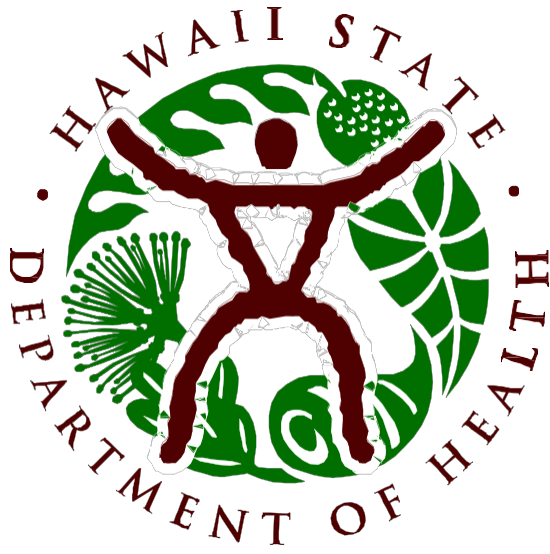




Communicable Disease and Public Health Nursing Division

Tuberculosis Control Branch

DOH TB Clearance Manual

To accompany
Chapter 11-164.2 of the Hawaii Administrative Rules

September 06, 2024



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1.0 Welcome

Aloha to the Hawaii Health Care Provider Community:

Hawaii historically has carried a heavy burden of tuberculosis (TB). Our location as a crossroads to regions with high rates of TB requires a state TB program that is robust and responsive. The Hawaii Administrative Rules (Chapter 11-164.2): Tuberculosis, were carefully tailored to our State's specific TB epidemiologic profile when it was updated in 2018. DOH recognizes that the current Hawaii requirements to screen health care providers for TB are more stringent than what is recommended by the CDC. The more conservative guidance has been adopted because CDC's recommendations are based on national rates of tuberculin skin test (TST) conversion and LTBI, both of which are significantly lower nationally than in Hawaii. For example, one Hawaii healthcare facility reported a TST conversion rate almost 14 times the national rate. Due to the higher prevalence of TB in the population and higher TST conversion rates, a more conservative TB screening program is necessary to protect Hawaii's health care workforce and our patients.

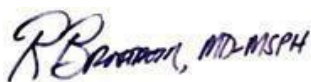
The TB Control Branch of the Communicable Disease and Public Health Nursing Division of the State Department of Health (DOH) created this "DOH TB Clearance Manual" to assist you with complying with the current requirements for TB screening and reporting. The updated edition, dated September 30, 2024 enhances our ability to provide up-to-date reporting requirements, targeted TB screening and testing to:

- quickly find and treat TB cases,
- efficiently identify high-risk residents for TB prevention, and
- minimize over-screening Hawaii residents who are at low risk for tuberculosis.

Additionally, Hawaii's health care providers should be comfortable with diagnosing TB as well as providing TB preventive therapy in their clinics. We strongly encourage health care providers who identify patients with inactive / Latent TB Infection (LTBI) to offer the life-long benefits of TB preventive treatment in accordance with Centers for Disease Control and Prevention ([CDC](#)) and American Thoracic Society (ATS) standards.

Health care providers may, at their discretion, consult with the TB Control Branch or refer a possible TB case for further workup or curative treatment. Toward that end, the TB Control Branch remains a strong partner as we accomplish our shared goals of TB prevention and reducing the unnecessary spread of TB in our community.

Mahalo for your valuable service to tuberculosis control in our State,



Richard Brostrom, MD-MSPH
Control Branch
CDC Pacific Regional TB Field Medical Officer

Genevieve Ley, MD, MPH, FACP Hawaii TB
Chief, TB Control Branch
Hawaii State Department of Health

2.0 Key Changes for our updated TB Clearance Procedures

The following list summarizes the major changes in Hawaii TB clearance requirements enacted in January 2024 and with this update in September 2024. from prior Hawaii TB clearance requirements:

1. With the implementation of a TB Risk Assessment, some low-risk individuals who required screening by the State of Hawaii in the past will no longer require a tuberculin skin test (TST) or other test for TB infection. For example, individuals born in the US, who have no TB symptoms and no additional TB risk factors, will have negligible risk for having inactive/latent TB infection or active TB disease. For these individuals, a TB Clearance can be obtained without performing a blood test or skin test for latent TB infection. TB clearance requirements for individuals living or working in healthcare facilities or residential care centers licensed or otherwise regulated by the department will still require an annual TB clearance but screening may not require a repeat chest X-ray (CXR). (January 2024)
2. In order for you to provide TB clearances for your patients to submit to employers, schools, and others who require TB screening by the State of Hawaii, the TB Clearance Form F has been updated (page 12). The Hawaii DOH strongly urges you to use Form F. If community clinicians are required to use a different form due to proprietary electronic medical records requirements, then this alternate form must contain the same wording as the DOH TB Clearance Form F. (January 2024)
3. Correctly interpreting a TST requires an understanding of each person's individual risk factors and the reason for testing. In accordance with [CDC](#) and ATS guidelines, the test should be read as positive at 5mm, 10mm, or 15mm depending upon individual risk factors. Rules for interpreting a TST test are described in TB Document I (page 15) in this manual. (January 2024)
4. The Interferon Gamma Release Assay ([IGRA](#)) blood test is an acceptable alternative to a TST. One IGRA blood test can be in lieu of a 2-step TST. An IGRA is commercially available as QuantiFERON Gold In-Tube (QFT-GIT) and Tspot. At this time, an IGRA-based blood test is not considered valid for persons under two years of age. (January 2024)
5. TB clearance procedures for patients with no documented previous positive test for TB infection entering long-term care facilities have been updated to clarify that a negative IGRA is an acceptable alternative to a TST and can be used in-lieu of a 2-step TST. In addition, a single negative TST and a chest x-ray that definitively excludes TB can be used for a TB clearance to expedite transfer between facilities. However, the second step TST must be completed after transfer and treatment for LTBI is recommended if indicated. These changes are reflected in TB Document B - Clearance Evaluation Procedures for Persons Living or Working in Health Care Facilities or Residential Care Settings (page 7) and TB Document F – TB Clearance Form (Page 12). (September 2024)

