

TESTING FOR TB INFECTION: Tuberculin Skin Testing (TST) or Interferon-gamma Release Assay (IGRA)

GENERAL INFORMATION

Refer to **World Health Organization (WHO) list of TB Incidence by Country, 2012** (Adapted from WHO website, 07/16/2013) at the end of this protocol for identification of TB-endemic countries.

Routine testing for TB infection with either TST or IGRA should not be performed for patients who are assessed to be at “LOW RISK” for tuberculosis.

IGRA is the preferred test for persons who have been previously vaccinated with Bacillus Calmette-Guérin (BCG); however, TST is not contraindicated for BCG-vaccinated individuals.

Targeted testing for TB infection may be performed to identify persons with increased risk of having TB infection who would benefit from treatment.

NOTE: A decision to test is a decision to treat. Consult Tennessee Tuberculosis Elimination Program (TTBEP) Central Office staff prior to starting a targeted testing initiative.

SUBJECTIVE

Evaluate/Document TB Risk Status:

Complete the “***TB Risk Assessment Tool***” (**TB RAT**) for all persons (child, adolescent or adult) who meet one or more of the following criteria:

- Being considered for TB infection testing, **OR**
- Had a cough \geq 2-3 weeks **AND** at least one of the following additional symptoms: fever, night sweats, weight loss, or hemoptysis; **OR**
- “High- risk” for TB (*see TABLE 1*); **OR**
- Responds “YES” to any of the questions on the “***TB Risk Assessment Questionnaire***” (*see TABLE 2*)

Pregnant women should be considered for TB infection testing only if they have a specific risk factor for TB infection (Note: There is no evidence that the TST or IGRA have adverse effects on the pregnant mother or fetus).

TABLE 1. Groups at High Risk for TB Infection (Immediate test for TB infection required)

1. Close contacts of a person known or suspected to have TB disease (i.e., those sharing the same household or other enclosed environments)
2. Foreign-born persons from TB-endemic countries (see **WHO list**)§
3. Health care workers who serve high-risk clients (use TST for annual testing)§
4. Mycobacterial laboratory workers (use TST for annual testing)
5. Persons with HIV infection or AIDS (in adults, use IGRA if possible)*
6. Persons with medical conditions or treatments that place them at high risk for progression to TB disease if infected with *M. tuberculosis* (includes diabetes, silicosis, leukemia or lymphoma, cancer of the head and neck or lung, immunosuppressive condition or therapy, end-stage kidney disease, gastrectomy or jejunioileal bypass, weigh < 90% of ideal body weight, pre/post-transplant (all tissue/solid organs requiring current anti-rejection medication), untreated/inadequate TB treatment [without a documented positive TB test result], diagnosed with TB infection within the past 2 years [without a documented positive TB test result], and smoking)**
7. Persons who inject or use illicit drugs§
8. Residents, staff, or volunteers who work or have ever worked in high-risk congregate settings (e.g., homeless shelters or correctional facilities)***§
9. Children under 18 years of age exposed to adults in high-risk categories
10. Persons who are currently or have ever been homeless§
11. Persons with radiographic or clinical findings suggesting TB disease
12. Residence or prolonged travel in a TB-endemic country (see **WHO list**)§
13. Other high-risk populations as locally defined by the Department of Health (designation as a locally-defined high-risk population will be based on the incidence of TB disease and infection for that specific area or population, and may include some medically underserved populations)

* All persons newly diagnosed with HIV infection should be tested for TB infection as soon as possible. Annual testing for TB infection is recommended only for HIV-infected patients who are at high risk of repeated or ongoing exposure to those with active TB.

** Once a negative test is documented for patients in this group, no repeat testing is necessary unless the patient has a new risk factor for TB exposure.

*** Residents, staff, or volunteers who work or have ever worked in a high-risk congregate setting are at high-risk for TB infection. TST should be used as the method of testing for any persons required to have annual testing. Children/youth in DCS custody residing in a congregate care setting (i.e., where testing for TB infection is required as long as the child/youth remains in the congregate care setting) should receive a TST (not IGRA) for the annual testing.

§Patients in these groups should receive initial testing for TB. Patients should be screened for symptoms and NEW risk factors for exposure or progression upon subsequent visits. If no new risk factors are present, testing for TB should not be done. Patients in these groups require annual testing only (not every visit) unless new risk factors are identified within the year.

TABLE 2. TB Risk Assessment Questionnaire (Administer to Children & Adolescents)

1. Are you or your child in close contact of a person with TB?
2. Are you or your child foreign-born or an immigrant or refugee from a country where TB is common (refer to **WHO list**)
3. Have you, your child, or any household member traveled to a country where TB is common (refer to **WHO list**) in the last 12 months?
4. Do you or your child have a medical condition or treatment of a medical condition that suppresses the immune system?
5. Do you or your child have HIV infection, or is he/she considered at risk for HIV infection?
6. Are you or your child exposed to the following individuals?
 - HIV-infected, homeless individuals, residents of nursing homes, institutionalized adolescents or adults, users of illicit drugs, incarcerated adolescents or adults, or migrant farm workers

If respondent reports “YES” to any of the above, you must complete a “*TB Risk Assessment Tool*” (TB RAT).

For **children and adolescents** who present for an EPSDT, administer the “*TB Risk Assessment Questionnaire*” (see **TABLE 2** above). If testing for TB infection is indicated, use the TST method.

OBJECTIVE

TST may be given on the same day as live virus vaccines (e.g., MMR and Varicella); however, if not given on the same day, TST should be delayed **at least 4 weeks** (28 days) after administration of a live virus vaccine (Note: Delaying the TST will remove the concern of any theoretical suppression of PPD reactivity from the vaccine).

Inject 0.1 ml PPD intradermally into the volar (palm side) surface of the left forearm; the scapula area may be used as an alternative site for persons who cannot receive the TST in the lower arm.

