Japan Pre-Entry TB Screening

Technical Instructions

December 2024

Infectious Disease Control Division,
Infectious Disease Control Department,
Health and Environmental Hygiene Bureau,
Ministry of Health, Labour and Welfare, Japan

List of Abbreviations

BCG	Bacille Calmette-Guérin
CJPQA	Centre for Japan-Pre-entry TB Screening Quality Assessment
CXR	chest X-ray
DST	drug susceptibility testing
J-IMS	JPETS Information Management System
IGRA	interferon-gamma release assays
INH	isoniazid
JPETS	Japan Pre-entry TB Screening program
LTBI	latent tuberculosis infection
NAATs	Nucleic Acid Amplification Tests
QFT	QuantiFERON
RIF	rifampicin
TB	tuberculosis
TST	tuberculin skin test
WHO	World Health Organization

Table of Contents

Documents marked with an asterisk (*) must be produced directly from the JPETS Information Management System (J-IMS).

1. Introduction to the pre-entry TB screening program for Applicants to the Certificate of Eligibility/visa for mid- to long-term stay

- According to the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases of Japan, active tuberculosis is grouped under Category II Infectious Diseases. Under the Immigration Control and Refugee Recognition Act, aliens diagnosed with infectious diseases under Category II shall be denied permission to land in Japan.

- This document is intended to provide technical guidance to those who are authorised by the Government of Japan to conduct tuberculosis (TB) screening.

- The Centre for Japan Pre-entry TB Screening Quality Assessment (CJPQA), located within the Research Institute of Tuberculosis, Japan, has been designated by the Government of Japan to manage Japan's pre-entry TB screening program (JPETS). For any queries regarding the screening program, send an email to the CJPQA (center_jpqa@jata.or.jp) carbon-copying to the Ministry of Health, Labour, and Welfare, Japan (tb_screening@mhlw.go.jp). Do not send X-ray film or the Applicant's personally identifiable information within the email.

- Throughout this document, the term "screening" denotes the process of screening individuals who apply for the Certificate of Eligibility or visa for mid- to long-term stay in Japan (the "Applicant") for active TB. The purpose of TB screening is to detect the suspected presence of active TB, as well as to contribute to Applicants' health and TB control in their home countries of Applicants by early diagnosis and appropriate treatment of TB.

- TB is a disease caused by an infection with a member of the *Mycobacterium tuberculosis* complex. It may exist as an active disease, with clinical signs or symptoms, or as a latent infection (i.e., latent TB infection, LTBI) where the infection has not progressed to active disease. This screening program is intended to identify bacteriologically positive pulmonary, tracheobronchial, pharyngeal, and laryngeal TB cases. However, Applicants with any other form of active TB that requires TB treatment, if nonetheless detected in the process of the screening, will be required to complete TB treatment before entering Japan. This screening program is not intended to identify LTBI cases.

- **For more information on the screening requirements and legal framework of JPETS,** please refer to the guidelines for JPETS on the Ministry of Health, Labour and Welfare website. (https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/kenkou/kekkaku-kansenshou03/index_00006.html)

2. Role of an appointed physician of the Panel Clinic

- The Applicants will be screened by physicians (as “Panel Physicians”) who have been registered by medical facilities (as “Panel Clinics”) that have been designated by the Government of Japan. The Panel Clinics will provide a list of registered Panel Physicians to the Government of Japan and inform immediately if any change(s) are made to the list. Details of the administrative arrangements for Panel Physicians and Panel Clinics are provided in **Annex A**.

- The Panel Physician will screen the Applicants as per the Technical Instructions. On occasions where the Panel Physician determines that the Applicant does not have active TB, the Panel Physician shall issue a TB Clearance Certificate (“the Certificate”, see **Annex B**). Only the Certificate issued via the JPETS information management system, J-IMS, will be acceptable (see below for the description of J-IMS).

- The Panel Physician shall issue the Certificate in both paper form (one copy) and electronic form upon completion of the medical examination to apply for a Certificate of Eligibility/visa to stay for Japan. If the applicant requests additional paper copies of the Certificate, the fee for issuance shall be determined at the discretion of each medical institution.

- The Panel Physician will be responsible for and oversee the entire screening process of each Applicant, confirm the Applicant's identification, and make a professional judgement as to whether or not the Applicant should be issued the Certificate.

- On all occasions where active TB is detected during the screening process, the Panel Physician must ensure that the Applicant is given clear and unambiguous advice about the need to start TB treatment immediately at the Panel Clinic or refer the Applicant to a TB medical facility which is capable of providing TB treatment according to the requirements of the WHO guidelines and national TB guidelines, using quality-assured anti-TB drugs (“TB Medical Facility”).

- If drug-resistant cultures are identified on the laboratory test of the Applicant (see Section 7), the Panel Physician will share this information with the TB Medical Facility, where the Applicant shall receive TB treatment without delay.

- On occasions where the public health authority must be notified about active TB cases as per local law, the Panel Physician must also share the diagnosis of active TB with the local, regional, or national authorities in the Applicant’s home country and record this fact at the Panel Clinic that

the Panel Physician belongs to.

- When the diagnosis of active TB is confirmed after referral to a TB Medical Facility, the Panel Physician will request that the physician-in-charge at the TB Medical Facility share this fact with the local health authority.

- Panel Clinics are required to record and manage all relevant information, including the Applicants' biodata, test results, and treatment outcomes, using the J-IMS. The Panel Physician holds the ultimate responsibility for the accuracy of the information and the data entered into J-IMS. See the Manual for JPETS Information Management System for details.

- Panel Clinics may outsource the laboratory examinations for active TB to Panel Laboratories that conduct at least smear examinations and culture tests for *Mycobacterium tuberculosis* if the Panel Clinics do not conduct the laboratory examinations for TB.

- Panel Clinics are responsible for outsourcing laboratory examinations for TB to Panel Laboratories capable of conducting tests for *Mycobacterium tuberculosis* in accordance with the instructions described in Section 7.

3. The screening process for TB in Applicants

1) General arrangements

- The Panel Clinic must be able to schedule an Applicant's appointment within 5 working days after receiving the Applicant's request for the medical checkup.

- The Panel Physician shall brief all Applicants on the purpose, nature, and extent of the TB screening process. Information leaflets may need to be used as necessary.

- The Applicant must complete an Informed Consent Form (see Section 4 and **Annex C**).

- Where Applicants are family members intending to travel together, the Panel Physician shall arrange for all family members to be screened together as much as possible.

