

Report of Verified Case of Tuberculosis (RVCT) Training

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Learning Objectives

- Understand the Report of Verified Case of Tuberculosis (RVCT) data variables captured though the Virginia Electronic Disease Surveillance System (VEDSS).
- Learn how to enter data, update, and manage tuberculosis investigations in VEDSS.
- Understand common data entry errors with RVCT data in VEDSS.



Overview of the RVCT

- RVCT must be completed for all verified cases of TB
- RVCT must be completed for burden cases such as transfer TB cases that have been counted by another area.
 - United States reporting areas include the 50 United States, the District of Columbia, New York City, Puerto Rico, American Samoa, Guam, Commonwealth of the Norther Mariana Islands, and the U.S. Virgin Island, and three freely associated states: Federated States of Micronesia, Republic of the Marshall Island, and Republic of Palau).
- RVCT is used in Virginia to capture initial data for presumptive TB cases which are ruled out to capture TB burden.



Additional Resources

- CDC has an extensive instruction manual for the 2020 RVCT which offers detail and additional examples.
- It is available on VDH's website <u>here</u>.
- Please reach out to <u>laura.r.young@vdh.virginia.gov</u> with questions and additional training needs/requests, or email <u>tuberculosis@vdh.virginia.gov</u>

2020 Report of Verified Case of Tuberculosis (RVCT) Instruction Manual August 2021

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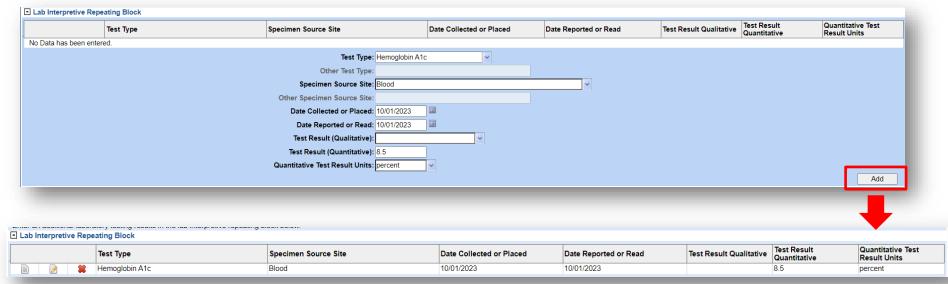
Data entry notes

- Partial dates:
 - o If the day is unknown, enter the first day of the know month as the date (e.g., 07/01/2022).
 - If the month and day are unknown, enter the first day of the know year as the date (e.g., 01/01/2022).
- Pending vs. unknown information
 - Leave items blank while information is pending.
 - Select "unknown" if data is truly unknown and will not ever be available.
- If a test is not performed
 - o Indicate "not done" as the result instead of leaving the item blank



Data entry notes

- Repeating blocks:
 - When entering data in a repeating block, you must click "add" to save the data, otherwise you will get an error message when you try to save the investigation. You will then see the data displayed in the row.





Data entry notes

- Editing data in repeating blocks:
 - After you have added data to a repeating block, you can edit or delete it using these buttons:



Click to delete

- Saving data in VEDSS:
 - Click the "submit" button at the top or bottom of the page:

Click to edit





Two new conditions in codes in VEDSS

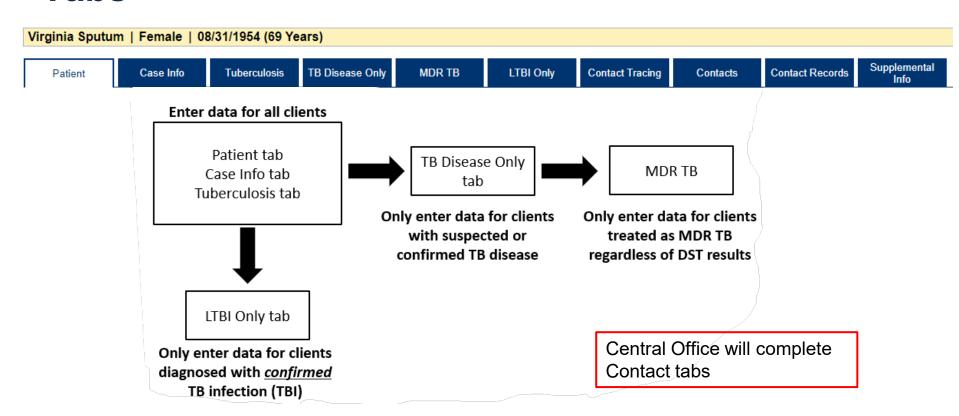
- Tuberculosis condition code and VEDSS paged used for 2009-2022 cases
- Latent TB infection condition code and VEDSS page used for LTBI for 2018-2023
- Tuberculosis (2020 RVCT) used for 2023 TB cases and forward
- Latent TB Infection (2020 TBLISS) condition codes used for 2024 LTBI cases and forward

Start Date	Conditions	Case Status
09/01/2020	Tuberculosis	Confirmed
10/01/2021	Latent TB infection	Not a Case
10/01/2023	Latent Tuberculosis Infection (2020 TBLISS)	Not a Case
10/05/2023	Tuberculosis (2020 RVCT)	Confirmed

The "2020" pages combine TB and LTBI into one page, but two different condition codes are used and there is change functionality between them. Certain "tabs" apply to both conditions and distinct tabs apply to each as well.



Tabs





2020 RVCT - What's New?

Item	Item Name
5	Case Already Counted by Another Reporting Area
12	Country of Usual Residence
15	Occupation and Industry
16	Other Risk Factors
19	Current Smoking Status at Diagnostic Evaluation
20	Lived Outside of the United States for >2 months (uninterrupted)
24	Date of Illness Onset/Symptom Start Date
26	Case Meets Binational Reporting Criteria?
27	Case Identified During a Contact Investigation of Another Case?
28	Contact Investigation Conducted for This Case?
29	Complete Table Below for All Known TB and LTBI Cases Epidemiologically Linked to this Case
32	If Initial Drug Regimen Not RIPE/HRZE, Why Not?
35	Was Genotypic/Molecular Drug Susceptibility Testing Done?
36	Was Patient Treated as MDR TB Case (Regardless of DST Results)?
43	Did the Patient Die?



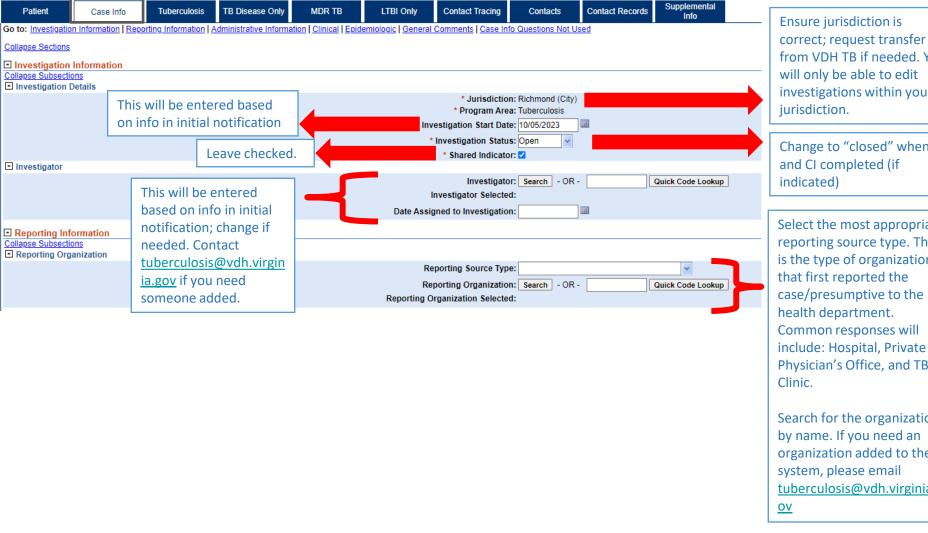
2020 RVCT – What's Updated?

Item	Item Name
2	Date Counted
6	Reporting Address
8	Sex at Birth
9	Ethnicity
10	Race
11	Nativity
13	Status at TB Diagnosis
14	Initial Reason Evaluated for TB
21	Tuberculosis Skin Test and All Non-DST TB Laboratory Test Results
22	Chest Radiograph or Other Imaging Study Results
23	Has the Patient Been Previously Diagnosed with TB Disease or LTBI?
31	Initial Drug Regimen
34	Was Phenotypic/Growth-Based Drug Susceptibility Testing Done?
38	Moved During Therapy?
40	Reason Therapy Stopped or Never Started?
41	Reason TB Disease Therapy Extended >12 Months, if applicable
42	Treatment Administration



A few VEDSS specific items on the case info tab

- Jurisdiction
- Investigation status
- Investigator
- Reporting Source Type
- Reporting Organization
- Hospitalization information
- Diagnosis Date
- Pregnancy information
- Outbreak information