3.0 TB Clearance Procedures

There are several different TB testing strategies in this updated edition of the TB Clearance Manual, depending on the reason for testing. Table 1 provides specific screening instructions for each category of state-mandated screening. These documents are designed to provide straightforward instructions for each category of TB screening.

To complete the proper screening procedures required for each resident, first determine the reason for screening. If the reason for TB screening is included in the list below, then this manual will provide updated screening instructions. If the reason for screening is not included on this list, and you have questions about the appropriate TB screening methodology, please call the TB Control Branch at the (808) 832-5731.

Negative skin test results alone, Quantiferon results alone, the TB Symptoms Screening Form H and the Risk Assessment Form G **do NOT** confer TB clearance. Once TB testing or screening is completed, **Form F needs to be issued to serve as the TB clearance** (page 12 of this manual).

Table 1. List of TB Clearance Procedures

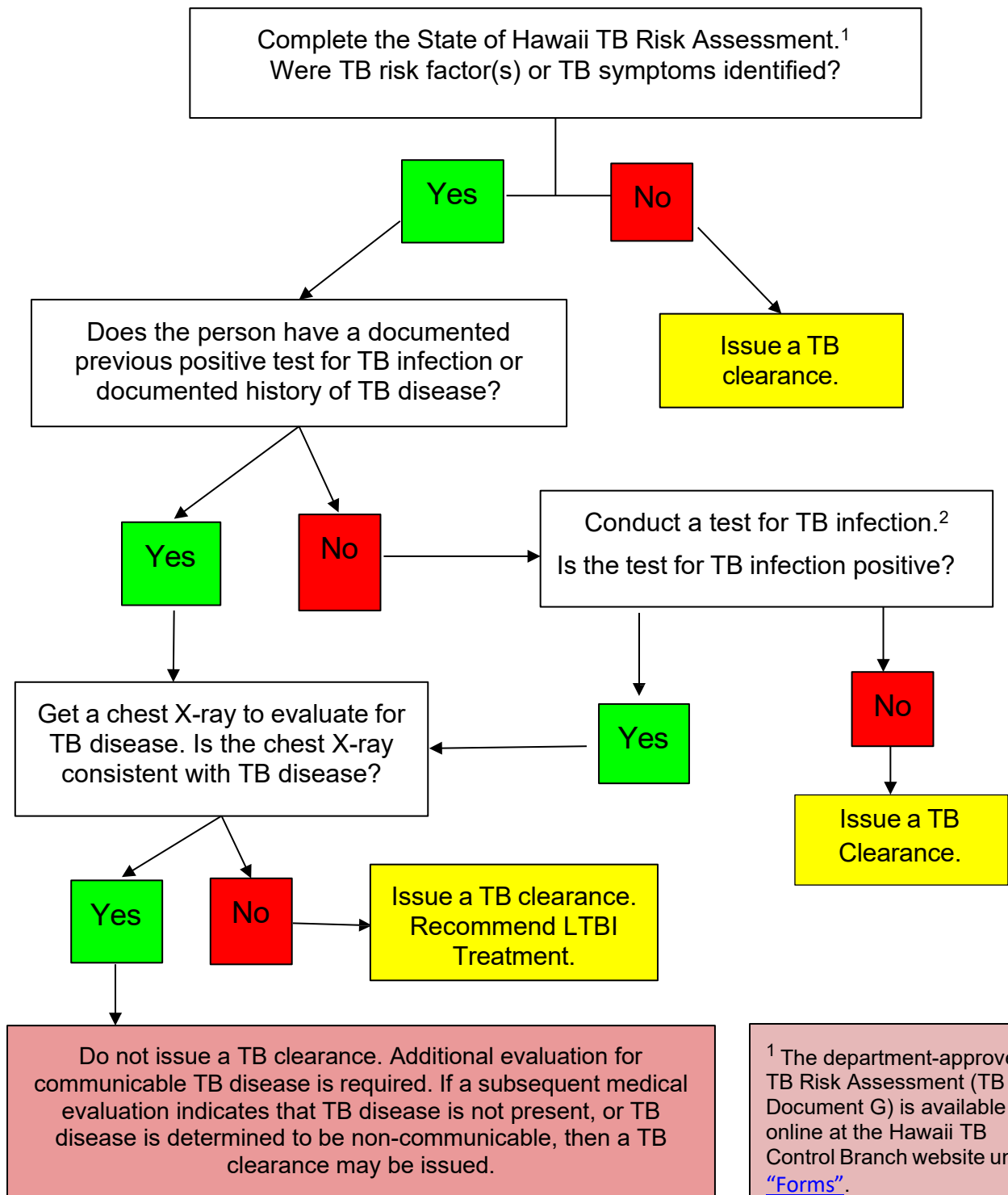
Reason for Screening	Refer to HAR Section	Procedure Document Name	Page
Primary and Secondary Schools: Personnel	§11-164.2-20	TB Document A	6
Primary and Secondary Schools: Attendance (Students)	§11-164.2-21	TB Document A	6
Post-secondary Schools: Personnel	§11-164.2-22	TB Document A	6
Post-secondary Schools: Attendance (Students)	§11-164.2-23	TB Document A	6
Child Care Facilities: Personnel	§11-164.2-24	TB Document A	6
Child Care Facilities: Attendance (Children)	§11-164.2-25	TB Document A	6