Two-step TST (initial visit) all persons who are required to receive serial testing for TB infection (e.g., health care or correctional facility workers) in order to ascertain a reliable baseline. Refer to “*TST Two-Step Protocol 3.470*”

NOTE: IGRA is not recommended by CDC for serial testing (those who require annual testing for TB infection).

TABLE 3. TTBEF Recommendations for TST for Infants, Children and Adolescents^{§§}**Children for whom immediate TST or IGRA is indicated:**

- Contacts of persons with confirmed or suspected contagious TB (contact investigations)
- Children with radiographic or clinical findings suggesting TB disease
- Children immigrating from countries with endemic TB (see **WHO list**), including international adoptees
- Children with travel histories to countries with endemic TB (see **WHO list**) and substantial contact with indigenous people from such countries

Children who should have annual TST:

- Children infected with HIV (TST only)

Children at increased risk of progression to active TB disease:

- Children with other medical conditions, including diabetes mellitus, chronic renal failure, malnutrition, congenital or acquired immunodeficiencies, and children receiving tumor necrosis factor (TNF) antagonist deserve special consideration. Without recent exposure, these children are not at increased risk of acquiring TB infection. Underlying immune deficiencies associated with these conditions theoretically would enhance the possibility for progression to severe TB disease. Initial histories of potential exposure to TB should be included for all of these patients. If these histories or local epidemiologic factors suggest a possibility of TB exposure, immediate and periodic TST or IGRA should be considered.
- An initial TST or IGRA should be performed before initiation of immunosuppressive therapy, including prolonged steroid administration, use of TNF-alpha antagonists, or other immunosuppressive therapy in any child requiring these treatments.

^{§§} Adapted from AAP Tuberculin Skin Test (TST) Recommendations for Infants, Children, and Adolescents (2012 Red Book, Table 3.76, page 740)

IGRA blood samples should be collected per TB Elimination Program guidelines and laboratory protocol.

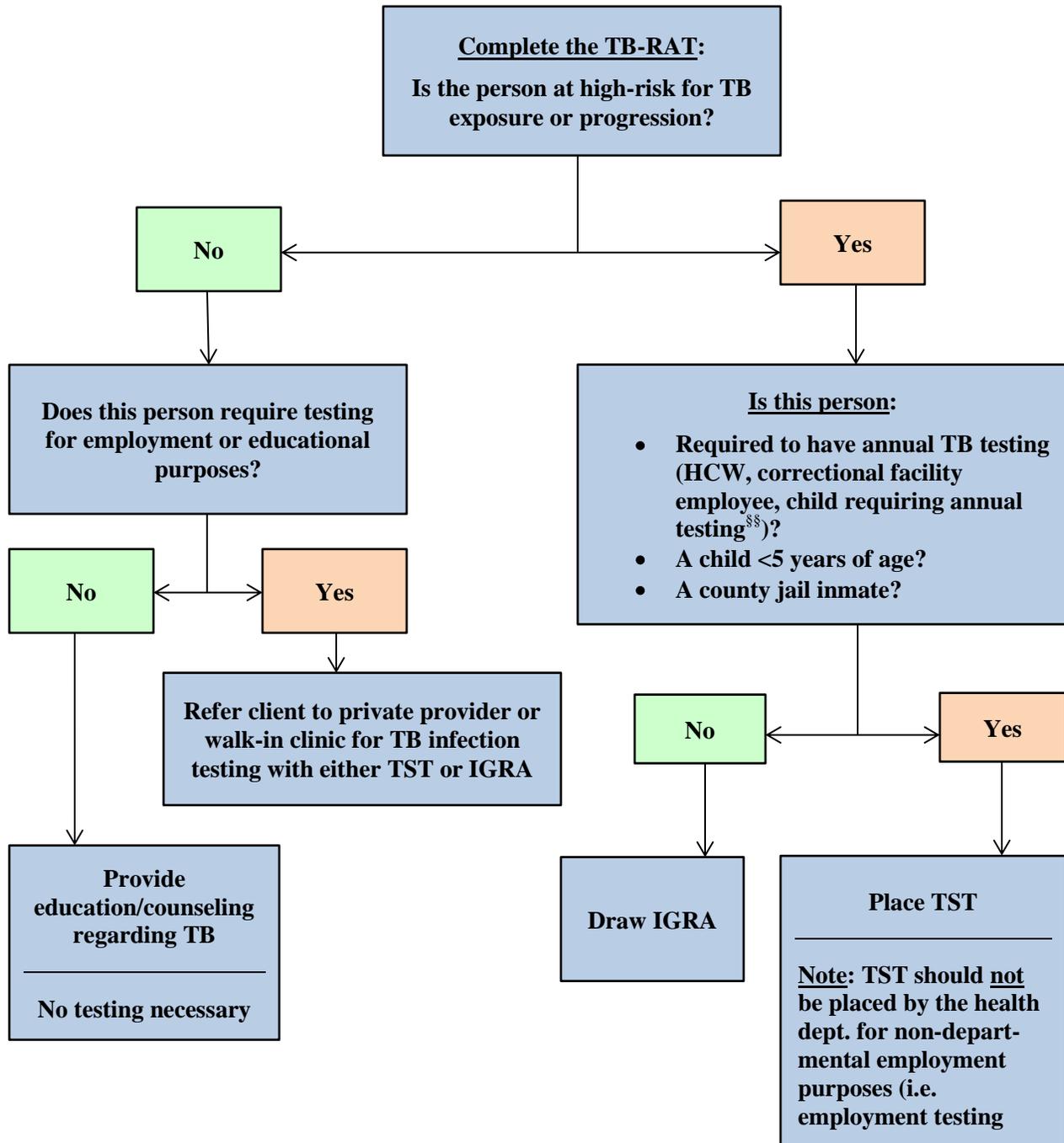
Refer to TB Elimination Program guidelines and Lab Manual for QuantiFERON[®]-TB Gold In-Tube assay collection and processing procedures.