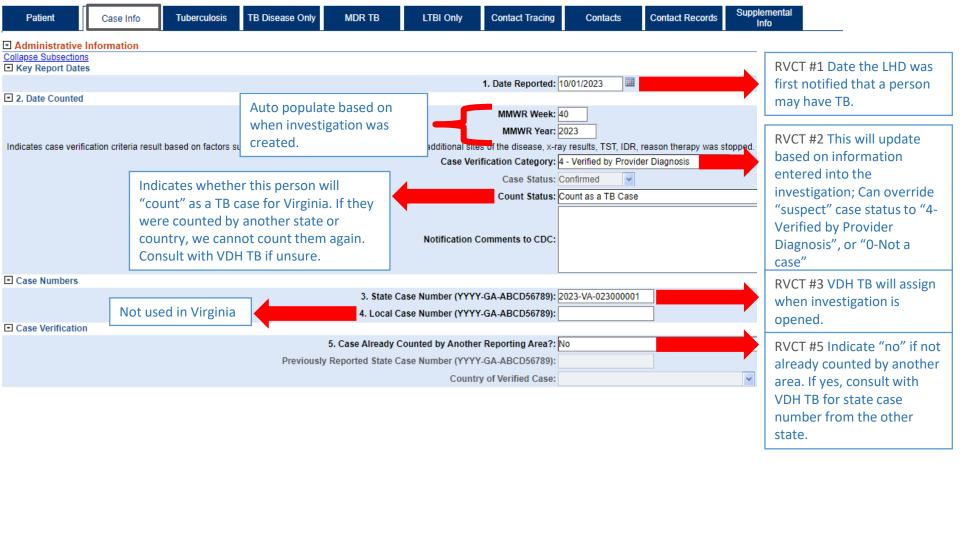
from VDH TB if needed. You will only be able to edit investigations within your iurisdiction. Change to "closed" when tx

and CI completed (if

Select the most appropriate reporting source type. This is the type of organization

case/presumptive to the health department. Common responses will include: Hospital, Private Physician's Office, and TB

Search for the organization by name. If you need an organization added to the system, please email tuberculosis@vdh.virginia.g







RVCT Variables



1. Date reported

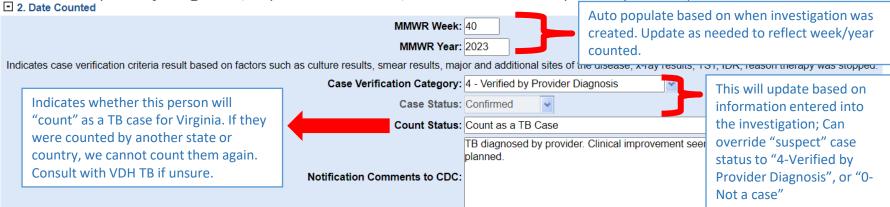
The date the health department first thought that the patient had TB or the
date the health department received notification from a provider that a patient
might have TB.

1. Date Reported: 10/01/2023



2. Date counted

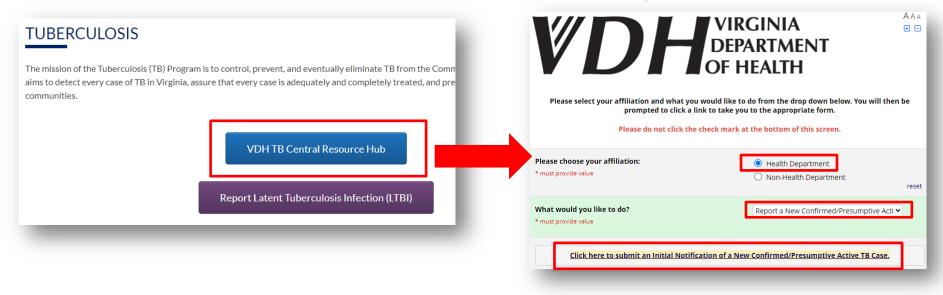
- The approximate date the case met an official TB surveillance case definition.
 - Laboratory confirmed (PCR/NAAT positive or culture positive)
 - Clinical case definition (positive test for infection, abnormal imagine, treatment with TB medications, completed diagnostic evaluation)
 - In Virginia, also want to see improvement on treatment and planned treatment completion.
 - Provider diagnosed case (does not meet laboratory confirmed or clinical case definition, but TB is primary diagnosis, improvement seen, and treatment completion planned)





Process for notifying VDH TB Program about a new presumptive or confirmed case

Submit an initial notification within three business days





3. State case number (RVCT number)

- Unique identifier use to facilitate communication between VDH and CDC.
 - Assigned by VDH TB Program when investigation opened.



4. Local case number

Not routinely used in Virginia

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Case Numbers

3. State Case Number (YYYY-GA-ABCD56789): 2023-VA-023000645

4. Local Case Number (YYYY-GA-ABCD56789):
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5. Case already counted by another reporting area?

- TB cases may be reported by multiple reporting areas due to patient movement, but the case is only counted for one area.
- Indicate "no" if not already counted by another area (either in the U.S. or if patient started TB treatment abroad). Consult with VDH TB if unsure or if state case number from another state is needed. If patient started treatment in another country, enter the county name.
- Indicate "yes" if counted by another area or treatment initiated in another country.

□ Case Verification	
5. Case Already Counted by Another Reporting Area?: No	~
Previously Reported State Case Number (YYYY-GA-ABCD56789):	
Country of Verified Case:	



Exercise

Samantha was diagnosed with TB and started treatment in California. After a month of treatment she moved to Virginia to start college. The LHD in Virginia receives an interjurisdictional notification from California via VDH TB Program and assumes care for this client.

Should the LHD submit an initial notification for this client?

- Yes
- No

How should "Case already counted by another reporting area" be answered?

- Yes
- No



6. Reporting address

 The reporting address should capture the patient's "usual residence" – where they live or sleep most of the time. Typically this is the address at the time of diagnosis.

6. Reporting Address for Case Counting	
Address Information As Of Date:	10/05/2023
Street Address 1:	101 W. Main Street
Street Address 2:	
City:	Richmond
State:	Virginia
Zip:	23220
County:	Richmond City
Country:	UNITED STATES
Census Tract:	
Is the Patient Residence within City Limits?:	Yes 💌



Determining Reporting Address

Patient Scenarios	How to Count	Reporting Address
Persons temporarily away from their usual residence (e.g., on vacation or a business trip), and who return to their usual residence to complete TB treatment.	Count in the reporting area for the patient's usual residence.	Enter city, county, ZIP Code, and census tract of the patient's usual residence.
Persons temporarily away from their usual residence (e.g., on vacation or a business trip), and who remain in the community that they were visiting to complete TB treatment.	Count in the reporting area where the TB diagnostic evaluation was initiated.	Enter city, county, ZIP Code, and census tract of location where the patient was staying when the diagnostic evaluation was initiated.
Persons without housing (e.g., persons experiencing homelessness or without a fixed residence)	Count in the reporting area where the TB diagnostic evaluation was initiated.	Enter city, county, ZIP Code, and census tract of location where the patient was staying when the diagnostic evaluation was initiated.
Students	 College or boarding school students on a typical yearly academic cycle should be counted by the reporting area where they live most of the year. Intermittent or part-time students without a regular cycle for moving between parental and school residences should be counted by the reporting area where they were living at the time that diagnostic evaluation was initiated. 	Enter city, county, ZIP Code, and census tract of the location where the patient stays in the reporting area that is counting the case.

Reach out to VDH TB to discuss additional or complex scenarios.



Exercise

Mabel lives in Richmond, VA. On May 1, 2021, she visits her sister in Boston, MA. During the visit, Mabel develops a bad cough and fever. She goes to the Boston Health Clinic and is diagnosed with TB disease. On June 3, 2021, Mabel returns home to Richmond, VA where she completes treatment.

What reporting address should be used for Mabel?

- A. Richmond, VA
- B. Boston, MA



- 7. Date of birth
 8. Sex at birth
 9. Ethnicity
 10. Race
- **7. Date of Birth**: 01/01/1992 8. Sex at Birth: Female 9. Ethnicity: Not Hispanic or Latino 10. Race: American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander □ White Other Refused to answer Not Asked Unknown (Use Ctrl to select more than one) Singaporean 1 Select more detailed Sri Lankan Detailed Race Asian: Taiwanese race category if known. Thai Vietnamese Selected Values: Vietnamese

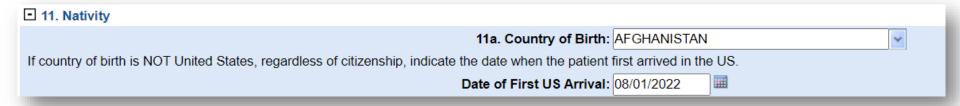
Reminder: Filipino falls under Asian, not Pacific Islander.



Updated

11. Nativity

- 11a. Country of Birth
 - Provide the actual country (or U.S. territory) of birth regardless of whether they were U.S.
 citizens at birth. If born in the United States, select "United States".
- Date of First U.S. Arrival
 - If born outside of the United States, enter the known or best estimated date of when the patient first arrived in the United States.



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Updated

11. Nativity (continued)

- 11b. Eligible for U.S. citizenship/nationality at birth?
 - Yes born in one of the U.S> states, D.C., Puerto Rico, Guam, the Northern Mariana Islands, or the U.S. Virginia Islands or born aboard to a parent who was a U.S. citizen.

Tuberculosis

- Example: Born in Brazil to a mother with U.S. citizenship and a father with Brazilian citizenship = Yes, eligible for U.S. citizenship, country of birth = Brazil
- 11c. Countries of birth for primary guardians
 - Complete only for patients less than 15 years old.





Exercise

You are completing an RVCT on Peter and you ask him where he was born. He tells you he was born in Germany. He says that his mother is a German citizen, but that his father is a U.S. citizen who was stationed abroad.

Was Peter eligible for U.S. citizenship when he was born?

- A. Yes
- B. No

What do you select as "Country of Birth"?

- A. United States
- B. Germany

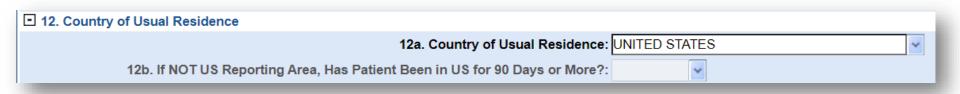


New

12a. Country of usual residence

 The country where the patient lives or sleeps most of the time, this may be different from where they are registered to vote, where they maintain a legal residence, etc. This includes persons who are in the U.S. for an extended period for work or study, even if they do not consider the U.S. to be "home".