- A legal guardian must accompany a minor. The definition of "a minor" shall be per the legislation of the Applicants' home country in which judicial decisions are made in case of a dispute regarding the screening and obtaining consent.

- The screening is based on chest radiography ("CXR"). Other tests such as a Tuberculin Skin Test (Mantoux method) or Interferon Gamma Release Assays (IGRA) are <u>not</u> acceptable alternatives to CXR for Applicants aged 5 years and above, even when the Applicant is willing to pay for such tests.

- Prior receipt of Bacille Calmette-Guérin (BCG) vaccination does not change the screening process, requirements, or required actions.

- If neither active nor old TB is suggested by the interview, physical examination, and CXR results, it will be judged that the Applicant does not have active TB disease and the Certificate shall be issued. The Panel Physician must complete the "Pre-Entry Tuberculosis Screening Results Report" (see **Annex D**) for all Applicants and attach it to the Certificate.

- All Applicants suspected of active or old TB, according to the results of any one of the interviews, physical examinations, and CXR shall undergo *Mycobacterium tuberculosis* tests using three sputum specimens collected each day for 3 consecutive working days (see Section 7 and **Annex E**).

- If any of the sputum test results positive for *Mycobacterium tuberculosis* complex from an Applicant, the Applicant shall be diagnosed as having active TB and the Certificate shall not be

issued.

- The Panel Physician is under no obligation to treat the Applicant; however, if the Panel Physician agrees to provide TB treatment, such treatment shall be per the WHO treatment guidelines as well as any national TB protocol, using only quality-assured drugs as recommended by the WHO.

- The Panel Clinic is not responsible for the quality of the TB treatment provided outside the Panel Clinic itself. However, irrespective of where the Applicant decides to receive TB treatment, the Panel Physician remains responsible for monitoring the TB treatment and collecting, to the best of his/her effort, relevant information regarding the treatment, including treatment start date, treatment regimen, laboratory test results, and treatment outcome of the Applicant.

- Treatment completion of Applicants with pulmonary TB must be verified with at least two sputum culture-negative results within 30 days after the end of the treatment. The two sputum specimens must be submitted to a laboratory designated by the Panel Clinic for laboratory testing as per the JPETS ("Panel Laboratory").

- Treatment completion of Applicants with extra-pulmonary TB will be confirmed by the physician-in-charge who provides treatment and care to the Applicant diagnosed with extra-pulmonary TB.

- Regarding the process to be followed when active TB is suspected despite negative sputum test results, see Section 8.

2) Screening categories and processes

There are different sets of screening items for the four categories of Applicants: general Applicants aged 15 years and above, children aged 5 to 14 years, children aged under 5 years, and pregnant women.

General screening items

While the general screening items apply to all categories, some considerations will be made for pregnant women, children aged 5 to 14 years, and children under 5 years on the day of screening. The general screening items are as follows:

- Interview, which must collect information on the following:
  - Symptom(s) in the last 3 months: cough, sputum expectoration, haemoptysis, night sweats, weight loss, lymphadenopathy, and fever (including a mild fever of 37.5 degrees Celsius or less).

- History of previous TB:
  * Ask if the Applicant has a history of active TB.
  * When the Applicant re-applies for the TB screening after diagnosis of active TB and treatment completion at the first round of screening (regardless of where the Applicant received his/her treatment), the Panel Physician must collect the "TB Treatment Certificate" (see **Annex F**). Then, the Panel Physician must complete the "TB Treatment Report" (see **Annex G**) and give it to the Applicant with the TB Clearance Certificate at the end of JPETS. "TB Treatment Report" (see **Annex G**) is intended to provide information regarding the Applicant's TB treatment that was provided within the JPETS program, to healthcare providers in Japan, in the event that the Applicant seeks medical attention after arriving in Japan.

- History of close contact with a case of active pulmonary TB within the past 2 years:
  * Ask if anyone in the Applicant's household has been diagnosed with active pulmonary TB within the past 2 years.
  * Ask if the Applicant had a history of close contact with a case of active pulmonary TB within the past 2 years (i.e., shared the same enclosed airspace, household, or other enclosed environments frequently or over a prolonged period of days or weeks).

- Immunodeficiency:
  * Ask if the Applicant has a history (within the past 6 months) of immunocompromised status or is currently immunocompromised (e.g., HIV infection, chronic renal failure, malignant tumour, etc.).
  * Ask if the Applicant has a history (within the past 6 months) of using or is currently using immunosuppressant agents (e.g., corticosteroids, anti-cancer drugs, anti-rheumatic drugs, etc.).

- Physical examinations including the following items:
  - Chest auscultation (breath sound)
  - Examinations of the neck (inspection, palpation)
  - Other examinations which the Panel Physician judges necessary.

- CXR (except for children aged under 5 years)

- Sputum examination (for Applicants with suspected active TB based on interview, physical examination, and/or CXR)

Considerations for pregnant women

- During pregnancy, there is a small risk of radiation exposure to the unborn baby, particularly during the first trimester. It is not recommended to perform CXRs during the first trimester. Therefore, pregnant women have two options:
  (1) Postpone the CXR (and application process) until after delivery.
  (2) Proceed with the CXR with double-layer lead shielding.
  Regardless of the options, the pregnant Applicant must be counselled and informed consent must be obtained and appropriately retained in the Applicant's record.

- As a special measure, if a pregnant woman has undergone CXR within the last 3 months at the same Panel Clinic in which she is currently receiving TB screening, the previous CXR may be used for clearance purposes provided that she meets both of the following conditions: (1) she has no signs or symptoms of TB, and (2) she has had no close contact with an active pulmonary TB patient within the past 2 years.

Considerations for children aged under 5 years

- The screening items for those under 5 years include symptoms, history of previous TB, history of household contact with a case of active pulmonary TB, and immunodeficiency or current use of immunosuppressant agents. <u>If any of the above items is present</u>, the children must undergo CXR, as with general Applicants. Those with an unknown history of previous TB and an unknown history of household contact with a case of active pulmonary TB must also undergo a CXR.

- However, children aged under 5 years <u>who do not have signs and symptoms suggestive of active TB, AND history of previous TB, AND history of household contact with an active pulmonary TB patient, AND are neither immunodeficient nor on immunosuppressant agents</u>, must undergo a Tuberculin Skin Test (Mantoux method) or IGRA. The TST results should be interpreted according to the guidelines of the US CDC or the national TB control guidelines. The IGRA results should be judged according to the criteria provided by the manufacturer.

- The IGRA should be either of the WHO-approved methods such as "Qiagen QuantiFERON-TB Gold Plus", "WANTAI TB-IGRA" or "Oxford Immunotec T-SPOT.TB".