Persons living or working in health care facilities or residential care settings licensed or otherwise regulated by the department: (3 categories listed below)	§11-164.2-26	TB Document B	7
I. Initial Evaluation Procedure for Persons with No Documented Previous Positive Test for TB Infection and No Documented History of TB Disease.			

II. Initial Evaluation Procedure for Persons with a Documented Previous Positive Test for TB Infection or a Documented History of TB Disease.	§11-164.2-26	TB Document C	8
III. Follow-up Annual TB Evaluation Procedure	§11-164.2-26	TB Document D	9
Food handlers	§11-164.2-27	TB Document E	10

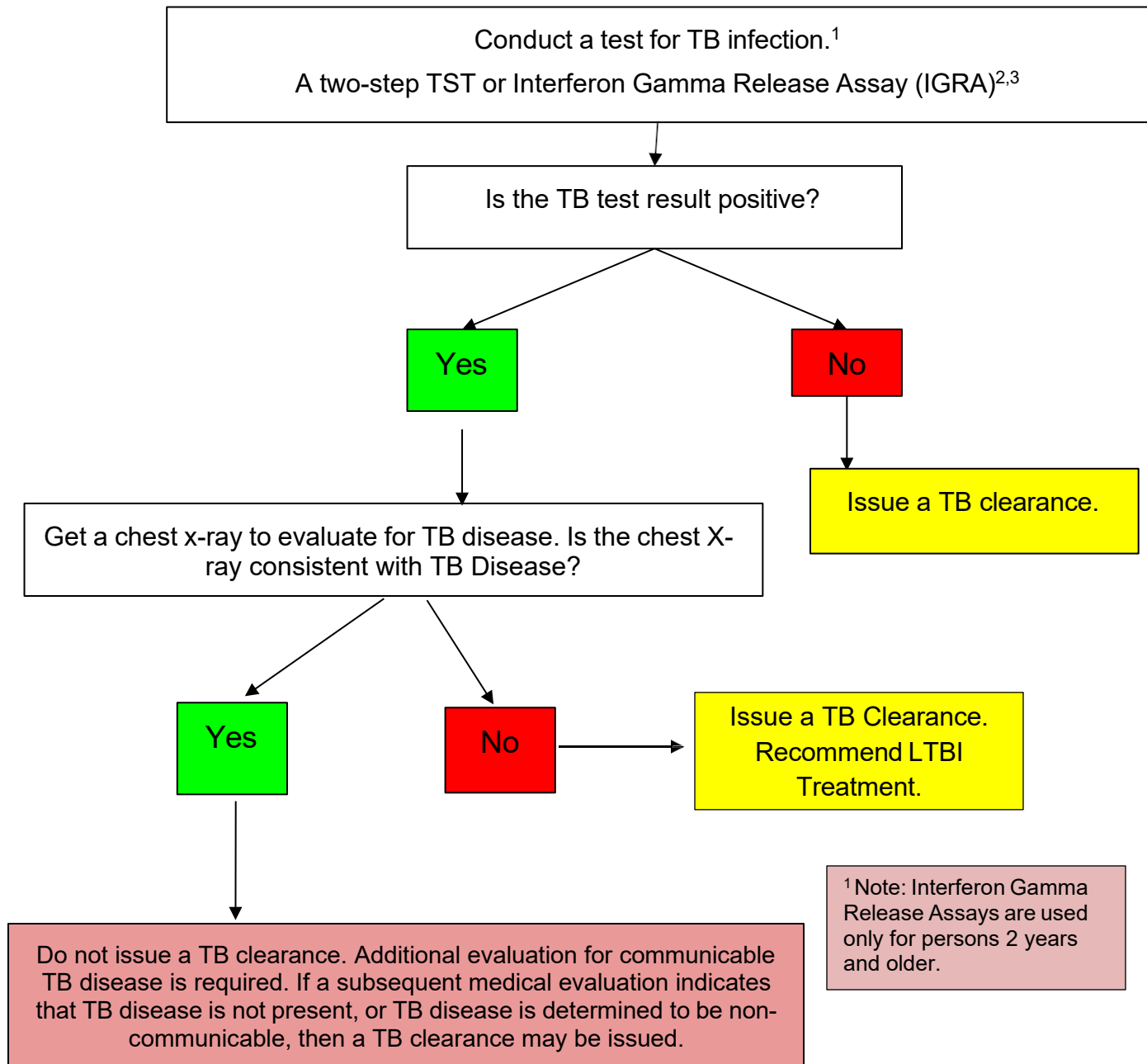
Procedure documents are provided in this manual to assist the community to implement Chapter 11-164.2, Hawaii Administrative Rules. These documents are also available on the Department of Health TB Control Branch website under [Forms](#). Questions regarding TB Clearance should be directed to the State of Hawaii Department of Health TB Control Branch Survey Section, (808) 832-5731, or your local Neighbor Island DOH TB Clinic (page 18).