12b. If NOT U.S. reporting area, has the patient been in the U.S. for 90 days or more at time of report?





Updated

13. Status at TB diagnosis

Purpose is to determine if the patient was alive at the time of diagnosis.

- Alive
 - Patient was alive at time positive lab results were known to provider
 - Patient started TB medications
- Dead
 - Patient was deceased at the time laboratory results confirming TB were known to the provider

13. Status at TB Diagnosis: Alive



Exercise

Ruth comes to the emergency room on April 30, 2023. She is diagnosed with pneumonia, given antibiotics, and discharged. She dies two weeks later on May 15, 2023. At autopsy, the pathology shows granulomatous changes consistent with TB disease. A lung biopsy culture is found to be positive for *M. tuberculosis* complex.

What is the status at TB Diagnosis?

- A. Alive
- B. Dead



Updated

14. Initial reason evaluated for TB

Contact investigation

Includes source case investigations

14. Initial Reason Evaluated for TB:	~	
14. Initial Reason Evaluated for TB:		

Screening

 Any type of planned screening for TB disease or LTBI in a specific population, other than through a contact investigations.

Other

Includes targeted or prioritized testing, intake in correctional setting, class B notifications, administrative screening for employment, etc.

TB symptoms

- Signs and symptoms consistent with TB
- Select only if patient as signs and symptoms at time of diagnostic evaluation and neither contact investigation or screening apply to the case. Select when TB symptoms are the reason that the patient came to the attention of the medical community.

Other

- Incidental chest radiograph, incidental lab results, unexpected clinical finding when TB was not being considered, etc.
- Room to provide detail if other selected

Unknown

Example: TB Symptoms

If a person with TB was initially encountered via a contact investigation and during that investigation was also noted to have TB symptoms, select "Contact Investigation" as the initial reason for the evaluation. However, if a patient seeks medical care because of TB symptoms, select "TB Symptoms" as the initial reason for the evaluation.



Exercise

- 1. Maria was evaluated by the health department after they received a B1 EDN notification for her.
- 2. The health department evaluated Sarah after she was exposed to TB from a colleague at work. She was later diagnosed with TB.
- 3. George went to the hospital coughing up blood and was evaluated for TB.
- 4. Sophie is living with HIV. At a recent visit to her provider she was tested for TB infection and had a new positive result.
- 5. While being cleared for surgery, Raul was notified that he had an abnormal chest x-ray concerning for TB.

Contact investigation

Screening

TB symptoms

Other

Unknown

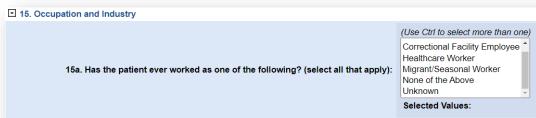




15. Current occupation and industry

15a. Has the patient **ever** worked as one of the following?

- Healthcare worker "healthcare personnel" paid or unpaid persons working in a healthcare setting.
- Correctional facility employee person working in a correctional facility. If they have worked as HCP within corrections, select both options.
- Migrant/seasonal worker person who is required to be absent from a permanent place of residence for the uprose of seeking employment, or who may vary their employment for the purpose of remaining employed while maintaining a permanent place of residence.
- None of the above
- Unknown select only when it cannot be confirmed or denied that the person ever worked in any of the above fields.



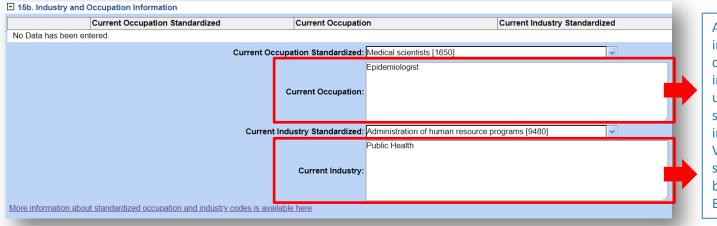


New

15. Current occupation and industry (continued)

15b. What is the patient's current occupation and industry?

- Complete for all patients 14 years and older.
- Current Occupation the type of job the patient has ben doing most recently, whether paid or unpaid.
- Current Industry the kind of business or industry the patient works in.



Add descriptive information for occupation/industry, including if client is unemployed, not seeking employment, incarcerated, etc.

VDH TB will do the standardized coding based on description.

Be specific.



15. Current occupation and industry (continued)

15b. Industry and occupation information

Current Occupation

- Ask, "What kind of work do you do?"
- o If the client has more than one job, collect information on all jobs
- If the client is a student, enter the level of study (e.g., "high school student")
- o If the client is unemployed or not seeking employment, do not leave "current occupation" blank. Example of entries include: "unemployed," "retired," "disabled", etc.
- Be descriptive: teacher (non-descriptive); preschool teacher (descriptive)
- Be specific: laborer (non-specific); roofer (specific)

Current Industry

- Kind of business or industry the client works in.
- Ask, "What kind of business or field do you work in?"
- Be descriptive: manufacturing (non-descriptive); automobile manufacturing (descriptive)
- Be specific: food industry (non-specific); restaurant (specific) or grocery store (specific)



16. Other risk factors

□ 16. Other Risk Factors			
Diabetic At Diagnostic Evaluation:	•		
Homeless in the Past 12 Months:	•		
Homeless Ever:	~		
Resident of Correctional Facility at Diagnostic Evaluation:	~		
17. If Resident of Correctional Facility at Diagnostic Evaluation, Type of Facility:			
Other 17. If Resident of Correctional Facility at Diagnostic Evaluation, Type of Facility:			
Resident of Correctional Facility Ever:	~		
Resident of Long Term Care Facility at Diagnostic Evaluation:	~		Provide a response,
18. If Resident of Long Term Care Facility at Diagnostic Evaluation, Type of Facility:			Yes, No, or
Other 18. If Resident of Long Term Care Facility at Diagnostic Evaluation, Type of Facility:			Unknown, for each
Injecting Drug Use in the Past 12 Months:			item. Use unknown
Noninjecting Drug Use in the Past 12 Months:	<u> </u>		only if information
Heavy Alcohol Use in the Past 12 Months:			is truly unavailable.
neavy Alcohol Ose III die Fast 12 Mondis.		L	
TNF Antagonist Therapy:	~		
Post Organ Transplantation:	~		
End Stage Renal Disease:	~		
Viral Hepatitis (B or C Only):	~		
Other Immunocompromise (other than HIV or AIDS):	~		
Other Risk Factor:	~		
Other Risk Factor Specify:			



16. Other risk factors (continued)

 Diabetic at diagnostic evaluation – The patient had diabetes when TB diagnostic evaluation was performed.

Tuberculosis

- Existing DM diagnosis, whether receiving treatment or not or
- Hemoglobin A1c ≥ 6.5% or
- Fasting plasma glucose ≥ 126 mg/dL or
- 2-hour plasma glucose ≥ 200 mg/dL during an oral glucose tolerance test or
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random please glucose ≥ 200 mg/dL
- Homeless in the past 12 months patient has experienced homelessness in the
 12 months preceding TB diagnosis evaluation
- Homeless ever patient has ever experienced homelessness

Someone experiencing homelessness may:

- Have no fixed, regular, and adequate nighttime residence
- A nighttime residence that is an operated shelter designed to provide temporary living, an institution that provides temporary residences for individuals intended to be institutionalized, a public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for humans
- Be in unstable housing situations, such as couch surfing



16. Other risk factors (continued)

- Resident of a correctional facility at diagnostic evaluation The patient
 was incarcerated or detained in a jail, prison, or other detention center when
 TB diagnostic evaluation was performed or initiated.
- Resident of a correctional facility ever patient has ever been incarcerated or detained in a jail, prison, or other detention center in their lifetime.
- Resident of long-term care facility at time of diagnostic evaluation –
 patient was a resident of a long-term care facility when TB diagnostic
 evaluation was performed or initiated.
- Injecting drug use in the past 12 months Patient used injection drugs in the past 12 months not prescribed by a healthcare provider; involves the use of hypodermic needles and syringes and may be intravenous, subcutaneous, or intramuscular.



16. Other risk factors (continued)

- Noninjecting drug use in the past 12 months The patient was incarcerated or detained in a jail, prison, or other detention center when TB diagnostic evaluation was performed or initiated. Per CDC, marijuana should always be recorded as noninjecting drug use, regardless of whether marijuana is legal for medicinal or recreational use. Also includes the misuse of licensed or prescription drugs.
- Heavy alcohol use in the past 12 months The National Institute on Alcohol Abuse and Alcoholism defines heavy alcohol use as binge drinking on 5 or more days in the month preceding diagnosis. Binge drinking is defined as a pattern of drinking that brings blood alcohol concentration levels to 0.08 g/dL. This typically occurs after four drinks for women and five drinks for men in about 2 hours.
- TNF-α antagonist therapy Patient recently received, or was receiving, tumor necrosis factor-alpha antagonist therapy when TB diagnostic evaluation was performed or initiated (e.g., Remicade, Humira)
- Post organ transplantation Patient has ever received a solid organ transplant (e.g., kidney, heart).