- **If the TST/IGRA results are negative,** the Certificate will be issued.

- **If the TST/IGRA results are indeterminate/invalid,** the final result must not be considered negative. In the case of indeterminate or invalid results from the IGRA, the Panel Physician should preferably repeat the examination using a different test from the one used in the initial test (i.e., if QuantiFERON [QFT] was used initially, T-SPOT should be used for the repeat test). If a different

test is not available, the Panel Physician may repeat the examination using the same test. No additional costs associated with re-examination will be charged to the applicant.

- **If the result of the second test is again indeterminate/invalid,** a CXR must be performed. If the CXR findings do not suggest active TB, the Applicant should be considered clear of TB disease, and as the infection status is unknown, referral for further assessment of prophylaxis treatment for LTBI is not required, and the Certificate can be issued. If the CXR indicates abnormal findings, the children will undergo a sputum examination, as is the case with general Applicants (see Section 7).

- **In case of borderline results from T-SPOT,** the Panel Physician should repeat the examination at no additional cost, preferably using a different test, i.e., QFT, if possible. If a different test (or QFT) is not available, the Panel Physician may repeat the examination at no additional cost using the same test. If the result of the second test using T-SPOT is borderline again, the result is interpreted as negative if the number of spots is five and as positive if the number of spots is six or seven. If the result of the second test is positive, CXR must be conducted. If it is negative, the Certificate can be issued.

- **If the TST/IGRA results are positive,** the children must undergo CXR. If the CXR does not indicate abnormal findings, the Certificate can be issued. However, when the Panel Physician judges that the Applicant needs LTBI treatment per the WHO treatment guidelines as well as the national TB guidelines, i.e., if the Applicant has any of the risk factors to develop active TB such as household contact history with a case of active pulmonary TB for the past 2 years or immunocompromised condition for the past 6 months, he/she must provide adequate information about LTBI to the children and the guardian and refer the children as far as possible to a TB Medical Facility that is capable of diagnosing LTBI and providing LTBI treatment for further assessment regarding the possible options for prophylactic treatment (see Section 8). If the CXR indicates abnormal findings, the children will undergo a sputum examination, as with general Applicants (see Section 7).

Considerations for children aged from 5 to 14 years

- For children aged between 5 and 14 years, who have any chronic disease, a history of previous thoracic surgery or cyanosis, or respiratory insufficiency that limits activity, a sputum examination can be performed, regardless of the CXR findings, at the discretion of the Panel Physician.

3) Sputum examination

- A sputum examination consists of a sputum smear microscopic examination and a culture examination. It is also recommended that WHO-recommended nucleic acid amplification tests

(NAATs) such as Xpert® MTB/RIF or Xpert® MTB/RIF Ultra or TB-LAMP are added once, if available (see Section 7).

- Where the CXR is suggestive of either active or old TB, as indicated in Section 6, a sputum examination must be performed. Additionally, a sputum examination is required for individuals with signs or symptoms suggestive of active TB, regardless of CXR findings.

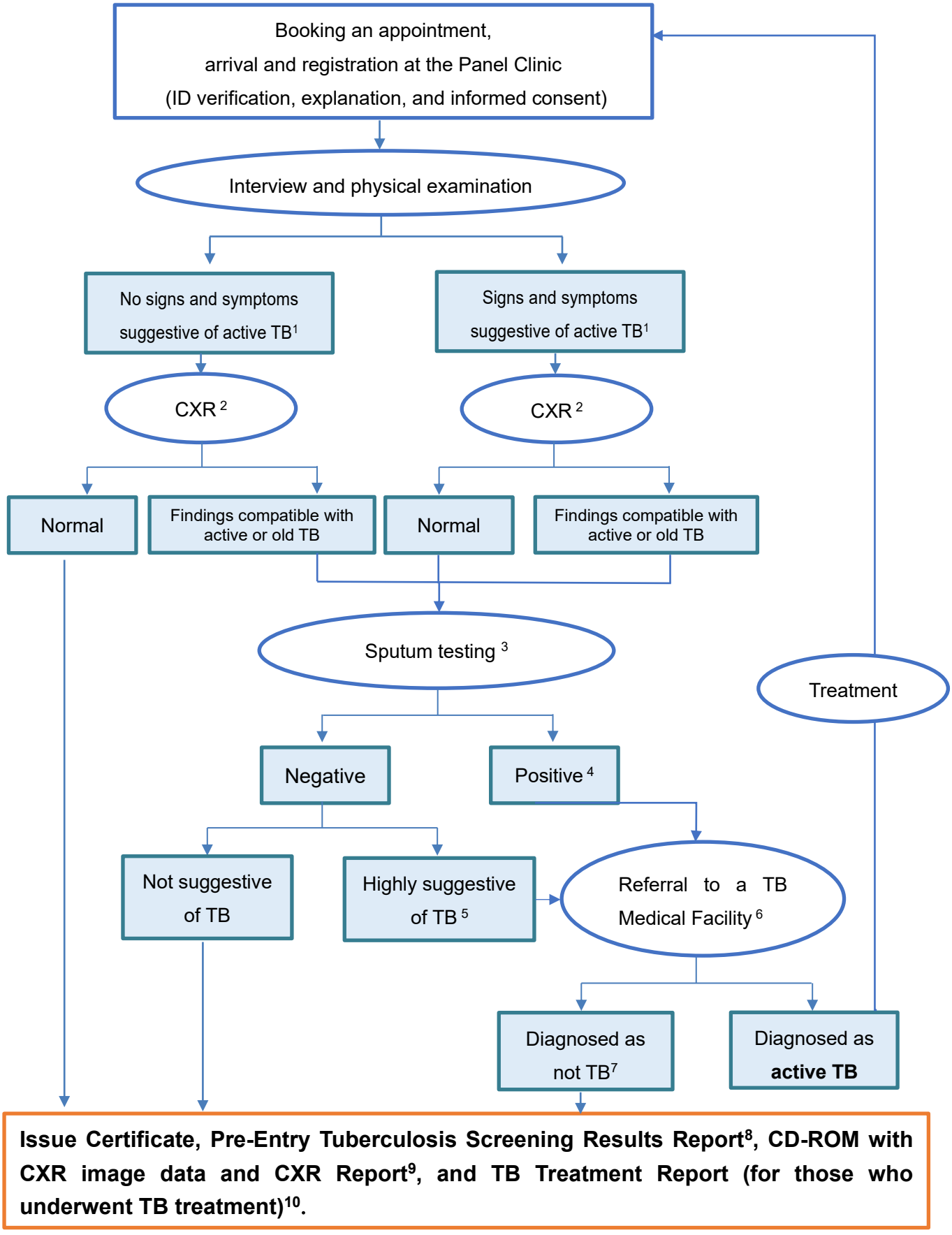
- The Applicant is required to submit three sputum specimens collected over 3 consecutive working days to the Panel Clinic or the Panel Laboratory.