IGRA method should **NOT** be used for the following patients:

- a) Children <5 years of age
- b) Any child, regardless of age, requiring TB testing as part of the EPSDT exam
- c) Any person disposition as “low-risk” through the TB Risk Assessment Tool (TB RAT)
- d) Health Care Workers (HCWs) and those who require annual testing
- e) Persons requesting TB testing for employment purposes (excludes eligible health department employees)

EXCEPTION: An IGRA may be used for testing persons meeting criteria “b” “c” or “d” above IF identified during a contact investigation as at risk for recent TB exposure.

FIGURE 1: Testing for TB Infection
Tuberculin Skin Testing (TST) or Interferon-gamma Release Assay (IGRA)



§§ See Table 3. Recommendations for TST for Infants, Children and Adolescents

ASSESSMENT

Read TST results within 48-72 hours. Palpate with the pads of fingertips for the presence or absence of induration (i.e., a hard, dense, raised formation); **do not measure any soft swelling or redness** that may be present at the site. The transverse diameter of the induration is measured across the forearm from the “thumb side” of the arm to the “little finger side” of the arm.

Record TST measurement in millimeters (mm) only

Interpret TST results (i.e., “positive” vs “negative”) in accordance with **TABLE 4, “*Interpretation of TST results by Risk Group*”**

A “**negative**” TST result (i.e., no induration present) in a person who returns for TST reading and interpretation more than 72 hours after placement **is not** considered valid; a repeat TST placement is required.

A “**positive**” TST result (i.e., induration is present) in a person who returns for TST reading and interpretation more than 72 hours after placement should be measured and documented in millimeters. A repeat TST is not necessary as a positive reaction may persist for up to one week after placement.

For persons with TST results interpreted as “**negative**” who undergo repeat TST placement, **an increase in induration diameter of ≥ 10 mm within a period of 2 years** should be considered a “**TST conversion**” indicative of recent infection with *M. tuberculosis*; such persons should be clinically evaluated for TB infection or active TB disease.

NOTE: As long as there is no history of prior severe reaction or allergy to the TB skin test, the TST may be repeated if the initial results are questionable or if there is no documentation of a prior result measured in millimeters (mm).

IGRA

Receipt of an IGRA result (i.e., QFT-GIT) can take between 3-5 days. The qualitative result will be indicated on the laboratory form as “**Positive**,” “**Negative**” or “**Indeterminate**.” Patients for whom the IGRA result is “Indeterminate” should have an IGRA of the same type repeated within 1-2 weeks.

TABLE 4. Interpretation of TB Test Results, By Risk Group**1. IGRA:**

- A “**Positive**” qualitative result noted on the laboratory form is an indication of infection with *M. tuberculosis*. It does not indicate when the infection occurred nor does it indicate if the infection has progressed to active TB disease.
- A “**Negative**” qualitative result indicates the person’s immune system did not detect the presence of *M. tuberculosis* when the specimen was drawn. If TB exposure has been recent, a repeat IGRA is indicated 8-10 weeks after he/she no longer has contact with the active case of TB, or 8-10 weeks after the person with active TB is no longer considered contagious.
- TST is preferred/recommended for children <5 years of age

2. TST Reaction ≥ 5 mm of induration – Interpret as “Positive**” if:**

- HIV-infected persons
- Recent contacts of persons with TB disease
- Fibrotic changes on chest radiograph consistent with prior TB
- Immunosuppressed patients, including those with organ transplants, those receiving the equivalent of ≥ 15 mg per day of prednisone for at least 1 month, chemotherapy, TNF-alpha antagonists, etc.*

3. TST Reaction ≥ 10 mm of induration – Interpret as “Positive**” if:**

- All foreign-born persons (recent immigrants within past 5 years) from high- prevalence countries
- Injection drug users
- Residents and employees of the following high-risk congregate settings: Prisons and jails, nursing homes and other long-term care facilities, hospitals and other health care facilities, residential facilities for patients with acquired immunodeficiency syndrome (AIDS), or homeless shelters
- Mycobacteriology laboratory personnel
- Persons with the following clinical conditions: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemias and lymphomas), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of $\geq 10\%$ of ideal body weight, history of gastrectomy or jejunioileal bypass surgery
- Children younger than 4 years of age
- Infants, children, and adolescents exposed to adults at high-risk

4. TST reaction ≥ 15 mm of induration – Interpret as “Positive**” if:**

- Person with no risk factors for TB[†]

* The risk of TB in patients treated with corticosteroids increases with higher dose and longer duration.

[†] For persons who are otherwise at low risk and are tested at the start of employment, a reaction of ≥ 15 mm induration is considered “positive.”

PLAN

Children < 4 years of age who are exposed to a person with active TB and have a negative initial TST must be:

- **Referred** promptly to the TB clinic for evaluation and possible treatment of LTBI, regardless of the TST result. Treatment can be stopped if, upon re-testing at 8-10 weeks after last exposure to the infectious TB case, the child's second TST remains negative.
- **Re-tested** with TST 8-10 weeks after he/she no longer has contact with the active case of TB, or 8-10 weeks after the person with active TB is no longer considered contagious.

If a TB test is “positive” (TST with induration present) or “Positive” (IGRA), refer the child promptly to the medical provider or regional TB clinic for evaluation to rule out active TB disease and consideration of treatment for TB infection.

Repeat TST as indicated (see **TABLE 3: Recommendations for Serial TST in Children**).

Adults who are exposed to a person with active TB and have a negative initial TST/IGRA must be

- **Referred** to the TB clinic for evaluation by medical provider if patient is immunocompromised or has symptoms of TB
- **Re-Tested** with same method initially used for testing (TST or IGRA) 8-10 weeks after last exposure

If a TB test is “positive” (TST with induration present) or “Positive” (IGRA), refer the patient promptly to the medical provider or regional TB clinic for evaluation to rule out active TB disease and consideration of treatment for TB infection.