16. Other risk factors (continued)

- End-stage renal disease Patient has end-stage renal disease when TB diagnostic evaluation was performed or initiated (e.g., patient on dialysis).
- Viral hepatitis (B or C only) Patient has ever had a diagnosis of hepatitis
 B or C (acute or chronic)
- Other immunocompromise (other than HIV/AIDS) Patient is immunocompromised because of either a medical condition (e.g., leukemia, Hodgkin's lymphoma, carcinoma of the head or neck), or immunosuppressive therapy, such as prolonged use of high-doses of corticosteroids.
- Other (specify) Additional risk factors may be captured here and specified in free text.



17. If resident of correctional facility at diagnostic evaluation, type of facility?

- Federal prison Confinement facility administered by a federal agency (except Immigration and Customs Enforcement); includes privately operated federal correctional facilities.
- State prison Confinement facility administered by a state agency; includes privately operated state correctional facilities.
- Local jail Confinement facility usually administered by a local law enforcement agency, intended
 for adults but sometimes containing juveniles; typically holds persons detained pending adjudication
 or for sentences of 1 year or less
- Other (specify) Includes Immigration and Customs Enforcement (ICE) detention centers, India reservation facilities (tribal jails), military stockades and jails, federal park police facilities, police lockups temporary holding facilities, and other correctional facilities including regional jails.
- Unknown patient was incarcerated when TB diagnostic evaluation was performed, but the type of facility is unknown.

Resident of Correctional Facility at Diagnostic Evaluation: Yes

17. If Resident of Correctional Facility at Diagnostic Evaluation, Type of Facility: Local Jail



18. If resident of long-term care facility at diagnostic evaluation, type of facility?

- Nursing home Freestanding facility with three or more beds that provides nursing care services. This
 does not include assisted living facilities.
- Hospital-based facility Distinct unit with three or more beds that is physically attached to, or managed by, a hospital.
- Residential facility Facility with three or more beds (i.e., classified as a residential facility or congregate residential setting) and is not classified as a nursing home, hospital-based facility, or alcohol or drug treatment facility. Provides personal care or supervision (not nursing care) to its residents. This includes assisted living facilities.
- Mental health residential facility Facility that provides 24-hour care in a hospital, residential treatment, or supportive setting.
- Alcohol or drug treatment facility Any long-term rehab or residential facilities designated for treatment of 30 days or longer.
- Other
- Unknown



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19. Smoking status at diagnostic evaluation

- Current every day smoker
- Current some day smoker
- Former smoker Patient has smoked at least 100 cigarettes/cigars in the lifetime and has quit.
- Never smoker Patient has not smoked at least 100 cigarettes/cigars in the lifetime
- Smoker, current status unknown Patient was a smoker or tobacco user, but current status is unknown
- Unknown if ever smoked

The definition of smoking includes use of vapes and e-cigarettes, but does not include chewing tobacco.

19. Current Smoking Status at Diagnostic Evaluation:





20. Lived outside of the United States for >2 uninterrupted months.

- Uninterrupted time outside of the U.S. can include multiple locations with a cumulative amount of time equaling 2 months or more as long as there is no return to the U.S. during that time.
 - This could be someone who had an established home outside of the United States, or someone who was in school, or just traveling for that amount of time.

20. Lived outside of US for More than 2 Months:



21. Tuberculosis skin test and all non-DST lab results

Tuberculosis

- This section contains specific space to enter required results for:
 - o HIV
 - TST
 - IGRA
 - Sputum smear
 - Sputum culture
 - Smear/Pathology/Cytology of tissue or other body fluids
 - Culture of tissue or other body fluids
 - Nucleic acid amplification test
- There is also a repeating block where additional results can be entered
 - Hemoglobin A1c



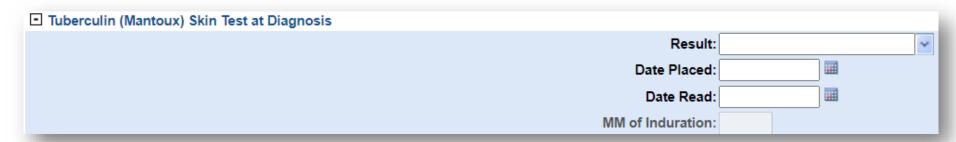
21. HIV status

- HIV Status		
	HIV Status:	*
	Collection Date:	
	Date Reported:	

- Patient self-report of HIV status is not acceptable.
- HIV serology results must be documented.
- A positive test can be from any date
- A negative test result must be less than a year before the TB diagnostic evaluation
- Indicate as appropriate if test was not offered or if the client (or family) refused testing.



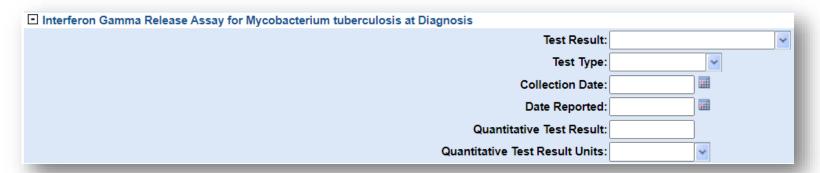
21. Tuberculin skin test



- A documented prior positive is acceptable, but not patient self report alone.
- Include induration.



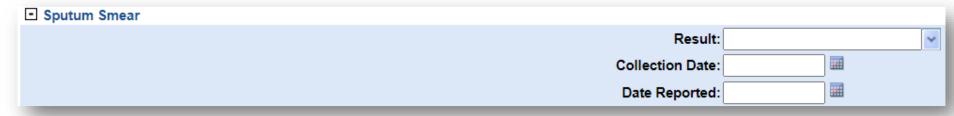
21. Interferon gamma release assay



- A documented prior positive is acceptable, but not patient self report alone.
- Indicate of the IGRA performed was a QFT or a T-Spot.



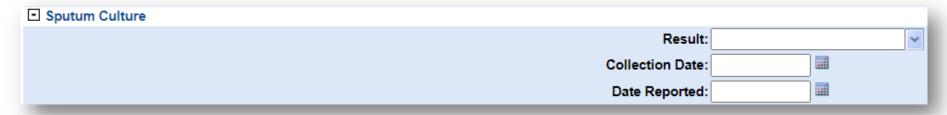
21. Sputum smear



- If the patient has a positive sputum smear result that is interpreted as consistent with TB by the clinician, capture the initial positive result here.
 Examples of positive results include: "few", "moderate", "many", "1+", etc.
 - o If a positive smear is attributed to an NTM infection, do not capture as positive here.
- If the patient never has a positive sputum smear result, capture the earliest collection date for the initial negative result.



21. Sputum culture



- If the patient has a positive sputum culture result for TB, capture the initial positive result here.
- If the patient never has a positive sputum culture result for TB, capture the earliest collection date for the initial negative result.



Exercise

Shauna has sputum collected on 5/1/2023. Her specimen is smear negative, but comes back culture positive for *M. avium*. The clinician still plans to treat Shauna as a clinical case of TB. Which option would be selected for sputum culture result? No additional sputum culture results are positive.

- A. Positive
- B. Negative
- C. Not Done
- D. Unknown



21. Smear/pathology/cytology of tissue or other bodily fluids



- If the patient has a positive smear result from a site other than sputum that is
 interpreted as consistent with TB by the clinician, capture the initial positive
 result here. If no testing of other sites is performed, select "not done" as the result.
 - o If a positive smear is attributed to an NTM infection, do not capture as positive here.
- If the patient never has a positive smear result from a site other than sputum, but did have testing performed, capture the earliest collection date for the initial negative result.



21. Culture of tissue or other bodily fluids culture

☐ Culture of Tissue or Other Bodily Fluids	
Results	
Specimen Source	;
Other Specimen Source	
Collection Date	:
Date Reported	:

- If the patient has a positive culture result for TB from a site other than sputum, capture the initial positive result here. If no testing of other sites is performed, select "not done" as the result.
- If the patient never has a positive culture result from a site other than sputum, but did have testing performed, capture the earliest collection date for the initial negative result.



21. Nucleic acid amplification (NAA) test result

Nucleic Acid Amplification Test Result	
Results:	~
Specimen Source:	
Other Specimen Source:	
Collection Date:	
Date Reported:	=

- If the patient has a positive NAA result from any site, capture the initial positive result here.
- If the patient never has a positive NAA result, but did have testing performed, capture the earliest collection date for the initial negative result.
- If no NAA testing was performed, select "not done" as the result.



NAA Testing at DCLS



DCLS | Division of Consolidated Laboratory Services

dgs.virginia.gov

NAAT Criteria

Real-time PCR on direct sputa

- Patients currently not on anti-tuberculosis therapy
- Patients without a previous positive MTBC result (NAAT and/or culture) within the past 12 months

Xpert MTB/RIF on direct sputa

- Patient on anti-tuberculosis therapy for less than 3 days
- Sufficient volume
- Non-pediatric patients



NAA vs. Culture

What other terms are used for NAA tests?

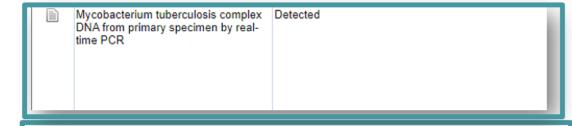
- NAAT
- Direct PCR
- GeneXpert
- Hain Test
- Amplified Mycobacteria tuberculosis (MTD) Direct

What other terms are used for a culture?

- Probe
- DNA probe
- Culture PCR



NAA vs. Culture Results from DCLS



NAAT =

Direct PCR M. tuberculosis complex/M. avium complex

Date Released:

Mycobacterium avium complex DNA by real-time PCR: DETECTED

Mycobacterium tuberculosis complex DNA by real-time PCR: Not Detected

Disclaimer: This test has not been cleared or approved by the U.S. Food and Drug Administration. The performance characteristics of this test have been validated by DCLS. The results from this assay should not be used independently to make decisions coordinate account of notices are a cubic health.