- See Section 7 in case of difficulty in collecting sputum specimens.

- The interpretation guide of the sputum test positive results is as follows:
  - When any of the WHO-recommended NAATs is applied to one of the sputum specimens:
    - Smear-positive result(s) with NAATs negative result is suggestive of non-tuberculosis mycobacterium (NTM) infection or contamination; hence the Panel Physician may wait for the culture test result(s).
    - Smear-positive or negative results with NAATs positive result indicates definite bacteriologically-positive active TB. Hence the Panel Clinic will start anti-TB treatment for the Applicant or will refer the Applicant to a TB Medical Facility for anti-TB treatment while waiting for the culture test results.
  - When any of the WHO-recommended NAATs is NOT applied, but the smear-positive result(s) is(are) obtained:
    - The Panel Physician should consider CXR findings, the NTM infection history, and other relevant clinical findings. The Panel Physician can make or suggest a diagnosis of active TB and refer the Applicant to a TB Medical Facility for anti-TB treatment depending upon only sputum-smear positive result(s).
    - If the culture test result(s) is(are) positive and identified as *M. tuberculosis*, this constitutes a definite diagnosis of bacteriologically-positive active TB. The TB Medical Facility should complete the anti-TB treatment.
    - If the culture test result(s) is(are) positive and identified not as *M. tuberculosis* but as an NTM, the TB Medical Facility may terminate the anti-TB treatment.
    - Even if the culture test result(s) is(are) negative or unknown, the TB Medical Facility may continue the anti-TB treatment until the end of the treatment course because active TB is not clinically excluded.

- Overview of the screening process flow is shown in Figures 1 and 2.

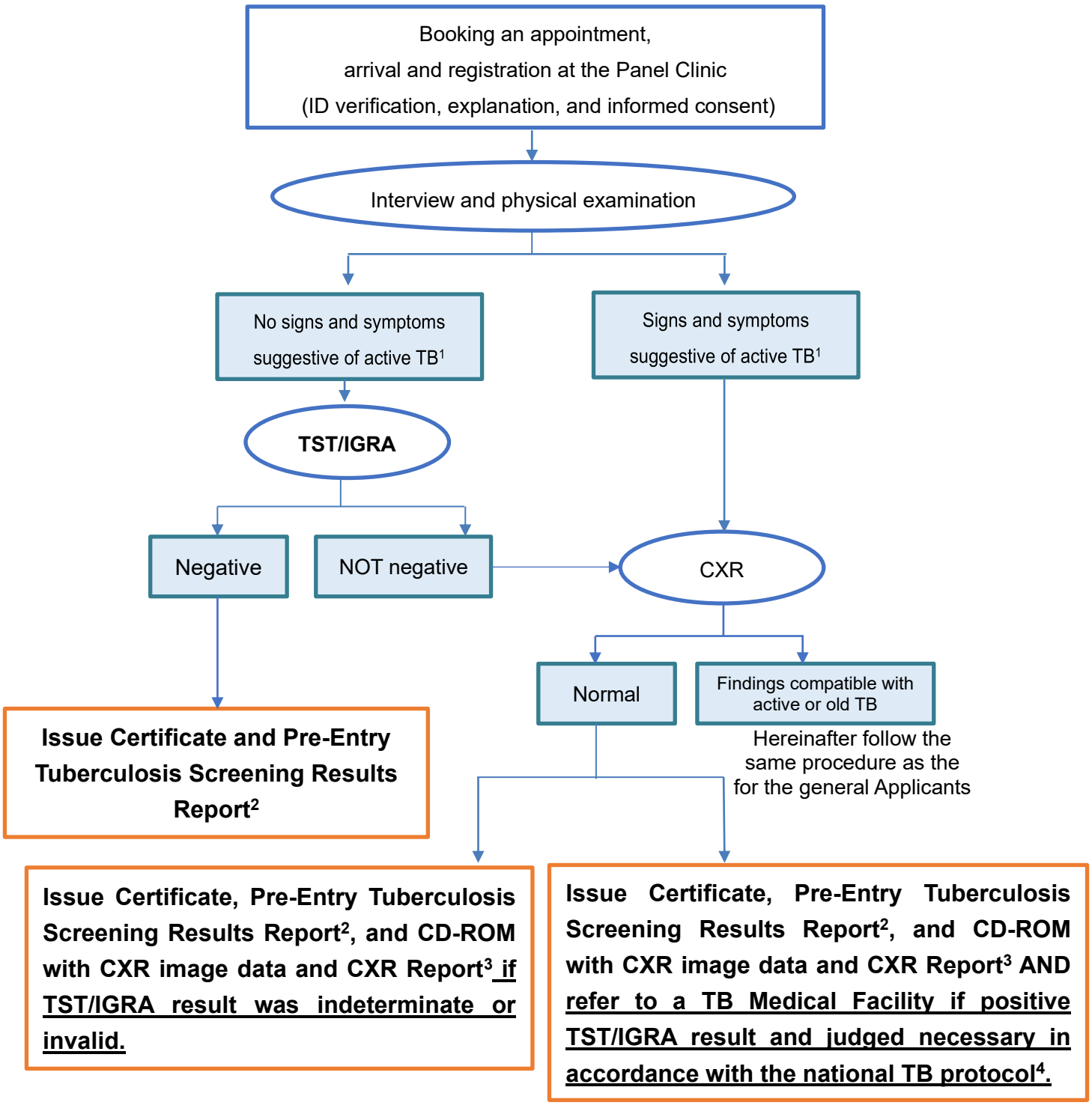
Figure 1 JPETS algorithm for general Applicants