TB Document A: TB Clearance Evaluation Procedures for First-time Entry to a Child Care Facility, Child Care Facility Personnel, First-time School Entry, School Personnel, Post - Secondary School Entry, and Post-Secondary School Personnel.



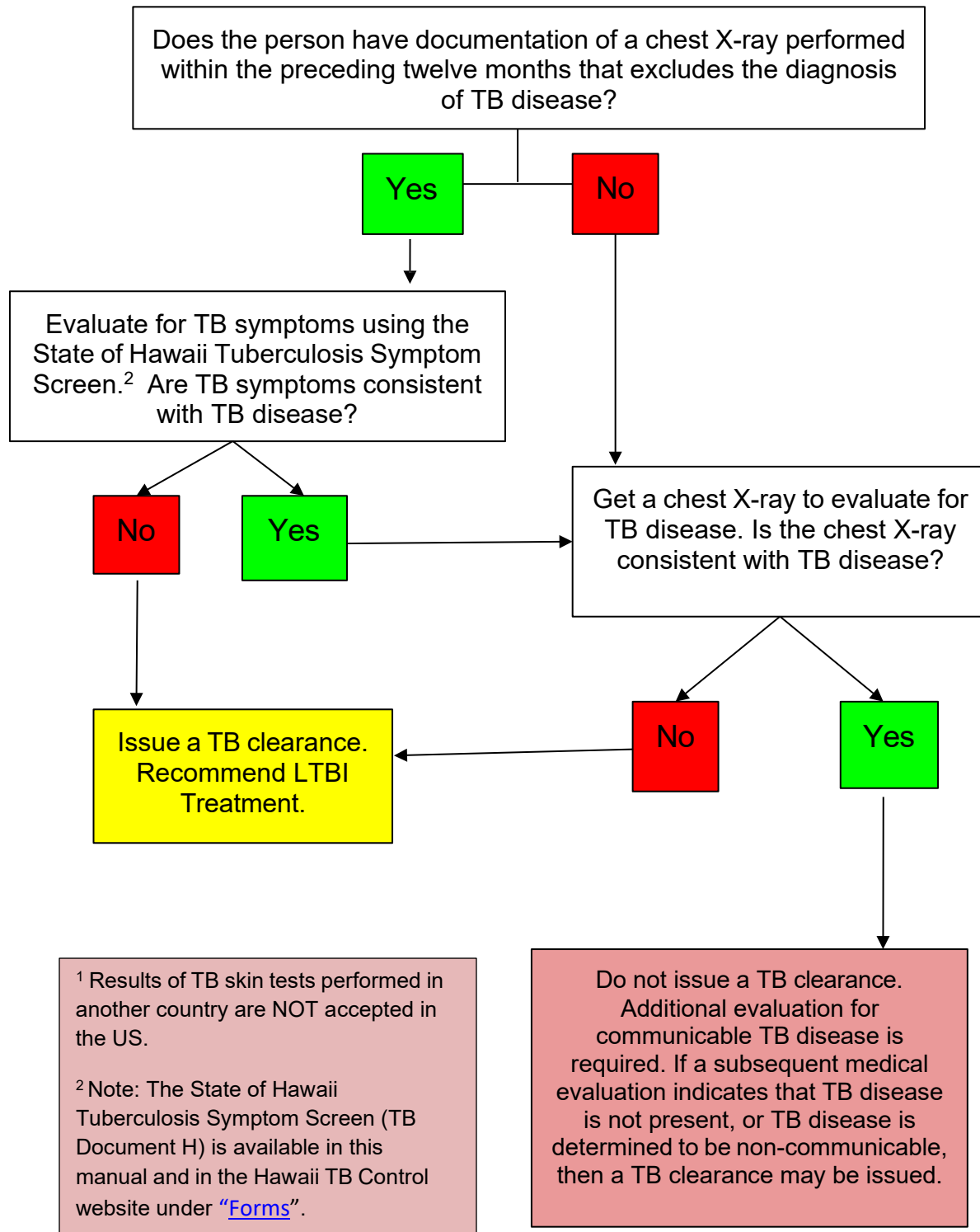
TB Document B: Clearance Evaluation Procedures for Persons Living or Working in Health Care Facilities or Residential Care Settings Licensed or Otherwise Regulated by the Department.

I. Initial Evaluation Procedure for Persons with **No Documented Previous Positive Test for TB Infection and No Documented History of TB Disease.**