GENEXpert

Date Released: 01/27/2020

Mycobacterium tuberculosis complex DNA detected by direct specimen Nucleic Acid Amplification Test. No rpoB gene mutations detected by direct specimen Nucleic Acid Amplification Test; probably Rifampin susceptible.

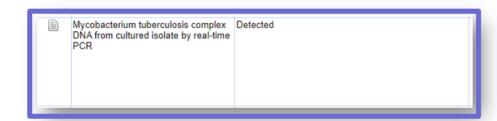
Comment: Results from the MTB/RIF test should be interpreted in conjunction with other laboratory and clinical data. If test results do not match clinical signs and symptoms, additional testing may be warranted. A result of "Mycobacterium tuberculosis complex DNA Not Detected" does not exclude the possibility of isolating a Mycobacterium tuberculosis complex organism from the specimen. Additionally, a result of "No rpoB gene mutations detected; probably Rifampin susceptible" does not exclude the possibility of Rifampin resistance. Test results may be affected by inhibitors and variability in specimen collection and transport.

Date Released: 01/18/2022

Date Released: 01/02/2020



NAA vs. Culture Results from DCLS



Culture =

Culture PCR M. tuberculosis complex/M. avium complex

Mycobacterium tuberculosis complex DNA by real-time PCR: DETECTED

Disclaimer: This test has not been cleared or approved by the U.S. Food and Drug Administration. The performance characteristics of this test have been fully established by DCLS. The results from this assay should not be used independently to make decisions regarding the management of patient care or public health.

Mycobacterial DNA Probe

M.tb complex probe : Positive

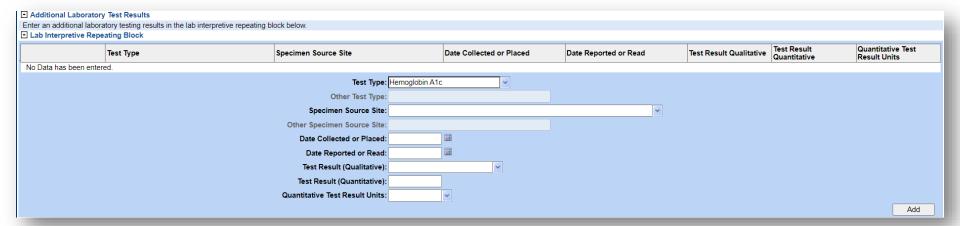
Drug susceptibility testing to follow.

Mycobacterium tuberculosis complex includes tuberculosis, M. bovis, M. bovis BCG, M. africanum, M. microti, and M. canetti all of which cause the clinical syndrome, tuberculosis. All laboratory results should be interpreted in conjunction with clinical findings.



21. Tuberculosis skin test and all non-DST lab results

- In the repeating block for additional lab results, include:
 - Hemoglobin A1c
 - CD4 count for people living with HIV
- You may include other results (Karius test, etc.)





21. Tuberculosis skin test and all non-DST lab results (continued)

Test	Test Type	Specimen Source Site	Date Collected or Placed	Date Reported or Read	Test Result (Qualitative)	Test Result (Quantitative)	Quantitative Test Result Units
CD4	CD4	Blood	Date collected	Date reported		Enter quantitative result	cells per mm ³ or percent
Culture	Culture	Source of specimen	Date collected	Date reported	Enter qualitative result		
Cytology	Cytology	Source of specimen	Date collected	Date reported	Enter qualitative result		
Fasting blood glucose	Do not have to record						
Hemoglobin A1c	Hemoglobin A1c	Blood	Date collected	Date reported		Enter quantitative result	percent
QFT	IGRA – QFT	Blood	Date collected	Date reported	Enter qualitative result		



21. Tuberculosis skin test and all non-DST lab results (continued)

Test	Test Type	Specimen Source Site	Date Collected or Placed	Date Reported or Read	Test Result (Qualitative)	Test Result (Quantitative)	Quantitative Test Result Units
T-spot	IGRA – Tspot	Blood	Date collected	Date reported	Enter qualitative result	Enter number of spots (if reported)	
Other nucleic acid tests	NAA	Source of specimen	Date collected	Date reported	Enter qualitative result		
Pathology	Pathology	Source of specimen	Date collected	Date reported	Enter qualitative result		
Smear	Smear	Source of specimen	Date collected	Date reported	Enter qualitative result	Enter quantitative result (e.g., <1, 4+, etc.)	
TST	Tuberculin skin test	Skin and skin appendages	Date placed	Date read	Enter qualitative result	Enter quantitative result	millimeter

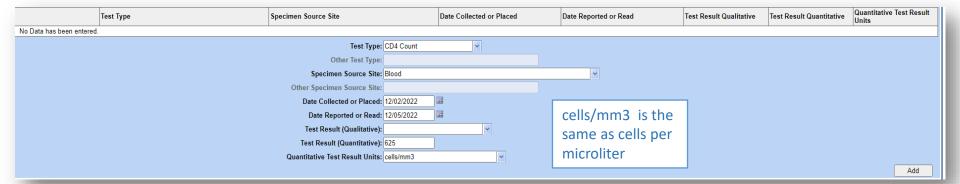


21. Tuberculosis skin test and all non-DST lab results (continued)

Example: CD4

CD4

Absolute Lymphocytes Absolute CD4 Percent CD4 1646 625 38 1000-4000 /uL 540-1660 /uL 32-60 % MEM





21. Tuberculosis skin test and all non-DST lab results (continued)

May be programmatically helpful to enter smear conversion results (i.e., the three consecutive negative smears that represent conversion), and sputum culture conversion results (i.e., the three consecutive negative cultures that indicate culture conversion.



22. Chest radiograph or other imaging results

- Response required for both, indicate "not done" as the result if applicable.
- If "consistent with TB" selected, indicate if there was evidence of cavity or miliary disease.

Consistent with TB includes hilar adenopathy, effusion, infiltrates, cavity,

scarring consistent with TB.

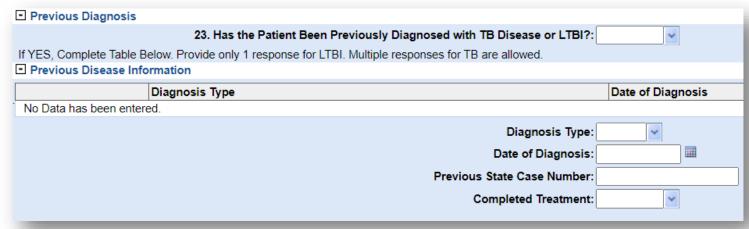
■ 22. Chest Radiograph and Other Chest Imaging Study Results		
	Initial Chest X-Ray Result:	~
	Initial Chest X-Ray Date:	=
	Evidence of a Cavity:	~
	Evidence of Miliary TB:	~
	Initial Chest CT Scan Result:	*
	Initial Chest CT Scan Date:	=
	Evidence of a Cavity:	~
	Evidence of Miliary TB:	~

Miliary TB is a clinical or radiologic finding, rather than a site of disease. Miliary TB is the result of a TB infection eroding into the bloodstream and form there disseminating throughout the body to multiple organs. It appears on radiographs as a great number of small (1 to 2 mm) well-defined nodules that look like millet seeds scattered throughout the lungs.



23. Has the patient been previously diagnosed with TB or LTBI?

- Indicate if the patient has a history of previous LTBI or TB disease
- If yes, provide additional detail about the diagnosis type, date (or approximate year) of diagnosis, and whether treatment was completed.
- For clients with a prior diagnosis of TB disease in Virginia, reach out to VDH TB to determine state case number.



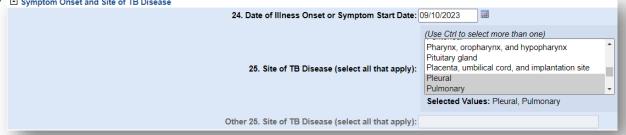


24. Date of illness onset/symptom start date

- Capture the approximate or exact date that the patient first noticed any sign or symptoms consistent with TB.
- If the patient reports not having experienced TB signs or symptoms, record the date of earlier clinical finding consistent with TB disease, such as date of first chest radiograph consistent with TB.

25. Site of TB disease

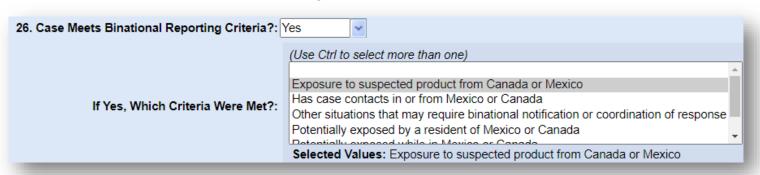
- Select all sites affected by the TB disease process.
- For miliary disease, select "pulmonary" and indicate in item 22 the miliary evidence from imaging.





26. Case meets binational reporting criteria

- A case meets binational reporting criteria if it meets one or more of the following criteria:
 - Exposure to a suspected product (e.g., unpasteurized milk or cheese) from Canada or Mexico
 - Has case contacts in or from Mexico or Canada
 - Potentially exposed by a resident of Mexico or Canada
 - Potentially exposed while in Mexico or Canada
 - Resident of Mexico or Canada
 - Other situations such as the patient crossed the border into the United States from Mexico or Canada during TB treatment, or the patient was referred to a U.S.-funded, binational TB program for treatment continuity.



Contact VDH TB with questions!



27. Case identified during a contact investigation of another case?

- Select "Yes" if the case was identified during the contact investigation or source case investigation of another case.
- If "Yes", select whether the patient was **fully** evaluated for TB during that investigation, regardless of whether the patient was diagnosed with TB at that time.
- Otherwise select "No" or "Unknown" as appropriate.

