluating time from TB diagnosis to start of MDR therapy.** |
| 1. **Was surgery performed to treat MDR TB?** [INV1161]   *NOTE: UNK is in the NND vocabulary; however, TB is not interested in that result* | {Y} Yes  {N} No Date:\_\_\_\_\_\_\_\_\_\_ [INV1162] |

|  |  |  |
| --- | --- | --- |
| 1. **SIDE EFFECTS** | | |
| **Side Effect** [42563-7] | **Experienced?** [INV1164] | **When?** [INV1163] |
| {35489007} Depression |  |  |
| {82313006} Suicide Attempt or Ideation |  |  |
| {36358004} Cardiac Abnormalities |  |  |
| {15188001} Hearing Loss |  |  |
| {60862001} Tinnitus |  |  |
| {445053006} Vestibular Dysfunction |  |  |
| {302226006} Peripheral Neuropathy |  |  |
| {236423003} Renal Dysfunction |  |  |
| {PHC1920} Vision Change/Loss |  |  |
| {117354009} Liver Toxicity |  |  |
| {68962001} Myalgia |  |  |
| {57676002} Arthralgia |  |  |
| {OTH} Other (Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |  |  |

**Experienced Options:** {Y} Yes, {N} No, {UNK} Unknown

**When Manifested Options:** {PHC1917} During Treatment, {PHC1918} At End of Treatment, {PHC1919} Both

**END OF MDR Supplemental**