1. Signs and symptoms include the following: 1) symptoms of active TB, 2) history of previous TB, 3) history of household contact with a patient with active pulmonary TB in the past 2 years, and 4) immunodeficiency or current use of immunosuppressant agents.
2. For pregnant women, see “Consideration for pregnant women” under Section 3.
3. It is also recommended that WHO-recommended NAATs such as Xpert® MTB/RIF or Xpert® MTB/RIF Ultra or TB-LAMP is added once, if available.
4. Positive results in either smear, culture or NAATs. The sputum-smear positive result(s) with NAATs negative result may indicate a non-tuberculosis mycobacterium (NTM) infection or contamination. Hence, the Panel Physician may wait for the culture test results before making an active TB diagnosis or referring the Applicant to a TB Medical Facility for diagnosis and treatment.
5. Interview, physical examination, or CXR results are highly suggestive of active TB.
6. TB Medical Facility for diagnosis and treatment can either be a Panel Clinic or a medical facility, as indicated in Section 2. The Panel Physician should consider CXR findings, the non-tuberculosis mycobacterium (NTM) infection history, and other relevant clinical findings. The Panel Physician can make or suggest an active TB diagnosis and refer the Applicant to a TB Medical Facility depending upon only sputum-smear positive result(s) among sputum tests.
7. The TB Medical Facility will refer the Applicant to the Panel Clinic if he/she determines the Applicant is NOT diagnosed with active TB. The Panel Clinic will re-assess the diagnosis considering the judgement made by the TB Medical Facility. However, NAATs or culture test positive result(s) should be a definite diagnosis of active TB requiring prompt and uninterrupted anti-TB treatment.
8. See Section 3 and Annex D.
9. See Section 6 and Annex J.
10. See Section 8 and Annex G.

TB: tuberculosis, CXR: chest X-ray, NAATs: Nucleic Acid Amplification Tests.

Figure 2 JPETS algorithm for children aged under 5 years



1. The Applicant must have negative results for ALL of the following items to proceed to TST/IGRA: 1) symptoms of active TB, 2) history of previous TB, 3) history of household contact with a patient with active pulmonary TB in the past 2 years, and 4) immunodeficiency or current use of immunosuppressant agents.
2. See Section 8 and Annex D.
3. See Section 6 and Annex J.
4. The Panel Physician should re-confirm if the Applicant has any of the risk factors to develop active TB such as household contact history with a patient with active pulmonary TB in the past 2 years or immunocompromised condition for the past 6 months.

TB: tuberculosis, TST: tuberculin skin testing, IGRA: interferon-gamma release assay, CXR: chest X-ray.

4. Consent for screening

- The Panel Physician may designate a person who will explain the Informed Consent to the Applicants, but it is the responsibility of the Panel Physician to ensure that Applicants are given sufficient information about the screening in a language that they understand (or steps are taken to ensure they understand), opportunity to ask questions, and time to reflect on answers; the Informed Consent Form must be completed before the screening process starts (see **Annex C**). Information provided to Applicants should cover the purpose of the TB screening, the entire screening process, its benefits and disadvantages, such as serious risks associated with the screening, and potential outcomes.

- Applicants are to be informed that they are entitled to withdraw their consent at any time after signing the form up to the completion of TB screening. However, the Panel Physician or the person designated by the Panel Physician to explain the Informed Consent must help the Applicants clearly understand that the Certificate will not be issued if they do not accept the examination instructed by the Panel Physician, which in turn may obstruct the application process for the Certificate of Eligibility/visa.

- The Panel Physician or the person designated by the Panel Physician to explain the Informed Consent, must ensure that Applicants also understand and accept that any screening results and any relevant personal information collected during the assessment process, including health records and CXR, may be shared with the Government of Japan and CJPQA.

- Where the Applicant is a minor or mentally incapacitated, the Informed Consent Form is only valid if it is signed by his/her legal guardian.

- Where the Applicant is mentally competent to give consent but is unable to sign the Informed Consent Form for physical reasons, the Panel Physician or the person in charge should request an independent witness (i.e., someone who is not a Panel Clinic staff member) in order to confirm that the Applicant has given consent whether orally or non-verbally and to sign the form on behalf of the Applicant.

- The Panel Physician must retain the Informed Consent Form for 5 years and make it available to the Government of Japan upon request.

5. Identification

- The Panel Physician holds the overall responsibility in the identification process of the Applicant.

- The identity of the Applicant must be verified by the Panel Physician, or an appropriate staff member designated by the Panel Physician, at the following stages of the screening: registration, interview and physical examination, CXR, sputum collection, and issuance of the Certificate or referral to a TB Medical Facility.

- As the proof of identification, the Applicant must present a valid passport.

- At each stage, as mentioned above, the staff must take all reasonable steps to check the validity of the passport by ensuring that the photograph and date of birth are consistent with the Applicant's appearance.

- When there are doubts about the Applicant's identity, the Panel Physician should request the Applicant to provide further documents to substantiate his or her identity and keep them on record. The Panel Physician must not issue the Certificate until the doubts are cleared.

6. Chest radiography (CXR)

- CXR should be performed on the day the Applicant is interviewed and undergoes a physical examination at the Panel Clinic.

- Applicants aged 15 years and above should undergo a standard postero-anterior view CXR. Applicants who are unable to remain in the position required for the standard postero-anterior view may undergo an antero-posterior CXR. Applicants under 15 years should undergo CXR in the standard lateral-view as well as postero-anterior view. Further details of the radiological process are provided in **Annex H**.

- The CXR image should be digitally captured and the CXR image data should be digitally managed.

- The CXR images should be interpreted by a radiologist registered with the Panel Clinic ("Panel Radiologist") as a primary reading and reviewed by the Panel Physician as a secondary reading.

- The Panel Radiologist should record the details of all abnormalities observed, whether due to TB or otherwise. Further guidance is provided in **Annex I**.

- The CXR should be repeated if the initial CXR image is suboptimal due to technical factors. The Applicant should not leave until the Panel Radiologist confirms that no additional CXR images are required. The Panel Radiologist may request the Applicant to undergo further CXR from a different view at no additional cost.

- Documents recording the interpretation results of the CXR must include the Applicant's full name, date of birth, and passport number, the dates on which the images were obtained and interpreted; and names of both the Panel Radiologist and the Panel Physician.

- When interpreting the CXR findings, the Panel Radiologist shall have the discretion to compare the results of the current CXR with any previous CXR taken for that Applicant, if available.

- In case of disagreement between the Panel Radiologist and the Panel Physician, the Panel Physician must discuss the results with the Panel Radiologist who provided the primary reading. The Panel Radiologist can review the CXR again and make corrections, if necessary. After discussion, the Panel Radiologist's final interpretation (along with the Panel Physician remarks) will be released.

- In a rare event where the Panel Physician still has queries on the reading even after discussing with the Panel Radiologist, the Panel Physician can send the case to the IOM Teleradiology Quality Control Center for the second opinion. The radiologist from the IOM Teleradiology Quality Control Center will review the image and address the concerns raised by the Panel Physician and provide his/her opinion. The Panel Radiologist will be involved in the re-reviewing process, if he/she is available. The final interpretation (along with the Panel Physician's remarks) made by the radiologist from the IOM Teleradiology Quality Control Center will be released, even if it disagrees with the Panel Radiologist's reading or the Panel Radiologist is not involved in the re-review process.