27. Case Identified During the Contact Investigation of Another Case?:	*	
If Yes, Evaluated for TB During that Contact Investigation?:	~	



Exercise

Laura is newly diagnosed with TB and you are entering her RVCT data into VEDSS. Six months ago, Laura was evaluated as part of a contact investigation at her work place. During that evaluation, her QFT was positive and her chest X-ray was normal. She was diagnosed with LTBI, but declined treatment at the time.

- 1. Was Laura identified during the contact investigation of another case?
- -Yes
- -No
- 2. If Yes, was Laura evaluated for TB during that contact investigation?
- -Yes
- -No



Exercise

Kevin is newly diagnosed with active TB disease. Upon reviewing his medical history, and during his initial interviews, Kevin indicates that he was a contact to a TB case 5 years ago at school and was evaluated as part of a contact investigation at that time. He had a negative IGRA two weeks after his last exposure, but never returned for second round testing.

- 1. Was Kevin identified during the contact investigation of another case?
- -Yes
- -No
- 2. If Yes, was Kevin evaluated for TB during that contact investigation?
- -Yes
- -No



28. Contact investigation conducted for this case?

- Select "Yes" if an adequate contact or source case investigation was conducted for this case, this typically involves multiple patient interviews, etc.
- This item should be answered for all cases, regardless of whether a contact investigation or source case investigation was warranted (e.g., extrapulmonary TB).

28. Contact Investigation Conducted for This Case?:

29. Epidemiologically linked TB and LTBI cases

 VDH TB will complete after receiving the 502, but you may enter known linkages. Consult VDH TB for state case numbers if needed.

[☑ 29. Linked Case Number								
					Linked Case Number				
ı		<u></u>	8	8	2023-VA-023000164				
			8	8	2023-VA-LTBI000123				
					Linked State Case Number:				



30. Date therapy started

 Date the patient began multidrug therapy for confirmed or presumptive TB disease. This should reflect the earliest date, even if that was in the hospital, and even if the program excluded those doses from their count.

30.	Date	Therapy	Started:	-



31. Initial drug regimen

- For each drug, indicate if it was part of the initial regimen prescribed for treatment of TB disease, even if the regimen was altered soon after.
- Clicking "standard regimen" will mark "Yes" for isoniazid, rifampin, pyrazinamide, and ethambutol.
- Clicking "mark rest no" will mark "No" for any drugs without a selection made. You can then edit individual answers.
- Do not enter pyridoxine (B6) as other drug

,		
	Standard Regimen (4)	
	Mark Rest 'No'	
Isoniazid:	~	
Rifampin:	~	
Pyrazinamide:	~	
Ethambutol:	~	
Streptomycin:	~	
Rifabutin:	~	
Rifapentine:	~	
Ethionamide:	~	
Amikacin:	~	
Kanamycin:	~	
Capreomycin:	~	
Ciprofloxacin:	~	
Levofloxacin:	~	
Ofloxacin:	~	
Moxifloxacin:	~	
Other Quinolones:	~	
Cycloserine:	~	
Para-Aminosalicylic acid:	~	
Linezolid:	~	
Bedaquiline:	~	
Delamanid:	~	
Clofazimine:	~	
Pretomanid:	~	
Other Drug Regimen:	~	
Other Drug Regimen Specify:		



32. If initial regimen not RIPE, why not?

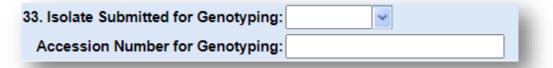
- If RIPE was not initial prescribed, indicate the most appropriate reason:
 - Drug contraindication/interaction
 - Drug susceptibility testing results already known
 - Suspected drug resistance (e.g., the patient was a contact of a drug-resistant case)
 - o Drug shortage (e.g., one or more RIPE drugs were unavailable due to a shortage.
 - Other (specify)
 - Unknown

32. If Initial Drug Regimen NOT RIPE/HRZE, Why Not?:	~	
Other 32. If Initial Drug Regimen NOT RIPE/HRZE, Why Not?:		



33. Isolate submitted for genotyping?

VDH TB will complete this item.



All cases with a culture positive TB result should have an isolate forwarded (or originating) at DCLS which will be submitted for genotyping.



34. Was phenotypic/growth-based drug susceptibility testing done?

- Indicate if phenotypic DST was performed (only possible if the patient had a culture positive result).
- If performed, provide susceptibility results for each drug.

If any degree of resistance is reported on the lab result, select "Resistant"

Include initial results from unique combinations of drug tested and specimen types. The goal is to capture any resistance that is known.

Drug Name	Date Collected	Date Rep	orted	Specimen Sou	rce
lo Data has been entered.	'				
			Standard St	usceptibilities (4)	
			Mark Re	st 'Not Done'	
	Di	rug Name:			~
	Other Di	rug Name:			
	Date	Collected:		=	
	Date	Reported:		=	
	Specime	n Source:			
	Other Specime	n Source:			
		Result:		~	







34. Was phenotypic/growth-based drug susceptibility testing done?

		Standard Susceptibilities (4)	Genotyping And Dr	ug Susceptibility Testing	
		Mark Rest 'Not Done'	⊡ Enter Default Valu	es	
	Drug	Name:	The values entered he	re will be applied to each row added.	
(Other Drug		Date Collect	ted:	
	Date Co		Date Report	ed:	
	Date Re	ported:			
,	Specimen S		Specimen Sou		<u> </u>
	Specimen S		Other Specir		/ Do not
Others	•				Do not
		rtesur.	Test Method (Option		complete
Test N	Method (Op	tional):	Other Test Met		complete
Other Test N	Method (Op	tional):	(Option	ai):	
		Clear			Submit Cancel
Drug Suscepti	tibility Testir	ng		1	Click "submit" when finishe
		34. Was phenotypic/growth-ba	sed drug susceptibility testing done?: Yes	~	
		For the initial susceptibility testing please send a respon	se for each test type in the value set. Changes	in susceptibility should be reported for each individua	l drug when change is identified).
Phenotypic Dr	rug Suscept	tibility Testing Information			
		Orug Name	Date Collected Date Reported	Specimen Source	Result
		Ethambutol	10/01/2023 10/09/2023	Sputum	Susceptible
		soniazid	10/01/2023 10/09/2023	Sputum	Susceptible
		Pyrazinamide	10/01/2023 10/09/2023	Sputum	Susceptible
	🞇 F	Rifampin	10/01/2023 10/09/2023	Sputum	Susceptible



Exercise

The following first-line DST results are received on August 21 from Lab #1 and second-line results are received September 19 from Lab #2:

Results from Laboratory #1	Results from Laboratory #2
INH – Low-level resistance	Rifabutin – Resistance
Rifampin – No resistance	Rifapentine – Testing not done
Pyrazinamide – No resistance	Ethionamide – Not known if test was done
Ethambutol – Resistance	Amikacin – Susceptible
Streptomycin – Testing not done	Kanamycin - Testing not done

What initial DST results should be entered into VEDSS?

Isoniazid: Resistant Rifabutin: Resistant

Rifampin: Susceptible Rifapentine: Not Done

Pyrazinamide: Susceptible Ethionamide: Unknown

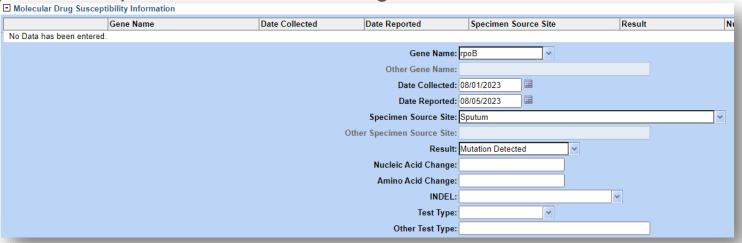
Ethambutol: Resistant Amakacin: Susceptible

Streptomycin: Not Done Kanamycin: Not Done



35. Was genotypic/molecular drug susceptibility testing done?

- VDH TB will complete this item.
- Indicates if genotypic or molecular DST was performed.
 - o GeneXpert (rpoB), MDDR testing at CDC, etc.
- If performed, provide results for each gene.





35. Was genotypic/molecular drug susceptibility testing done?

Results for Molecular Detection of Drug Resistance (Pyrosequencing; INH and RMP only);

Drug	Locus *	Result	Interpretation		
Rifampin	гров	No mutation	Probably Rifampin susceptible. (97% of RMP-R isolates in our in-house evaluation of 550 clinical isolates have a mutation at this locus.)		
	inhA	No mutation			
Isoniazid	katG	Mutation: AGC>ACC, Ser315Thr	Isoniazid resistant. (100% of isolates in our In-house evaluation of 550 clinical isolates with this mutation are INH-R.)		
	fabG1 No mutation				

^{*}A negative result (e.g., no mutation) does not rule out contributory mutations present elsewhere in the genome.

GENEXpert

Date Released: 01/27/2020

Mycobacterium tuberculosis complex DNA detected by direct specimen Nucleic Acid Amplification Test. No rpoB gene mutations detected by direct specimen Nucleic Acid Amplification Test; probably Rifampin susceptible.

Comment: Results from the MTB/RIF test should be interpreted in conjunction with other laboratory and clinical data. If test results do not match clinical signs and symptoms, additional testing may be warranted. A result of "Mycobacterium tuberculosis complex DNA Not Detected" does not exclude the possibility of isolating a Mycobacterium tuberculosis complex organism from the specimen. Additionally, a result of "No rpoB gene mutations detected, probably Rifampin susceptible "does not exclude the possibility of Rifampin resistance. Test results may be affected by inhibitors and variability in specimen collection and transport.