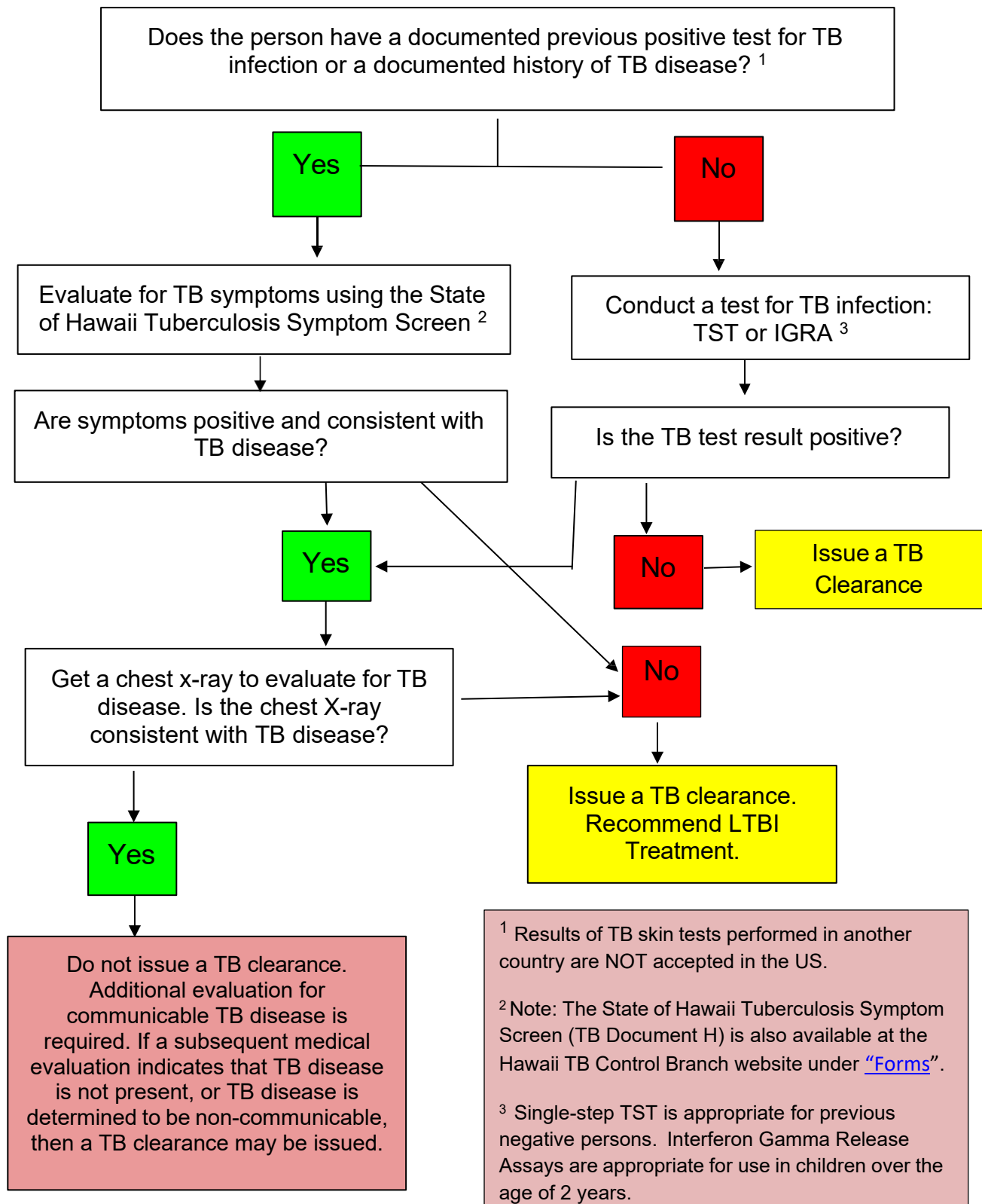
TB Document C: TB Clearance Evaluation Procedures for Persons Living or Working in Health Care Facilities or Residential Care Settings Licensed or Otherwise Regulated by the Department of Health.

II: Initial Evaluation Procedure for Persons with a Documented Previous Positive Test For TB Infection or a Documented History of TB Disease¹