- The radiologist from IOM Teleradiology Quality Control Center will discuss the findings with the Panel Physician and the Panel Radiologist after the re-review process, if necessary.

- Applicants with signs, symptoms and/or any radiological findings compatible with active or old TB shall not be issued a Certificate and must be directed to undergo laboratory sputum testing (see **Annex I** for CXR interpretation, and **Annex E** for details on laboratory sputum testing).

- "Radiological findings compatible with active or old TB" that require laboratory sputum testing include the following:
  i. radiological findings listed under section A and B in **Annex I**, or
  ii. radiological findings listed under section C in **Annex I** if the Applicants show any signs or symptoms, irrespective of the duration, that are suggestive of pulmonary TB, or
  iii. radiological findings listed under section D in **Annex I**, if the Applicants show any signs and typical symptoms, irrespective of the duration, that are suggestive of pulmonary TB, for example, prolonged cough lasting 2 weeks or longer.

  Applicants with no abnormal CXR findings may also be requested to submit three sputum specimens if they show signs and typical symptoms suggestive of pulmonary TB.

- Applicants without signs and symptoms of TB and whose CXR are confirmed to be free of any radiological findings compatible with active or old TB will be issued a Certificate by the Panel Physician.

- In a rare event whereby the Panel Physician judges from the interview, physical examinations, or the CXR findings that the Applicant requires the immediate attention of a specialist, the Panel Physician may refer the Applicant to a specialist immediately for further assessment or treatment before sputum examination results become available, if conducted. In this case, the screening process may be put on hold temporarily. Once the patient returns from the specialist and the Panel Physician confirms that the Applicant is cleared of TB, the Certificate may be issued.

- The Panel Physician should record the following items when resuming the screening process after medical treatment for other diseases:
  (1) Confirmed or tentative diagnosis (other than active or old TB) that was suspected based on the CXR findings.
  (2) Final diagnosis and details of treatment, if provided.
  (3) Whether or not the sputum examination for TB was conducted and the results.

- The Panel Physician provides the digital CXR image data that is saved in a CD-ROM and the printed CXR Report (see **Annex J**) to the Applicant in addition to the Certificate.

- Digital CXR data must be saved in a standardised Digital Imaging and Communications in Medicine (DICOM) format in compliance with the Portable Data for Imaging (PDI) profile, as specified by the Integrating the Healthcare Enterprise (IHE).[1]

[1] https://www.ihe.net/resources/technical_frameworks/#radiology

7. Laboratory examination for *Mycobacterium tuberculosis*

- Laboratory examination for active TB in the screening may only be conducted in Panel Laboratories conducting at least smear examinations and culture tests for *Mycobacterium tuberculosis*.

- Laboratory examination for active TB must consist of three sputum specimens – one specimen collected daily for three consecutive working days in the early morning. It is, however, acceptable to collect the first sputum specimen on the first day as a spot when the Applicant visits the Panel Clinic.

- The 3 consecutive days may include a break over the weekend.

- The Panel Physicians will issue the Certificate to the Applicant after the sputum examinations only when none of the results of the culture examinations is positive for *Mycobacterium tuberculosis*.

- The Panel Physicians must promptly start TB treatment at the Panel Clinic or refer the Applicant to a TB Medical Facility if any of the sputum examination results are positive or any of the available information strongly suggests the presence of active TB.

1) Specimen collection

- The Panel Physician must either perform on-site sputum specimen collection or arrange the collection in a Panel Laboratory. Specimens collected at other locations (e.g., at the Applicant's house) cannot be accepted.

- If the Panel Physician delegates this procedure to a nurse or assistant, the Panel Physician remains accountable for the integrity of this part of the screening procedure, regardless of where the sputum collection occurs.

- Sputum collection must commence within 7 days of CXR. If three specimens have NOT been collected within 7 days, the collection should start from the eighth day. If three specimen collections are not completed within the next 7 days, the Applicant will forfeit the chance of the Certificate being issued.

- The specimens should be securely and promptly transported to the Panel Laboratory with appropriate provision for cool-chain integrity (no exposure to high temperature or risk of freezing). The Applicants should not be allowed to transport specimens.

- All specimens must arrive at the Panel Laboratory within 4 hours of collection. If transportation requires more than 1 hour, the specimens must be refrigerated (i.e., from 4 to 10 degrees Celsius, but not frozen) and transported to the Panel Laboratory within 24 hours after specimen collection.

- When transportation requires more than 24 hours after specimen collection as an exceptional situation, the specimens must be refrigerated (i.e., from 4 to 10 degrees Celsius, but not frozen) with temperature monitoring, and transported to the Panel Laboratory as soon as possible.

- The specimens should be processed and examined within 24 hours of receipt by the Panel Laboratory.

- For the Applicants who are unable to produce sputum specimens, alternative methods of sputum collection (e.g., sputum induction by hypertonic saline inhalation or aspiration of early morning gastric fluid) can be used. A Certificate cannot be issued to Applicants who have been requested to undergo a sputum examination but have failed to submit the necessary sputum specimens.

- Further details of the procedure for correct sputum collection are provided in **Annex E**.

2) Laboratory practice

- The Panel Laboratory must follow the WHO guidelines ("Practical manual on tuberculosis laboratory strengthening, 2022 update")[2] for quality assurance (QA) activities on TB diagnostic tests (p55-64, p120-140). The panel laboratory should regularly monitor the quality indicators of each examination (p120-132) and perform quality control and external quality assessment (EQA).

- The EQAs for both smear examination and drug susceptibility testing are mandatory.

- The Panel Laboratory must submit all Standard Operation Procedures (SOPs) documents of the laboratory tests to the CJPQA.

- Smear and culture examinations for JPETS should be performed in the same laboratory, and the quality of each examination should be monitored monthly.

- Drug susceptibility testing (DST) can be outsourced to a separate laboratory from the laboratory performing the smear and culture examinations.

- Each specimen must be examined by smear microscopy for acid-fast bacilli (AFB) by auramine

[2] https://www.who.int/publications/i/item/9789240061507

staining or Ziehl–Neelsen staining and by culture on liquid or solid media for mycobacteria. If organisms suspected of mycobacteria are detected from culture, it is essential to identify the mycobacterial species at least up to the *M. tuberculosis* complex level. It is also recommended that WHO-recommended NAATs such as Xpert® MTB/RIF or Xpert® MTB/RIF Ultra or TB-LAMP is added once, if available.