35. Was genotypic/molecular drug susceptibility testing done?

Drug Name	Gene name
Isoniazid	katG
Rifampin	гроВ
Pyrazinamide	pncA
Ethambutol	embB
Bedaquiline	atpE, rv0678, pepQ
Second line injectables (kanamycin, amikacin, capreomycin)	rrs



36. Was the patient treated as an MDR case (regardless of DST results)?

- Yes patient was treated as an MDR TB case at any point during their therapy (e.g., clinical diagnosis of TB with known contact to an MDR TB case)
 - Do not select "Yes" if second-line TB drugs were used for reasons other than presumed or confirmed resistance (e.g., drug shortage, drug intolerance, interactions, etc.)
- No the patient was not treated as an MDR TB case
- Unknown

If "Yes" is selected, the MDR TB Supplemental Tab must be completed.



37. Sputum culture conversion documented?

- Complete this item for patients who had an initial positive sputum culture.
 - Yes Initial sputum specimen was culture positive followed by at least one negative sputum culture after which there are no additional positives.
 - No Initial sputum specimen was culture positive and no subsequent sputum specimens were culture-negative
 - Unknown results of follow-up cultures are not known or it is not known whether follow-up cultures were done.

Tollow-up cultures were dolle.	
■ Sputum Culture Conversion Documented	
37. Sputum Culture Conversion Documented?:	~
If Yes, date specimen collected for FIRST consistently negative sputum culture:	
If No, reason for not documenting sputum culture conversion:	
Other If No, reason for not documenting sputum culture conversion:	

The specimen captured as the conversion specimen collection date should not be in the initial set of sputa.

If there are any positive sputum cultures after what is considered sputum culture conversion, the sputum culture "calendar"/"calculator" resets.



37. Sputum culture conversion documented?

If conversion was not documented, selected the most appropriate

reason:

Option (select one)	Description
No follow-up sputum despite induction	Repeat sputum collection was attempted (including induced sputum collection), but because of clinical improvement, patient was not able to produce sputum.
No follow-up sputum and no induction	Repeat sputum collection was attempted, but induced sputum collection was not attempted and patient was not able to produce sputum.
Died	Patient died before having an opportunity to submit sputum to document whether the sputum culture had converted.
Patient lost to follow-up	Patient was lost to follow-up before having an opportunity to submit a sputum to document whether the sputum culture had converted.
Patient refused	Patient refused to provide a sputum specimen for a repeat culture.
Other (specify)	A reason not included in the above choices (e.g., treatment failed or the patient moved outside the United States).
Unknown	It is not known why a repeat sputum culture was not obtained.



Recommended Sputum Sample Collection Schedule for Monitoring Smear and Culture Conversion in Pulmonary Cases

Virginia Department of Health Tuberculosis Program

Purpose	Monitoring	Frequency	Number of specimens	Comments
Determine infectiousness and	Initial contact with client	Collect 3 consecutive specimens	Minimum of 3 samples, with one collected in the early	At least one specimen collection should be observed/coached by HD staff.
Confirmation of TB disease			morning.	At minimum, samples should be at least 8 hours apart.
			If diagnosis was confirmed	nodis aparti
			before the client was reported, collect 3	Guidance for high quality sputum collection.
			additional specimens to	Submit specimens to the lab as soon as
			determine if infectious.	possible. Do not hold and submit specimens in a batch.
Establish the earliest date a client can be	Smear conversion or smear	Collect one specimen every 7–10 days; with maximum of 3/month	Total number of specimens will vary from client to client.	Single specimens should be observed by HD staff when feasible.
considered	improvement*	One specimen should be collected	onene to onene	Collecting a specimen 55 – 60 days after
non-infectious		55-60 days after treatment initiation	When there is evidence of	treatment initiation provides valuable
and can be		If urgent to remove from	increasing difficulty with spontaneous sputum	information about treatment response
removed from isolation		isolation, upon the first negative	production collect a	Additional criteria to release from isolation
isolation		smear follow with collecting one every other day. If any have a positive smear resume 7-10 day frequency	specimen every 7 days, not every 10 days	"Controlling Tuberculosis in the United States," 11/4/2005, Vol. 54, No. RR- 12, Page 9, Box 3
Monitor for	Culture	Collect one sample every 7-10 days,	Until 2 consecutive sputum	Single specimens should be observed by HD
response to treatment	conversion	with maximum of 3/month, until 2 consecutive sputum cultures are	cultures are negative with no positive culture results	staff when feasible.
and		negative with no positive culture	thereafter.	If unable to produce sputa spontaneously,
Determine need		results thereafter.		several 20 minute induction attempts on
for extension of				different days, including early AM, should be
treatment		Continue monthly collection until		undertaken before deciding that a client can
		treatment completion for: Rifamycin		no longer produce sputum.
		resistance; MDR/XDR-TB; HIV+		



Exercise

Jose's has the following sputum culture results. Based on this information, what would you select as the collection date for the culture conversion?

- Collection 1:
 - o Coll. 9/1/2023 culture positive
 - o Coll. 9/2/2023 culture positive
 - o Coll 9/2/2023 culture negative
- Collection 2:
 - o Coll 9/9/2023 culture negative
- Collection 3
 - o Coll 9/17/2023 culture negative
- Collection 4
 - Coll 10/1/2023 culture negative



38. Moved during therapy?

- Document if the patient moved to an area where another reporting area must now provide or coordinate TB care (i.e., out of the state or out of the United States.
 - This variable no longer captures movement within the state



If patient moved to another state or out of the country, specify the new state or country. If the patient moved out of the country, indicate if a transnational referral was made, such as through CureTB.



38. Moved during therapy? – Examples

Moved from	Moved to	Select
Arlington, VA	Richmond, VA	Do not report as moved
Fairfax, VA	Boston, MA	Out of State
Roanoke, VA	Guam	Out of State
Norfolk, VA	Brazil	Out of the U.S.



39. Date therapy stopped

The last date the patient took TB medications

39. Date Therapy Stopped:	#	
---------------------------	---	--

The interval between **Date Therapy Started** and **Date Therapy Stopped** is meant to encompass the entire period (including interruptions in therapy) that the patient was receiving medications.



40. Reason therapy stopped or never started?

- Completed therapy If clinician determines that the patient has completed adequate therapy (sometimes this may be less than the planned duration of treatment).
- Lost The patient could not be located either before the start or the for the completion of treatment.
- Patient choice Patient refused to start or complete therapy (previously "uncooperative or refused")
- Adverse treatment event therapy permanently stopped due to an adverse event due to TB medications
- Not TB Complete diagnostic evaluation did not substantiate the diagnose of TB (e.g., M. bovis BCG was isolated from clinical specimen, alternate dx, etc.)
- **Died** Patient was alive at diagnosis but died either before the start or prior to completing treatment
- Dying Treatment was stopped or never started by clinician or at patient request because patient's condition was terminal and death was imminent.
- Other Therapy was discontinued for some other reason (including that the patient moved out of the United States)
- Unknown

If patient leaves the United States during treatment and completion **cannot** be verified through CureTB or through VET, select "**Other**"

40. Reason Therapy Stopped or Never Started:	*	
Other 40. Reason Therapy Stopped or Never Started:		



41. Reason TB therapy extended >12 months, if applicable?

41. Reason TB Disease Therapy Extended Beyond 12 Months, If Applicable (select all that apply):

Adverse Drug Reaction Clinically Indicated for Reasons Other Than Above Inability to Use Rifampin Selected Values:

- Inability to use rifampin (resistance, intolerance, etc.) Rifampin, or another rifamycin such as rifabutin) could not be used to treat the patient (e.g., drug-resistant TB, rifampin intolerance), resulting gin treatment protocol lasting more than 12 months.
- **Adverse drug reaction –** Patient had a significant adverse drug reaction or experience an adverse treatment event from TB medications (other than a rifamycin) that prolonged therapy.
- **Nonadherence** There were barriers to the patient's adherence to TB treatment (e.g., treatment interruption), resulting in extension of therapy beyond 12 months.
- Failure A culture tested positive 4 or more months after treatment began, resulting gin prolonged therapy.
- **Clinical indicated (other reasons) Clinical indications (other than adverse drug reactions)** include central nervous system TB (e.g., meningitis, sever liver disease, or other criteria specified by the clinician.
- Other (specify)
- Unknown

The 12 month time period is calculated using date therapy started and date therapy stopped, so it includes treatment interruptions, etc.



42. Treatment administration

- DOT Select if directly observed therapy was used for any doses for the patient.
- EDOT Select if electronic DOT (i.e., VET video enhanced therapy), was used to document adherence to the medication regimen for any doses.
- **Self-administered** Select if any does of medication were taken by the patient not under DOT or eDOT (including weekend doses).

Select all that apply. For many Virginia clients, all three will be selected.

42. Treatment Administration (select all that apply):

Use Ctrl to select more than one)

Directly Observed Therapy (DOT)
Electronic DOT (Video Enhanced Therapy)
Self-Administered
Unknown

Selected Values:



43. Did the patient die (either before diagnosis or at any time while being followed by TB program?

- Yes The patient died for any reason either before the TB diagnosis was made or at any point after TB diagnosis while being followed by the TB program.
 - o If "Yes" selected, record the date of death
 - If "Yes" selected, indicate if TB or complications of TB treatment contributed to death
- No The patient was alive at the time that the TB program stopped following the patient.