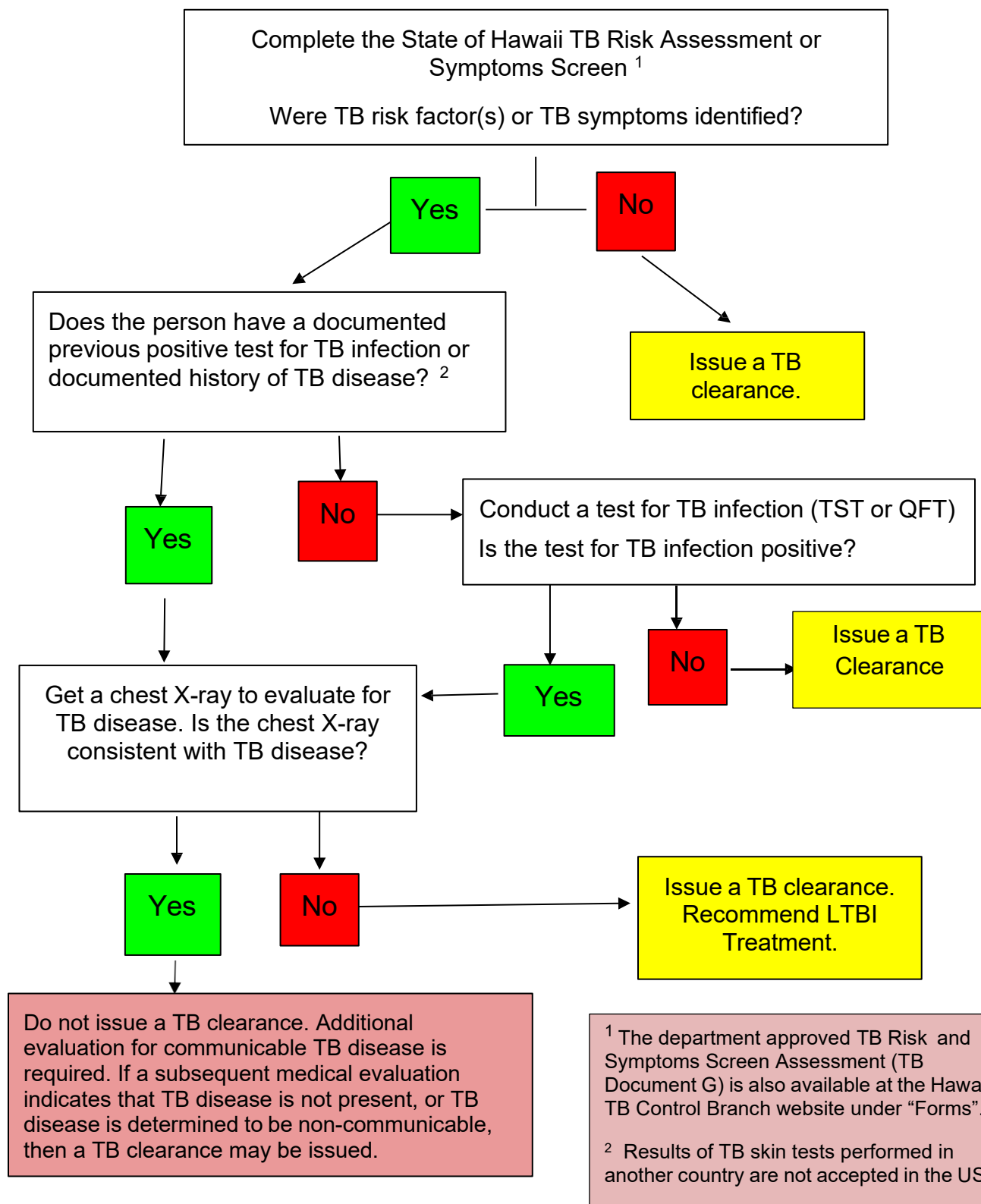


TB Document D: TB Clearance Evaluation Procedures for Persons Living or Working in Health Care Facilities or Residential Care Settings Licensed or Otherwise Regulated by the Department of Health.

III: Follow-up Annual TB Evaluation Procedure



TB Document E: TB Clearance Evaluation Procedures for Food Handlers



4.0 TB Clearance Resource Documents

In addition to the TB clearance procedures, there are several essential resource documents to assist clinicians who are screening individuals in Hawaii. Table 2 lists these resource documents.

Table 2. List of TB Clearance Resource Documents

Resource Document Name	Resource Document Name	Page
State of Hawaii TB Clearance Form	TB Document F	12
State of Hawaii TB Risk Assessment for Adults and Children	TB Document G	13
State of Hawaii TB Symptom Screen	TB Document H	14
State of Hawaii List of Approved Tests for TB Infection	TB Document I	15
State of Hawaii List of High Risk Countries	TB Document J	17
State of Hawaii Notifiable Disease Report for Tuberculosis (with Definitions and Instructions)	TB Document K	17
State of Hawaii Tuberculosis Case / Suspect Follow-Up Report	TB Document M	17

Resource documents are provided in this manual to assist to the community to implement Chapter 11-164.2, Hawaii Administrative Rules. These documents are also available on the Department of Health TB Control Branch website under “[Forms](#)”. Questions regarding TB Clearance should be directed to the Survey Section of the Hawaii Department of Health TB Control Branch Survey Section, (808) 832-5731, or your local Neighbor Island DOH TB Clinic (page 18).



TB Document F: State of Hawaii TB Clearance Form

Hawaii State Department of Health
Tuberculosis Control Program

Patient Name	DOB	TB Screening Date

I have evaluated the individual named above using the process set out in the DOH TB Clearance Manual dated 1/10/2024 (rev 08.20.24) and determined that the individual does not have TB disease as defined in section 11- 164.2-2, Hawaii Administrative Rules.

I. Screening for schools, child care facilities, or food handlers (*TB Document A or E*)

☐ Negative TB risk assessment
☐ Negative test for TB infection: TST: mm, date read: ; or QFT (date:)
☐ Positive test for TB infection: TST: mm, date read: ; or QFT (date:) and negative chest X-ray (date:)

II. Initial Screening for Health Care Facilities or Residential Care Settings (*TB Document B or C*)

☐ Negative Risk Assessment: Children 1-17 yrs old, who are household members in residential care settings
☐ Negative test for TB infection (2-step TST or QFT or single TST plus negative CXR): TST #1: mm, date read ; TST #2: mm, date read ; or QFT (date:) ; or TST: mm, date read plus negative chest X-ray (date:)
☐ New positive test for TB infection: TST: mm; date read or QFT (date:) negative CXR date:
☐ Previous positive test for TB infection, negative symptoms screen and negative CXR within previous 12 mos: Date of CXR:
☐ Previous positive test for TB infection, and negative CXR: Date of CXR:

III. Annual Screening for Health Care Facilities or Residential Care Settings (*TB Document D*)

☐ Negative risk assessment (children 1-17 yrs old, who are household members in residential care settings)
☐ Negative test for TB infection: TST: mm, date read ; or QFT (date:)
☐ New positive test for TB infection: TST: mm, date read: ; or QFT (date:) and negative chest X-ray (date:)
☐ Previous positive test for TB infection and negative symptoms screen

Signature or Unique Stamp of Practitioner: _____

Printed Name of Practitioner: _____

Healthcare Facility: _____

Address: _____

Phone Number: _____ Fax: _____

This TB clearance provides a reasonable assurance that the individual listed on this form was free from tuberculosis disease at the time of the exam. This form does not imply any guarantee or protection from future tuberculosis risk for the individual listed.