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Report of the Committee on Infectious Diseases. Elk Grove Village, IL, 2012

WHO List: TB Incidence by Country, 2012 (Adapted from WHO website, 07/16/2013)

	COUNTRY	PTBMIS Code	INCIDENCE
A	Afghanistan	001	High
	Albania	002	Low
	Algeria	003	High
	American Samoa	004	Low
	Andorra	005	Low
	Angola	006	High
	Anguilla	007	High
	Antarctica	008	No data
	Antigua and Barbuda	009	Low
	Argentina	010	High
	Armenia	224	High
	Aruba	251	Low
	Australia	011	Low
	Austria	012	Low
	Azerbaijan	225	High
	B	Bahamas	013
Bahrain		014	Low
Bangladesh		015	High
Barbados		016	No data
Belarus		226	High
Belgium		017	Low
Belize		018	High
Benin		019	High
Bermuda		020	Low
Bhutan		021	High
Bolivia (Plurinational State of)		022	High
Bonaire, Saint Eustatius and Saba		253	Low
Bosnia and Herzegovina		227	High
Botswana		023	High
Bouvet Island		024	No data
Brazil		025	High
British Indian Ocean Territories		026	No data
British Virgin Islands		027	Low
Brunei Darussalam		028	High
Bulgaria		029	High
Burkina Faso (Upper Volta)		247	High
Burma (Myanmar)		030	High

	COUNTRY	PTBMIS Code	INCIDENCE
	Burundi	031	High
C	Cambodia (Kampuchea)	228	High
	Cameroon	032	High
	Canada	033	Low
	Cape Verde	034	High
	Cayman Islands	035	Low
	Central African Republic	036	High
	Chad	037	High
	Chile	038	High
	China	039	High
	China (Taiwan)	040	No data
	China, Hong Kong SAR	087	High
	China, Macao SAR	116	High
	Christmas Island	041	No data
	Cocos (Keeling) Islands	042	No data
	Colombia	043	High
	Comoros	044	High
	Congo	045	High
	Cook Islands	046	Low
	Costa Rica	047	Low
	Cote d'Ivoire (Ivory Coast)	098	High
	Croatia	229	Low
	Cuba	048	Low
	Curacao	255	Low
	Cyprus	049	Low
	Czech Republic	230	Low
	Czechoslovakia	050	No data
D	Democratic People's Republic of Korea (North Korea)	106	High
	Democratic Republic of the Congo	257	High
	Denmark	051	Low
	Djibouti	052	High
	Dominica	053	Low
	Dominican Republic	054	High
E	East Germany	071	Low
	Ecuador	055	High
	Egypt	056	Low
	El Salvador	057	High
	England (United Kingdom of Great Britain and Northern Ireland)	204	Low

	COUNTRY	PTBMIS Code	INCIDENCE
	Equatorial Guinea	058	High
	Eritrea	259	High
	Estonia	231	High
	Ethiopia	059	High
F	Falkland Islands	060	No data
	Faroe Islands	061	No data
	Federated States of Micronesia	245	High
	Fiji	062	High
	Finland	063	Low
	France	064	Low
	French Guiana	065	No data
	French Polynesia	066	High
	French Southern and Antarctic Lands	067	No data
G	Gabon	068	High
	Gambia	069	High
	Georgia	232	High
	Germany	246	Low
	Germany (East)	071	Low
	Germany (West)	072	Low
	Ghana	073	High
	Gibraltar	074	No data
	Gilbert Islands (Kiribati)	105	No data
	Great Britain (United Kingdom of Great Britain and Northern Ireland)	204	Low
	Greece	075	Low
	Greenland	076	High
	Grenada	077	Low
	Guadeloupe	078	No data
	Guam	079	High
	Guatemala	080	High
	Guinea	081	High
	Guinea-Bissau	082	High
	Guyana	083	High
H	Haiti	084	High
	Heard and McDonald Islands	085	No data
	Honduras	086	High
	Hong Kong (China, Hong Kong SAR)	087	High
	Hungary	088	Low
I	Iceland	089	Low
	India	090	High

	COUNTRY	PTBMIS Code	Incidence
	Indonesia	091	High
	Iran (Islamic Republic of)	092	High
	Iraq	093	High
	Iraq-Sauid Arabia Neutral Zone	094	No data
	Ireland	095	Low
	Israel	096	Low
	Italy	097	Low
	Ivory Coast (Cote d'Ivoire)	098	High
J	Jamaica	099	Low
	Japan	100	High
	Johnston Atoll	101	No data
	Jordan	102	Low
K	Kazakhstan	233	High
	Kenya	104	High
	Kiribati (Gilbert Islands)	105	High
	Korea, Democratic People's Republic of (North Korea)	106	High
	Korea, Republic of (South Korea)	107	High
	Kosovo	248	No data
	Kuwait	108	High
	Kyrgyzstan	234	High
L	Lao People's Democratic Republic (Laos)	109	High
	Laos (Lao People's Democratic Republic)	109	High
	Latvia	235	High
	Lebanon	110	Low
	Lesotho	111	High
	Liberia	112	High
	Libya (Libyan Arab Jamahiriya)	113	High
	Libyan Arab Jamahiriya	113	No data
	Liechtenstein	114	No data
	Lithuania	236	High
	Luxembourg	115	Low
M	Macao (China, Macao SAR)	116	High
	Macedonia (The Former Yugoslav Republic of Macedonia)	219	High
	Madagascar	117	High
	Malawi	118	High
	Malaysia	119	High
	Maldives	120	High
	Mali	121	High