- However, the WHO recommended NAATs cannot replace smear and culture examinations of three sputum specimens.

- Smear microscopic tests should follow the guideline ("Mycobacteriology Laboratory Manual")[3]. Further details regarding the reading smear are provided in **Annex E.**

- The specimens must be cultured for at least 6 weeks in liquid media and 8 weeks in solid media unless a positive result was obtained earlier. The culture results, whether positive or negative, should be reported to the Panel Physician as soon as the results are known.

- Positive *M. tuberculosis* cultures should undergo drug susceptibility testing (DST) in the Panel Laboratory per the WHO guidelines. If any drug resistance is detected, the Panel Laboratory should report it to the Panel Physician without delay. The Panel Physician must also share the DST results with the physician in charge of TB treatment at the TB Medical Facility immediately. For details, see Section 8.

- The DST should include isoniazid (INH) and rifampicin (RIF). If there is resistance to either INH or RIF, additional DSTs covering at least one of the fluoroquinolones, such as levofloxacin or moxifloxacin, should be conducted. The DSTs may also cover other anti-TB drugs per the National TB Control Guidelines as necessary, though the Government of Japan does not request the Panel Clinic to do the other DSTs.

- The Panel Physician should retrieve all additional DST results from the physician in charge of TB treatment at the TB Medical Facility conducted per the National TB Control Guidelines and input them in the J-IMS.

- See Section 8 for cases where culture results are indeterminate (e.g., due to bacterial contamination) or when there is a discrepancy between the results from culture and smear microscopy or WHO-recommended NAATs.

[3] https://npin.cdc.gov/publication/mycobacteriology-laboratory-manual

8. Outcome of screening

- Applicants who refuse the screening process shall not be issued the Certificate.

Applicants aged under 5 years:

1) Whose TST or IGRA results are negative:

- The Panel Physician shall issue the Certificate so that Applicants may proceed with their application process for the Certificate of Eligibility / visa for mid- to long-term stays.

2) Whose TST or IGRA results were indeterminate or invalid, but whose CXR was free of any radiological findings compatible with active or old TB:

- The Panel Physician shall issue the Certificate, attached with CXR data saved in a CD-ROM and "CXR Report" (see **Annex J**), so that Applicants may proceed with their application process for the Certificate of Eligibility / visa for mid- to long-term stay.

3) Whose TST or IGRA results were positive, but whose CXR was free of any radiological findings compatible with active or old TB:

- The Panel Physician shall issue the Certificate, attached with CXR data saved in a CD-ROM and "CXR Report" (see **Annex J**), so that Applicants may proceed with their application process for the Certificate of Eligibility / visa for mid- to long-term stay.

- The Panel Physician must re-confirm whether the Applicant with TST or IGRA -positive result has any of the following risk factors for developing active TB, namely household contact history for the past 2 years or immunocompromised condition for the past 6 months, and determine whether the Applicant should be referred to a TB Medical Facility for further assessment.

- If the Panel Physician determines that the Applicant requires a referral to a TB Medical Facility for further assessment, the Panel Physician must provide adequate health education and information about LTBI regarding possible options for prophylactic treatment to the Applicant and the guardian and refer the Applicant to a TB Medical Facility that is capable of providing LTBI treatment according to the WHO treatment guidelines as well as any national TB guidelines.

- The Panel Physician should, to the best of his/her effort, collect the following information regarding TST/IGRA-positive Applicants who have been referred to a TB Medical Facility: whether or not the Applicant has started LTBI treatment; and if yes, the treatment regimen and expected treatment duration.

4) Who have been diagnosed with active TB

- The Certificate is not to be issued. The same procedure as that for other Applicants diagnosed with active TB will be applied. See below for details.

All other Applicants:

1) Applicants whose culture results of all three specimens are negative:

- The Panel Physician or the physician-in-charge will judge whether the Applicants do not have active TB. Then, the Panel Physician will issue the Certificate.

2) Applicants whose sputum examination results of all three specimens are indeterminate (due to bacterial contamination, for example):

- The Panel Physician should request the Applicant to submit additional three sputum specimens for examination. However, no additional costs shall be charged in such cases.

3) Applicants whose sputum examination results of a combination of negative and indeterminate (due to bacterial contamination, for example) and/or NTM:

- The Panel Physician or the physician-in-charge will judge whether the Applicants do not have active TB and issue the Certificate if he/she finds that they do not.

4) Applicants with suspected active TB with signs or symptoms or CXR findings despite all negative sputum test results:

- The Panel Physician should write a letter of referral to a TB Medical Facility after providing adequate and sufficient explanation to the Applicant (see **Annex K**). In such cases, the Panel Physician postpones issuing the Certificate and the screening process. The Panel Physician may resume the screening process when he/she receives a diagnosis report from the TB Medical Facility indicating that the Applicant does not have active TB. The diagnosis report must be obtained directly from the physician responsible for making the diagnosis, and not via the Applicant.

5) Applicants who have been diagnosed with active TB, either based on interview, physical examinations, CXR, or sputum examination results:

- The Certificate is not to be issued and the Panel Physician must give the Applicant clear and unambiguous advice about the need to start TB treatment immediately; TB treatment should be started at the Panel Clinic or the Applicant must be referred to a TB Medical Facility.

- If the Applicant decides to receive TB treatment at a TB Medical Facility outside the Panel Clinic, the Panel Physician should share the culture and DST results with the physician-in-charge of the Applicant's TB treatment as soon as the results become available.

- The Panel Physician or the physician-in-charge at the TB Medical Facility will notify the authorities responsible for TB control in the case of active TB, according to the national TB guidelines.

- The Panel Clinic is not responsible for the quality of the TB treatment provided outside the Panel Clinic itself. However, irrespective of the sites where the Applicant decides to receive TB treatment, the Panel Physician remains responsible for monitoring the TB treatment status and collecting, to the best of his/her effort, relevant information regarding the treatment, including the treatment start date, treatment regimen, laboratory test results, and treatment outcomes.

- When the Panel Physician refers the Applicant to a TB Medical Facility for TB treatment, the Panel Physician must request the TB Medical Facility to provide the relevant information about the Applicant's TB treatment, as mentioned above, to the Panel Physician, and request to issue a "TB Treatment Certificate" (see **Annex F**) upon TB treatment completion.

- For Applicants intending to re-start the screening process after treatment completion, the Panel Clinic must receive and verify the "TB Treatment Certificate" (see **Annex F**) issued from the TB Medical Facility.