TB Document G: State of Hawaii TB Risk Assessment for Adults and Children

Hawaii State Department of Health
Tuberculosis Control Program

1. Check for TB symptoms

- If there are significant TB symptoms, then further testing (including a chest x-ray) is required for TB clearance.
- If significant symptoms are absent, proceed to TB Risk Factor questions.

☐ Yes ☐ No	Does this person have significant TB symptoms? Significant symptoms include <u>cough for 3 weeks or more</u> , PLUS least one of the following:					
	<table border="0"> <tr> <td>☐ Coughing up blood</td> <td>☐ Fever</td> <td>☐ Night sweats</td> </tr> <tr> <td>☐ Unexplained weight loss</td> <td>☐ Unusual weakness</td> <td>☐ Fatigue</td> </tr> </table>	☐ Coughing up blood	☐ Fever	☐ Night sweats	☐ Unexplained weight loss	☐ Unusual weakness
☐ Coughing up blood	☐ Fever	☐ Night sweats				
☐ Unexplained weight loss	☐ Unusual weakness	☐ Fatigue				

2. Check for TB Risk Factors

- If any “Yes” box below is checked, then TB testing is required for TB clearance
- If all boxes below are checked “No”, then TB clearance can be issued without testing

☐ Yes ☐ No	Was this person born in a country with a high TB case rate (refer to TB Document J)? (eg. Not born in the United States, Canada, Australia, New Zealand, Western Europe, Northern Europe, or Japan.)
☐ Yes ☐ No	Has this person traveled to (or lived in) a country with a high TB case rate for four weeks or longer?
☐ Yes ☐ No	At any time has this person been in contact with someone with <i>infectious TB disease</i>? (Do not check “Yes” if exposed only to someone with latent TB)
☐ Yes ☐ No	Does this person have a health problem that affects the immune system, or is medical treatment planned that may affect the immune system? <i>Includes HIV/AIDS, organ transplant recipient, treatment with TNF-alpha antagonist (e.g. Humira, Enbrel, Remicade), or steroid medication for a month or longer.</i>
☐ Yes ☐ No	For children under age 16: Someone born in a country with a high TB case rate (eg. Not born in the United States, Canada, Australia, New Zealand, Western Europe, Northern Europe, or Japan) is living or has lived in the same household.

Provider Name with Licensure/Degree:

Person's Name and DOB:

Assessment Date:

Name and Relationship of Person Providing Information (if not the above-named person):



TB Document H: State of Hawaii TB Symptom Screen

Hawaii State Department of Health
Tuberculosis Control Program

TB Symptom		Onset and Duration of Symptoms
1. Cough for ≥ 3 weeks duration	☐ No ☐ Yes	
2. Coughing up blood	☐ No ☐ Yes	
3. Fever	☐ No ☐ Yes	
4. Night sweats	☐ No ☐ Yes	
5. Unexplained weight loss	☐ No ☐ Yes	Amount:
6. Unusual weakness or fatigue	☐ No ☐ Yes	Duration:

Interpreting the TB Symptom Screen

If the client responds "Yes" to having a cough for ≥ 3 weeks duration AND "Yes" to at least one of the other symptoms (#2-#6), perform a test for TB infection and refer the client for a chest X-ray to rule out TB disease.



TB Document I: State of Hawaii List of Approved Tests for TB Infection

Hawaii State Department of Health
Tuberculosis Control Program

DOH-Approved Tests for TB Infection

The following is a DOH-approved list of tests for TB infection for the purposes of TB screening as required by the state. These tests are approved by the U.S. Food and Drug Administration (FDA) for the diagnosis of TB infection. Additionally, CDC has provided guidance on test application and interpretation of results.

1. Tuberculin Skin Test (TST)*

The TST is used to determine if a person is infected with *Mycobacterium tuberculosis*. If a person is infected, a delayed-type hypersensitivity reaction is detectable 2 - 8 weeks after infection (2-12 weeks for children ≤ 5 years old). The skin test is administered intradermally using the Mantoux technique by injecting 0.1ml of 5 TU purified protein derivative (PPD) solution. The reading and interpretation of TST reactions should be conducted within 48 to 72 hours of administration.

- Training is essential for health care providers to gain proficiency in the administration and interpretation of the TST.
- The TST should not be performed on a person who has written documentation of either a previous positive TST result or treatment for TB disease.
- Patients or family members should never measure TST results; this should only be done by a trained health care professional.
- Interpretation of the TST result is the same for person who have had Bacille de Calmette et Guérin (BCG) vaccination and those who have not received BCG, because a majority of BCG cross-reactivity wanes with time.
- **Results of TST performed in another country are NOT accepted in the US.**
- A positive tuberculin skin test is determined as follows.