	COUNTRY	PTBMIS Code	Incidence
	Malta	122	Low
	Marshall Islands	261	High
	Martinique	123	No data
	Mauritania	124	High
	Mauritius	125	High
	Mexico	126	High
	Micronesia (Federated States of)	245	High
	Midway Islands	127	No data
	Moldova (Republic of Moldova)	238	High
	Monaco	128	Low
	Mongolia	129	High
	Montenegro	239	Low
	Montserrat	130	Low
	Morocco	131	High
	Mozambique	132	High
	Myanmar (Burma)	030	High
N	Namibia	133	High
	Nauru	134	High
	Navassa Island	135	No data
	Nepal	136	High
	Netherlands	137	Low
	Netherlands Antilles	138	No data
	New Caledonia	139	High
	New Hebrides	140	No data
	New Zealand	141	Low
	Nicaragua	142	High
	Niger	143	High
	Nigeria	144	High
	Niue	145	High
	Norfolk Island	146	No data
	North Korea (Democratic People's Republic of Korea)	106	High
	Northern Ireland (United Kingdom of Great Britain and Northern Ireland)	204	Low
	Northern Mariana Islands	147	High
	Norway	148	Low
O	Oman	149	Low
P	Pakistan	150	High
	Palau	263	High
	Panama	151	High

	COUNTRY	PTBMIS Code	Incidence
	Papua New Guinea	152	High
	Paracel Islands	153	No data
	Paraguay	154	High
	Peru	155	High
	Philippines	156	High
	Pitcairn Islands	157	No data
	Poland	158	High
	Portugal	159	High
	Puerto Rico	160	Low
Q	Qatar	161	High
R	Refused Information	998	
	Republic of Korea (South Korea)	107	High
	Republic of Moldova	238	High
	Reunion	162	No data
	Romania	163	High
	Russian Federation (Russia)	240	High
	Rwanda	164	High
S	Saint Christopher and Nevis (Saint Kitts and Nevis)	165	Low
	Saint Kitts and Nevis (Saint Christopher and Nevis)	165	Low
	Samoa (Western Samoa)	216	High
	San Marino	170	Low
	Sao Tome and Principe	171	High
	Saudi Arabia	172	Low
	Senegal	173	High
	Serbia	241	Low
	Seychelles	174	High
	Sierra Leone	175	High
	Singapore	176	High
	Sint Maarten (Dutch part)	265	Low
	Slovakia	267	Low
	Slovenia	242	Low
	Solomon Islands	177	High
	Somalia	178	High
	South Africa	179	High
	South Korea (Republic of Korea)	107	High
	South Sudan	183	High
	Spain	180	Low
	Spratly Islands	181	No data
	Sri Lanka	182	High

	COUNTRY	PTBMIS Code	Incidence
	St. Helena	166	No data
	St. Lucia	167	Low
	St. Pierre and Miquelon	168	No data
	St. Vincent and the Grenadines	169	High
	Sudan	183	High
	Suriname	184	High
	Svalbard and Jan Mayen	185	No data
	Swaziland	186	High
	Sweden	187	Low
	Switzerland	188	Low
	Syria (Syrian Arab Republic)	189	Low
	Syrian Arab Republic (Syria)	189	Low
T	Taiwan	040	Low
	Tajikistan	243	High
	Tanzania (United Republic of Tanzania)	190	High
	Thailand	191	High
	The Former Yugoslav Republic of Macedonia	219	High
	Timor-Leste	269	High
	Togo	192	High
	Tokelau	193	High
	Tonga	194	Low
	Trinidad and Tobago	195	High
	Trust Territory of the Pacific Islands	196	No data
	Tunisia	197	High
	Turkey	198	High
	Turkmenistan	244	High
	Turks and Caicos Islands	199	High
	Tuvalu	200	High
U	Uganda	201	High
	Ukraine	223	High
	Union of Soviet Socialist Republics	202	No data
	United Arab Emirates	203	Low
	United Kingdom of Great Britain and Northern Ireland	204	Low
	United Republic of Tanzania	190	High
	United States Mis Pacific islands	206	No data
	United States of America	205	Low
	Unknown	999	
	Upper Volta	207	High
	Uruguay	208	High

	COUNTRY	PTBMIS Code	Incidence
	US Virgin Islands	212	Low
	Uzbekistan	246	High
V	Vanuatu	271	High
	Vatican City	209	No data
	Venezuela	210	High
	Viet Nam	211	High
W	Wake Island	213	No data
	Wallis and Futuna Islands	214	High
	West Bank and Gaza Strip	070	Low
	West Germany	072	Low
	Western Sahara	215	No data
	Western Samoa (Samoa)	216	High
Y	Yemen (Aden)	217	High
	Yemen (Sana)	218	High
	Yugoslavia	219	No data
Z	Zambia	221	High
	Zimbabwe (S. Rhodesia)	222	High

TUBERCULIN SKIN TESTING, TWO STEP PROCEDURE

GENERAL INFORMATION

Two-step testing is done to detect waning sensitivity to infection with *Mycobacterium tuberculosis*

A person entering the health care field (with potential for direct patient contact) must be two stepped (i.e., first time employed in nursing home, hospital, health department, home health agency) regardless of age unless they can show documented proof within past 12 months of a PPD skin test

IGRAs are not recommended for those who require serial testing annually (health care workers, correctional facility employee, child requiring serial testing).

SUBJECTIVE:

Complete TB/LTBI Risk Assessment Tool at initial visit
(Note: Not to be used for Health Department employees)

OBJECTIVE:

Inject 0.1 ml PPD intradermally into the volar (palm side) surface of the left forearm; the scapula area may be used as an alternative site for persons who cannot receive the TB skin test in the lower arm.

ASSESSMENT:

Read the tuberculin skin test in **48 to 72 hours**:

Palpate with the pads of your fingertips for the presence or absence of induration (a hard, dense, raised formation); **do not measure any soft swelling or redness** that may be present at the site. The diameter of the induration is measured across the forearm from the thumb side of the arm to the "little finger side" of the arm or vice versa by measuring the transverse diameter of induration.

Record TST results in millimeters only; do not record as positive or negative

A **non-reactive** TST result (i.e., no induration present) in a person who returns for TST reading and interpretation more than 72 hours after placement **is not** considered valid; repeat TST placement is required.