Mortality Information As Of Date:		=
43. Did the Patient Die (either before diagnosis or at any time while being followed by TB program:	~	
Date of Death:		
Did TB or Complications of TB Treatment Contribute to Death?:	~	



MDR Supplemental Tab

- Complete, regardless of DST results, for cases treatment with MDR TB medications including patients:
 - Confirmed to have MDR TB (or XDR TB) through laboratory evidence of resistance to at least isoniazid and rifampin or
 - o Presumed to have MDR TB (e.g., contact to known MDR-case), or
 - Not thought o have MDR TB, but are treated with second-line TB drugs for other reasons (e.g., drug shortage, drug intolerance, interactions, adverse events).





MDR Supplemental Tab

				inaicat	es a Requirea Fiela
Patient Case Info Tuberculosis TB Disease Only MDR TB LTBI Only	Contact Tracing Contact	acts Contact Records	Supplemental Info		
■ Multi-Drug Resistant (MDR)					Back to top
Collapse Subsections MDR Treatment Course					
History of Treatment Before Current Episode:	~				
2. Date MDR TB Therapy Started for Current Episode:					
3. Drugs Ever Used for MDR Treatment					
Drug		Length of Time Ad	ministered		
No Data has been entered.					
Drug:	~				
Other Drug:					
Length of Time Administered:	~				
201981 01 11110 1411111111111111111111111111					Add
■ MDR Treatment Course Continued					Add
4. Date Injectable Medication Stopped (If no injectable drugs were used leave blank.):	=				
5. Was Surgery Performed to Treat MDR TB?:					
If Yes, Date of Surgery:					
□ 6. Side Effects					
	ide Effect Experienced			When?	
No Data has been entered.	and an				
Side Effect:		V			
Other Side Effect:					
Side Effect Experienced:	~				
When?:	~				
					Add



MDR Supplemental Tab

Complete for all patients who are:

- Confirmed to have MDR TB (or XDR TB) through laboratory evidence of resistance to at least isoniazid and rifampin or
- Presumed to have MDR TB (e.g., contact to known MDR-case), or
- Not thought to have MDR TB, but are treated with second-line TB drugs for other reasons (e.g., drug shortage, drug intolerance, interactions, adverse events).



1. History of Treatment before current episode

 Patient self-report of treatment for a previous episode of MDR TB disease is acceptable if documentation is not available.

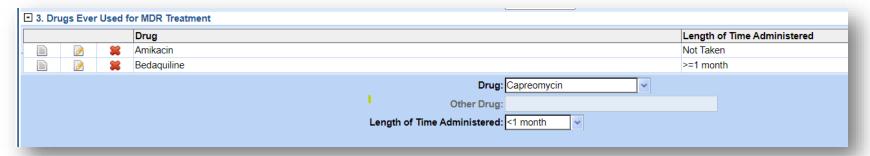
2. Date MDR TB therapy started for current episode

 Date the patient first began a drug regimen containing at least two second-line drugs.

1. History of Treatment Before Current Episode:	*	
2. Date MDR TB Therapy Started for Current Episode:		



3. Drugs ever used for MDR Treatment



- Provide a response for all drugs in the drop down (there is no autofill option).
- This should reflect treatment for the current episode.
- Duration of therapy is cumulative.



4. Date injectable medication was stopped

- Provide the last date the injectable was given.
- If patient never received injectables, leave blank.

5. Was surgery performed to treat MDR TB?

- Indicate if surgery was performed as part of MDR treatment, and if so, the date, or an estimated date, of the surgery.
- A biopsy done to diagnose MDR TB is not considered surgery for treatment, but excisional biopsy for the treatment of extrapulmonary TB is considered surgical treatment.

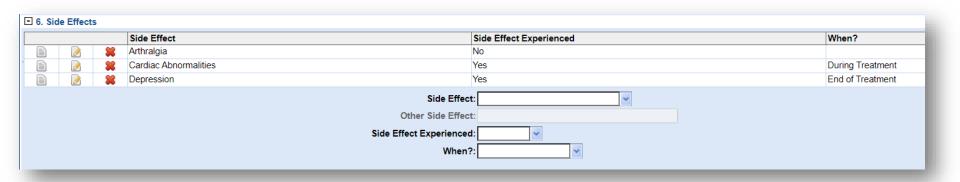
4. Date Injectable Medication Stopped (If no injectable drugs were used leave blank.):	
5. Was Surgery Performed to Treat MDR TB?:	
If Yes, Date of Surgery:	





6. Side effects

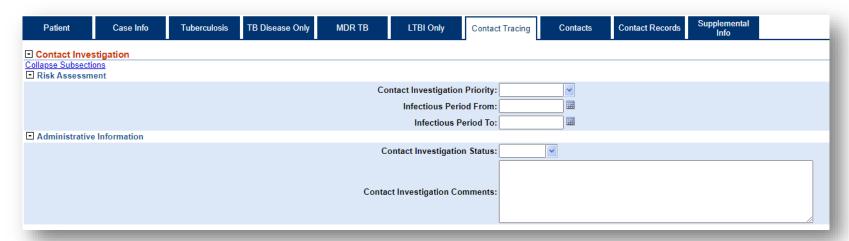
 Provide a response for each possible side effect in the drop down (there is no autofill option) and if experienced indicate if it was during treatment or after the treatment was stopped, or both.





Contact Tracing Tab

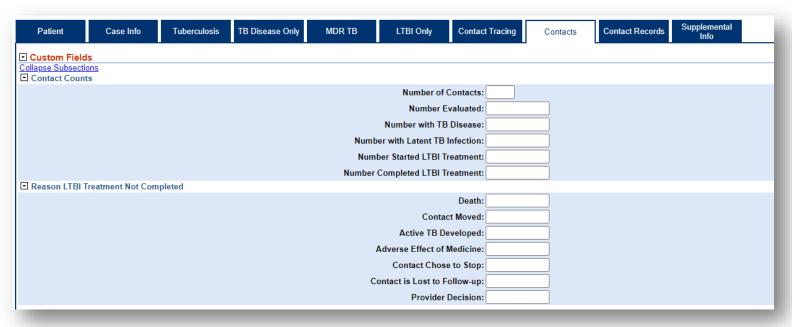
- Captures contact investigation information and comments
- VDH TB enters when 502 submitted





Contacts Tab

- Captures summary contact investigation information
- VDH TB enters when 502 submitted





Supplemental Info Tab

Shows associated labs, morbidity reports, uploaded documents, etc.

Patient	Case Info	Tuberculosis	TB Disease Only	MDR TB	LTBI Only	Contact Tracing	Contacts	Contact Records	Supplemental Info		
Go to: Association	s Notes and Attachi	ments <u>History</u>			•	·			_		
Collapse Sections											
□ Associations											
Collapse Subsection											
Associated La	b Reports										
Date Received		Repor	ting Facility/Provider				Date Collecte	ed	Test	Results	P
Nothing found to d											
■ Associated Mo	orbidity Reports										
Date Received				Condition		R	eport Date			Туре	Obse
Nothing found to d											
■ Associated Tree	eatments										
Date			Treatment					Treatr	nent ID		
Nothing found to d	isplay.										
Associated Va	ccinations										
Date Administere	d				Vaccine	Administered					Vaccir
Nothing found to d	isplay.										
□ Notes And At	tachmente										
Collapse Subsection											
■ Notes											
Date Added					Added	Ву				Note	
Nothing found to	display.										
 Attachments 											
Date Added				Added By				File Name			Descrip
Nothing found to	display.										



Within 3 days

• Initial Notification to VDH TB Program of new presumptive/confirmed case via REDCap (name, dob, address, site of disease, nurse case manager, etc.)

Within 1-2 weeks o

• All initial info for RVCT (race, ethnicity, country of birth, month/year arrival, primary reason evaluated, TST/IGRA result, Chest imaging, risk factors, occupation, date treatment started, initial drug regimen, etc.

Data entry timeline

Within 8 weeks of

• Update lab results (Smears, NAA, Cultures)

Within 4 weeks of culture confirmation

• Enter initial drug susceptibility results (growth-based, VDH TB will assist with molecular results)

Within 1 week of t

• Case completion information (Culture conversion, tx completion date, reason treatment stopped, DOT, moved during tx, etc.)



Coming soon in 2024: LTBI

Patient	Case Info	Tuberculosis	TB Disease Only	MDR TB	LTBI Only	Contact	t Tracing	Contacts	Contact Records	Supplemental Info	
TBLISS Speci											
■ LTBI Treatmen											
				Wa	as LTBI Treatment	Offered:		~			
					25. LTBI Therapy S	tarted?: Y	'es	~			
					Treatment Sta	=				1	
					ecify Initial LTBI R	-			~		
				Other Sp	ecify Initial LTBI R	- =					
				Oth	Treating Provid ner Treating Provid					~	
					TBI Treatment Not						
				•	TBI Treatment Not	=]	
					26. Date Therapy S	=		III		J	
				27. Treatn	nent Administration		Directly O		(DOT)		
				28. Reas	on LTBI Therapy S	topped:			~		
					son LTBI Therapy S]	
NTSS State Case	Number should be	entered as 4 digit re	port year+ 2 letter state		9 digit alphanumeric er (YYYY-GA-ABCI	_					
					vent (select all tha		(Use Ctrl to Death Hospitalize	~	one)		
PLEASE IMMEDIA			TS RESULTING IN HO			_	RUGEVEN	NTS@CDC.GOV			



Questions?

- Contact Laura Young
 - <u>laura.r.young@vdh.virginia.gov</u>
 - 0 804-836-6059
- You can also always email <u>tuberculosis@vdh.virginia.gov</u>