A TST reaction of ≥ 5 mm of induration is considered positive in the following individuals:

- **HIV-infected persons**
- **Recent contacts of a person with infectious TB disease**
- **Persons with fibrotic changes on chest radiograph consistent with prior TB**
- **Patients with organ transplant(s) and other immunosuppressed patients (including patients taking the equivalent of ≥ 15 mg/day of prednisone for 1 month or more, or those taking TNF- α antagonists, e.g. Humira, Enbrel, Remicade)**

A TST reaction of ≥ 10 mm of induration is considered positive in the following individuals:

- Arrivals to the United States from countries with high incidence for TB ***
- Residents, volunteers, or employees of high-risk congregate settings (e.g. correctional facilities, long-term care facilities, hospitals and other health care facilities, residential facilities for patients HIV/AIDS, and homeless shelters)
- Persons with clinical conditions that increase the risk for progression to TB disease, eg. diabetes, chronic/end stage renal disease, smoking, cancer.
- Injection drug users
- Children under 16 years old living in a household who are exposed to adults from a country with an elevated TB rate

A TST reaction of ≥ 15 mm of induration is considered positive in the following individuals:

- Persons with no known risk factors for TB

2. Interferon–Gamma Release Assays (IGRAs)**

IGRAs are used to determine if a person is infected with *Mycobacterium tuberculosis* by measuring the immune response to TB proteins in whole blood. These tests were initially FDA approved for children aged 5 years and older. **However, it has now been acceptable practice to administer the IGRA test to children aged 2 years and older.**

At present, there are two U.S. Food and Drug Administration (FDA)-approved IGRA tests commercially available in the United States:

- QuantiFERON[®]-TB Gold-in-Tube test (QFT-GIT)
- T-SPOT[®] TB test
- **Results of IGRA tests performed in another country ARE accepted in in the US.**

* CDC Tests for TB Infection accessed on 4/19/2023 at <http://www.cdc.gov/tb/publications/LTBI/diagnosis.htm>.

** Sources: accessed on 11/21/23

American Academy of Pediatrics. Red Book: 2021-2024 report of the committee on infectious diseases. 32nd ed. American Academy of Pediatrics. 2021. Available at: Guidelines for the Prevention and Treatment of Opportunistic Infections in Children with and Exposed to HIV V-30. Available at: <https://publications.aap.org/redbook/book/347/Red-Book-2021-2024-Report-of-theCommittee-on>

Rose W, Kitai I, Kakkar F, Read SE, Behr MA, Bitnun A. Quantiferon Gold-in-tube assay for TB screening in HIV infected children: influence of quantitative values. BMC Infect Dis. 2014;14:516. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25248406>.

Mandalakas AM, van Wyk S, Kirchner HL, et al. Detecting tuberculosis infection in HIVinfected children: a study of diagnostic accuracy, confounding and interaction. Pediatr Infect Dis J. 2013;32(3):e111-118. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/23190784>.

Cruz AT, Marape M, Graviss EA, Starke JR. Performance of the QuantiFERON-TB gold interferon gamma release assay among HIV-infected children in Botswana. J Int Assoc Provid AIDS Care. 2015;14(1):4-7. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25149414>.

Mazurek GH, Jereb J, Vernon A, et al. Updated guidelines for using Interferon Gamma Release Assays to detect Mycobacterium tuberculosis infection-United States, 2010. MMWR Recomm Rep. 2010;59(RR-5):1-25. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/20577159>.

*** See Document J: Countries with High Incidence for TB



TB Document J: Countries with High Prevalence for TB

Hawaii State Department of Health
Tuberculosis Control Program

We deleted the list of countries with “high incidence” for TB to eliminate the need to constantly update this list. Instead, we are referring you to the WHO website for the most recent reported case rates for individual countries:

Please refer to https://worldhealthorg.shinyapps.io/tb_profiles/

We define “high incidence” as having an annual TB case rate of over 20 per 100,000.
Being born in or having travelled to a high incidence country constitutes a risk factor.



TB Document K: Notifiable Disease Report for Tuberculosis

Hawaii State Department of Health
Tuberculosis Control Program

Please refer to https://health.hawaii.gov/tb/files/2020/09/Hawaii-TB_NDR.pdf



TB Document L: Notifiable Disease Report for Tuberculosis Definitions and Instructions

Hawaii State Department of Health
Tuberculosis Control Program

Please refer to https://health.hawaii.gov/tb/files/2020/09/9.22.20_Notifiable-Disease-Report-NDR-Form_Definition-Instructions-rev-1-25-16.pdf



TB Document M: Tuberculosis Case / Suspect Follow up

Hawaii State Department of Health
Tuberculosis Control Program

Please refer to <https://healthpias.hawaii.gov/tb/files/2013/09/Tuberculosis-Case-Suspect-Follow-Up-Report-Rev.-5-2010.pdf>

5.0 Hawaii State Department of Health Tuberculosis Clinic Locations

Please call one of the following locations to refer a patient for TB care:

Oahu

TB Clinic at Lanakila Health Center
1700 Lanakila Avenue, Ground Floor
Honolulu, HI 96817
Phone: (808) 832-3539

Maui

Maui Public Health Nursing
54 High Street
Wailuku, HI 96793
Phone: (808) 984-2127

Molokai

Molokai Public Health Nursing
Kaunakakai, HI 96748
Ph: 553-7880

Lanai

Lanai Public Health Nursing
Lanai City, HI 96763
Ph: 565-7114

Kauai

Kauai Public Health Nursing
Kauai District Health Office
3040 Umi Street
Lihue, HI 96766
Phone: (808) 241-3387

East Hawaii (Big Island) Hilo

Public Health Nursing Hilo
State Office Building
75 Aupuni Street, Room 106
Hilo, HI 96720
Phone: (808) 974-6025

West Hawaii (Big Island) Kona

Public Health Nursing Kona
Health Center
79-1015 Haukapila Road
Kealahou, HI 96750
Phone: (808) 322-1500