Interpret TST results (i.e., "reactive" vs. "non-reactive") as outlined below:

"Interpretation of TST results by Risk Group."

1. TST Reaction ≥ 5 mm of induration

- HIV-infected persons
- Recent contacts of patients with TB disease
- Fibrotic changes on chest radiograph consistent with prior TB

- Immunosuppressed patients, including those with organ transplants, those receiving the equivalent of ≥ 15 mg per day of prednisone for at least 1 month, chemotherapy, TNF-alpha antagonists, etc.*

2. TST Reaction ≥ 10 mm of induration

- All foreign-born persons (recent immigrants within past 5 years) from high prevalence countries
- Injection drug users
- Residents and employees of the following high-risk congregate settings: Prisons and jails, nursing homes and other long-term care facilities, hospitals and other health care facilities, residential facilities for patients with acquired immunodeficiency syndrome (AIDS), or homeless shelters
- Mycobacteriology laboratory personnel
- Persons with the following clinical conditions: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (e.g., leukemia and lymphoma), other specific malignancies (e.g., carcinoma of the head or neck and lung), weight loss of $\geq 10\%$ of ideal body weight, history of gastrectomy or jejunoileal bypass surgery.
- Children younger than 4 years of age or infants, children, and adolescents exposed to adults at high-risk

3. TST Reaction ≥ 15 mm of induration

- Person with no risk factors for TB

If the initial reading is non-reactive, repeat the skin test one to three weeks after the first test.

If the initial reading is reactive, do not proceed to second test.

A **reactive** TST result (i.e., induration is present) in a person who returns for TST reading and interpretation more than 72 hours after placement should be measured and documented in millimeters.

If second test has no significant induration, consider it non-reactive, depending on clinical situation, and record measurement in millimeters

For persons with TST results interpreted as “**non-reactive**” who undergo repeat TST placement, an increase in induration diameter of ≥ 10 mm within a period of 2 years should be considered a TST conversion indicative of infection with *M. tuberculosis*; such persons should be clinically evaluated for LTBI or active TB disease.

Note: TB/LTBI Risk Assessment Tool does not need to be completed twice unless a patient returns to the clinic at a later time and it is determined that they have a new exposure or risk factors, in which case another TB/LTBI Risk Assessment Tool should be completed

PLAN:

All reactive tuberculin skin test should be referred to a private physician or to a tuberculosis clinic for a chest radiograph and further evaluation

Document results in record in millimeters, even if negative, and give results in writing to patient

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American Academy of Pediatrics, 2012:736-759.

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Report of the Committee on Infectious Diseases. Elk Grove Village, IL

TUBERCULOSIS, CASE OR SUSPECT (INITIAL VISIT)

SUBJECTIVE

Symptoms may include the following:

Cough >2 weeks	Chills
Hemoptysis	Night sweats
Chest pain	Weight loss
Fever	Fatigue
Referral from physician	

OBJECTIVE

Productive cough	Respirations normal or labored
Thin, pale	Documented weight loss
HIV status	Jaundice, yellow eyes
Positive or negative tuberculin skin test (TST)	
Positive, negative or indeterminate IGRA (Indeterminate should be repeated)	
Positive or negative smear, cultures, or culture pending	
Abnormal chest X-ray	
Other diagnostic tests/results	

Baseline measurement from TB clinic to include CMP, CBC with platelets and differential, and HIV. (Routine laboratory monitoring for toxicity is generally not needed in individuals with normal baseline.)

Clinical information from other providers, hospital

ASSESSMENT

Tuberculosis suspect (culture report not available)

Tuberculosis case (culture report or nucleic acid amplification test result is positive, indicate site of infection)

Latent Tuberculosis Infection (LTBI)

PLAN

Have patient wear surgical mask if symptomatic; nurse must wear n-95 mask

Initial Nursing Assessment:

Face to face contact will be made within 24 hours of notification of new infectious (sputum smear positive or cavitory on chest x-ray) TB suspect/case; this contact may be in the home, office, hospital, or other facility

Explain contact investigation and begin identifying contacts

Face to face contact visit will be made within 3 working days of notification of a newly diagnosed case or suspect who is:

- sputum smear negative,
- culture pending or culture positive,
- abnormal chest x-ray non-cavitary

Records should be obtained within 24 hours of report of suspect

Conduct Home Assessment:

If the initial visit is not a home visit, nurse should make a home visit to assess the home environment within 3 working days from notification; preferably the home visit should be made prior to patient's discharge from hospital, but no later than 24 hours after discharge from a hospital (see TB Guidelines)

Nurse must ensure that no immunosuppressed persons or children <4 years of age are in the home if an infectious patient is being discharged home

Provide Screening Evaluation:

Consider psychosocial, cultural background, and language/literacy level

Provide interpreter services as needed

Complete TB/LTBI Risk Assessment Tool (if not done previously) and evaluate history, including onset and duration of symptoms and signs for TB (as listed above)

Evaluate for possible pregnancy

Screen for any contraindications to anti-tuberculosis drugs (using PH 2040, Screening and Monitoring Forms)

Observe patients and family's ability and availability of resources to cope, adherence to medications regimen, and compliance with follow-up

If being treated by private physician, obtain record of physical exam, chest X-ray report, significant lab tests (sputum cultures, liver functions, and WBC) and medication orders

Ascertain whether MD will follow or if Health Department to follow; if Health Department to follow, refer to TB Clinic

Assure that a focused physical exam and chest X-ray have been performed by TB clinic MD/NP; if not done, refer back to TB clinic

Begin contact investigation

If patient is hospitalized, notify hospital of isolation discharge requirements

If patient is discharged from hospital, obtain and send copy of all records (notes, lab, and radiology reports, physician orders, and medication sheets) to regional TB clinic

Obtain and Document the Following Information:

Physician referral of suspect, case, or orders for anti-TB drugs

Known contacts

HIV status/other TB risk factors

PPD skin test history (including measurement) or previous IGRA test (including dates and results)

Previous history of –

Tuberculosis disease

TB infection (LTBI)

Administration of anti-TB medications

Symptoms including –

Date of first symptom

Weakness, weight loss, anorexia

“Flu-like” episode, chills, fever

Productive cough, chest pain, blood in sputum

Night sweats

Other health problems including –

HIV or immunosuppression

Diabetes mellitus

Liver or kidney disease

History of alcohol or drug abuse

Current medications (including OTCs and herbal medicines)

LMP

Allergies

Other evaluation by private MD, other providers, or health care facility

Special patient needs

Treatment:

Instruct on home isolation precautions until no longer infectious, or place patient on isolation if indicated

Measure height, weight, and vital signs initially.

Obtain weight and vital signs monthly

Directly observed therapy (DOT) is the standard of care for all TB cases

Dispense anti-tuberculosis drugs as prescribed by TB clinic physician (only those medications approved by TB clinic MD may be dispensed)

If on ETHAMBUTOL perform visual acuity (Snellen chart) and Red/Green color discrimination monthly; if patient wears glasses, check vision with glasses and note this in record

If STREPTOMYCIN or an AMINOGLYCOSIDE (Capreomycin, Amikacin) is to be used, obtain BUN and creatinine; patient should be questioned at baseline and monthly about possible hearing loss or tinnitus, and monitor vestibular function using the Romberg at baseline and monthly

At treatment initiation, if not drawn in TB clinic, draw CMP, CBC with platelets and differential

and HIV (if not known); all labs to be reviewed by physician
 Issue 3 sputum containers, dated and numbered (if pulmonary TB or to rule out pulmonary TB)
 with instructions for collecting in AM
 Collect first sputum specimen in clinic in person by sputum induction using 3% sodium
 chloride.
 Issue patient 2 pre-labeled and dated cans for use the next 2 consecutive days for natural sputum
 collection
 Complete all required fields on lab requisition
 DOT worker should pick up sputums at home on the day of collection for mailing to the lab from
 the local health department

Perform Contact Investigation (see TB Guidelines)

All high-risk contacts should be tested within 7 working days
 Completion of initial medical assessments of high-risk contacts should be completed within 10
 working days of contact identification.
 Document all contact information on PH 1631, “TB Contact Record”

NOTE: IGRA test is preferred for baseline testing for contacts ≥ 5 years of age.
 All contacts should receive an IGRA or TST if they have a documented negative PPD or IGRA
 history.

All high-risk contacts (from all environments) that have a positive IGRA or Positive TST are to
 have a chest X-ray and evaluation by an MD or APN.
 Contacts that have an initial negative TST or IGRA but are at risk of progression to active TB
 (i.e., children < 4, immunosuppressed persons, pregnant women, dialysis patients, HIV+, etc.)
 are to have a chest X-ray and evaluation by an MD or APN as soon as possible.

All contacts with an initial negative IGRA or TST should have a repeat IGRA or TST at 8-10
 weeks after contact is broken (last exposure) with the suspect/case; only one IGRA or TST is
 needed if contact has been broken for more than 10 weeks when initially tested.

NOTE: Use consistent method of testing for evaluation of a contact

Example:

- if IGRA is drawn initially, then at 8-10 weeks, IGRA will be repeated
- if Tubersol PPD is placed initially, then at 8-10 weeks, a second PPD will be placed
 using Tubersol
- if Aplisol PPD is placed initially, then at 8-10 weeks, a second PPD will be placed
 using Aplisol

Any contact that has an **indeterminate** IGRA is to be retested within 1-2 weeks.

Consult with regional TB nurse/physician for preventative therapy on ALL children who are
 close contacts of infectious or potentially infectious cases of TB, regardless of skin test results.

Document on contact record (PH 1631).

When contact investigation is completed, send a copy of PH 1631 to Regional TB office.

Provide Follow-up

If patient is being followed by Health Department TB physician, schedule monthly return appointments to TB clinic.

If patient is being followed by a private provider, schedule monthly visit with PHN to dispense medication(s) and document any medication side effects.

Obtain monthly office visit medical record notes from private provider prior to monthly PHN visit at health department.

For patients with active TB:

- Ensure DOT as ordered by physician until regimen is completed
- Assess for side effects each time DOT is given
- Weigh at every TB clinic visit
- Ensure baseline labs and sputum culture results are in chart
- Report any symptoms suggesting toxicity promptly to the treating physician and obtain appropriate lab specimens as ordered
- If on ETHAMBUTOL, perform monthly vision checks including visual acuity and color red/green discrimination
- If on STREPTOMYCIN or an AMINOGLYCOSIDE (Capreomycin, Amikacin), perform monthly Romberg and hearing evaluation (see TB Guidelines)
- Repeat liver testing if indicated (underlying liver disease, alcohol use symptoms) or as ordered by physician
- Issue sputum containers (set of 3) at least monthly but should be more frequently if patient is infectious; three sputum cultures must be obtained at one month and two months as ordered by physician (document reason if unable to obtain and notify Regional TB clinic), remind physician to order at 2 months if not done
- Sputum cultures must be done every month until patient has 3 consecutive negative cultures for 2 consecutive months
- When culture sent to outside labs, contact private provider or lab to ensure culture and sensitivity are ordered and that culture isolate is sent to state lab
- Send a copy of completed drug monitoring sheet to the regional TB clinic monthly
- Ensure TB clinic is aware of all culture and sensitivity results

Provide Referral:

Current medication intolerance and/or adverse reactions

Abnormal laboratory findings

Pregnancy

Non-adherence

REFERENCES

- CDC. Core curriculum on TB: What the Clinician Should Know, 5th Ed., 2011.
- CDC. [Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC](#) *MMWR* 2005; 54 (No. RR-15, 1-37)
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TUBERCULOSIS, Treatment of Latent Tuberculosis Infection (LTBI)

Latent Tuberculosis Infection (LTBI) is an asymptomatic state in persons who are infected with Mycobacterium tuberculosis and have future risk of developing active TB, but is not currently infectious to others.

SUBJECTIVE:

History of positive Mantoux skin test or positive IGRA
Physician referral
History of positive HIV status
Previous treatment for LTBI
Contact to TB case or suspect
Risk factor(s) for TB on TB/LTBI Risk Assessment Tool (RAT)
Clinical information from other providers if applicable

OBJECTIVE:

Positive tuberculin skin test
Positive IGRA
Normal chest x-ray
No symptoms of TB

ASSESSMENT:

Positive tuberculin skin test
Positive IGRA
Immunosuppressed with known contact to TB case/suspect regardless of TST results
Child <4 years and contact to TB case/suspect regardless of TST results
Pregnant and contact to TB case/suspect regardless of TST results
Diabetic patients with a documented positive test or positive IGRA who cannot prove that they have completed adequate LTBI treatment should be assessed for new risk factors

PLAN:

Provide Screening Evaluation:

Complete TB/LTBI Risk Assessment Tool (TB RAT)
Provide TB testing, if appropriate
Make appointment for patient with the regional TB clinic for evaluation if not previously done and/or consult with TB clinic staff
Notify TB physician of any patient with TB symptoms
Patient will be evaluated by physician in TB clinic. Evaluation will include focused physical exam, chest x-ray (including PA and lateral for children), and appropriate lab tests, if indicated by physician
Obtain records from other providers
Obtain medical history
Record any allergies or previous adverse reactions to medications

Assess and document all current medications (prescription, OTCs, or home remedies)
 Assess and document history of substance abuse (alcohol or drugs)

Treatment:

Perform baseline laboratory tests CMP, CBC with platelets & without differential, (including HIV if not already drawn) for:

- Persons with chronic liver disease (see TB Guidelines)
- Those whose initial evaluation suggests a liver disorder
- Those with immunosuppression (HIV etc.)
- Pregnant women and those in the immediate post-partum period (i.e., those within 3 months after delivery)
- Those who use alcohol regularly

Testing can be considered on an individual basis for those taking other medications for chronic medical conditions

Obtain written medical order by physician for appropriate anti-tuberculosis medication
 Obtain copy of last office visit if seen by private provider

If patient is a child, notify regional clinic for recommendations and/or specific orders
 All children <4 years of age who are contacts to TB cases/suspects are to receive LTBI therapy until 10 week follow-up skin test is negative (window therapy)

Children (≤ 18 years of age) are to receive directly observed preventive therapy (DOPT) throughout LTBI

Dispense only one (1) month supply of drugs as ordered by physician

- If patient is going out of town for an extended period, consult with TB clinic regarding dispensing more than one-month supply of medication
- If patient buying medication, obtain name of drug store and monitor monthly pick-up

Monitor for possible contraindications prior to initiating drug therapy, especially liver disease or factors that may contribute to liver disease (i.e., liver toxic medications, and alcohol abuse) and document on drug monitoring form (notify TB clinic of any contraindications)

Consult with regional TB clinic regarding special circumstances (obtain approval from Regional TB physician to dispense medication orders from private providers; review chart to assure appropriateness)

If patient has stopped TB medication

- less than 2 months ago, PHN may restart after consulting with TB Physician and carefully monitoring for signs and symptoms of active TB
- greater than 2 months ago, TB physician must re-evaluate patient

Document treatment completion or reasons not completed

Provide Health Teaching:

Discuss specific drug dosage, the anticipated benefits and possible side effects (especially liver toxicity)

Educate patient on whom to contact (give name and number) if side effects develop, including contact for holidays and weekends (emergency room, etc.)

Provide “*Patient Medication Instruction Sheet*”

Advise patient to stop the drug if adverse reactions occur. Provide name and number of person to contact for instructions.

Educate patient about the importance of disclosing any other medications (prescription, over-the-counter, or home remedies) including use of alcohol or drugs

Educate patient about adverse effects of alcohol use with LTBI medications

Educate patient about the importance of keeping appointments and date of next clinic visit

Provide Documentation:

Send a copy of record, prescriptions and test results to regional TB clinic

Document patient’s verbalized understanding of risks/benefits and willingness to take LTBI treatment

Document TB/LTBI education materials given

Provide Follow up:

Set up tickler card system or utilize computerized tracking for follow-up

If patient does not pick up medication monthly,

- attempt to contact him/her by phone
- send letter requesting patient to contact the office
- make home visit,
- send non- compliance letter from TB physician outlining risks (send a copy to regional clinic along with copy of drug monitoring record)

Dispense only one (1) month supply of drugs as ordered by physician

Complete clinical evaluation monthly for contraindications and signs/symptoms of adverse reactions while on therapy and notify TB clinic of any signs/symptoms

Ask patient monthly about new medications (prescription, over-the-counter, home remedies)

Provide laboratory monitoring if indicated by clinical evaluation (or ordered by physician)

If any test exceeds the upper limit of normal (ULN), send results to TB clinic or private physician for review; if liver enzymes (SGOT/SGPT) exceed ULN by three (3) times with symptoms, or by five (5) times without symptoms, or bilirubin is over the ULN at any level, notify TB clinic immediately for special orders

Contact patient if appointment not kept

Provide Referral:

Refer patient to private physician or tuberculosis clinic:

SGOT/SGPT > 3x ULN with symptoms, or > 5x ULN even without symptoms, or any abnormal bilirubin

Symptoms of adverse reactions or drug toxicity (fill out the FDA 3500 voluntary form and send to the State TB Medical Director for review)

Patient develops symptoms of active tuberculosis

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American Academy of Pediatrics. Tuberculosis. In: Pickering LK, Baker C, Kimberlin DW, Long SS, eds. 2012 Red Book

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