- For Applicants with pulmonary TB intending to re-start the screening process after treatment completion, treatment completion must be verified by negative sputum culture results of two sputum specimens– one specimen collected each day for two consecutive working days in the early morning, obtained within 30 days after treatment completion. Collecting the first sputum specimen on the first day as a spot when the Applicant visits the Panel Clinic is acceptable. The sputum specimens must be submitted to a Panel Laboratory.

- Treatment completion of Applicants with extra-pulmonary TB depends on the judgement of the physician-in-charge who provided treatment and care to the Applicant.

- The Applicant may only re-start the TB screening process after "treatment completion" is confirmed by the Panel Physician, and only at the same Panel Clinic, but not within 6 months of the previous examination, at an additional fee (standard test fee). Under exceptional circumstances, whereby the initial Panel Clinic is no longer able to provide screening services, the Applicant may choose another Panel Clinic. In that case, the Panel Clinic re-starting the screening process must notify the CJPQA of the change for its authorisation.

- The Panel Physician and the Panel Radiologist shall compare the CXR films obtained before and after treatment and consider the findings of the interview and the physical examination.

- When the Panel Physician determines that the Applicant no longer has active TB, that is, with no progression findings on the CXR and no significant findings in the interview and the physical examination, the Certificate may be issued. If undetermined, the Panel Physician may request the Applicant to submit another set of three sputum specimens (see Section 7).

- The Panel Physician must also complete the “TB Treatment Report” (see **Annex G**) and provide it along with the Certificate.

- The Panel Physician shall issue the Certificate in both paper and electronic formats (see Section 2).

9. Validity period of the TB Clearance Certificate

The Certificate shall be valid for 180 days from the date of the CXR.

When the Applicant, who has been cleared of active TB, meets either of the following conditions, the validity period of the Certificate is reduced from 180 days to 90 days.

1) One or more family member(s) who lived with the Applicant had been diagnosed with active infectious pulmonary TB within 2 months before the Applicant underwent CXR.
2) The Applicant has shared the same enclosed airspace, household, or other enclosed environments for a prolonged period (days or weeks) with a person who had been diagnosed with active infectious pulmonary TB within 2 months before the Applicant underwent CXR.

Acknowledgement

This Technical Instructions was drafted by the Government of Japan with reference to the “UK Tuberculosis Technical Instructions,” provided by Public Health England, September 2013, Version 6, and March 2019, Version 7. The Government of Japan is grateful for the comments and advice from the International Organization for Migration (IOM) in preparation for the publication of the Technical Instructions.

Annex A. Administrative arrangements

- Each medical facility that intends to conduct pre-entry TB screening needs to be designated as a Panel Clinic by the Government of Japan. Accordingly, all physicians in charge of the screening (“Panel Physician”), radiologists in charge of interpreting the CXR image (“Panel Radiologist”), and laboratories in charge of conducting laboratory testing (“Panel Laboratory”) need to be registered in advance by the CJPQA. In case of any change(s) made to the registration list, the Panel Clinic shall promptly notify the CJPQA.

- Panel Clinics must follow the guidelines set out in the Technical Instructions when providing TB screening for JPETS. All staff, including physicians, radiologists, radiological and medical technologists, and administrative staff of both Panel Clinics and Panel Laboratories must familiarise themselves with the Technical Instructions and ensure that they are aware of any updates or changes made to the Instructions.

- Panel Physicians must have a valid medical doctor license under the law of the country concerned and have sufficient experience in diagnosing TB (preferably 5 years or more).

- Panel Radiologists must have a valid medical doctor licence under the law of the country concerned and sufficient experience in interpreting CXR images.

- Radiological technologists and medical technologists must have a valid licence under the law of the country concerned and sufficient experience in performing CXR and laboratory examinations, respectively.

- All staff, including physicians, radiologists, radiological and medical technologists, and administrative staff of both Panel Clinics and Panel Laboratories, must not have any pre-existing conflicts of interest. Should any emerge during the period of designation, they must be brought to the attention of the Government of Japan through the CJPQA immediately.

- All staff, including physicians, radiologists, radiological and medical technologists, and administrative staff of both Panel Clinics and Panel Laboratories, must protect the privacy of the Applicants’ personal and medical information.

- Panel Laboratories registered by the Panel Clinic must receive external quality assurance approved by the Government of Japan.
- TB Medical Facilities shall carry out TB diagnosis and treatment according to the WHO or national TB guidelines for TB diagnosis and treatment and with the use of high-quality drugs and devices

in accordance with the WHO's recommended standards.

- Panel Physicians must comply with the code of conduct in that country.

- The Panel Physician should comply with medical and health services and any other relevant regulations in the country concerned.

- The Panel Physician holds the ultimate responsibility for the entire process of the pre-entry TB screening, including activities not conducted by the Panel Physician (e.g., bacteriological examinations).

- The Panel Clinics and the Panel Laboratories must respond to audit requests by the Government of Japan. They also must submit data necessary for assessment and monitoring of the screening (e.g., medical records, CXR images, laboratory examination results including the quality indicators of each laboratory examination ("Practical manual on tuberculosis laboratory strengthening, 2022 update" [2] Annex 2, p120-132) and the data necessary to follow the Applicant after entering Japan (e.g., passport number, identification number) when requested by the Government of Japan or the CJPQA.

- The Panel Clinic shall securely retain the CXR images, medical record, Informed Consent Forms as well as all laboratory results, referral letters, and details of treatment for 5 years and make them available when the Government of Japan or the relevant authorities request them.

- The Panel Physician must provide the digital CXR data saved in a CD-ROM and the "CXR report" (**Annex J**) to all Applicants who undergo CXR, together with the Certificate.

- The Panel Physician must provide the Pre-Entry Tuberculosis Screening Results Report (**Annex D**) to all Applicants, together with the Certificate.

- The Panel Physician must provide the TB Treatment Report (**Annex G**) to all Applicants who are diagnosed with active TB during the course of the screening, initiated and completed TB treatment, and are cleared of TB at the end of the second round of screening, together with the Certificate.

- The Government of Japan or the CJPQA evaluates the Panel Clinic and Panel Laboratory by auditing the processes of TB screening through a visit and assessment of the data of TB

[2] https://www.who.int/publications/i/item/9789240061507

screening. The Government of Japan may guide the Panel Clinic based on the results of audits and evaluations and can request the Panel Clinic to remove certain registered Panel Physicians, Panel Radiologists, radiological technologists, medical technologists, or Panel Laboratories.

- The Government of Japan requests that the Panel Clinic improve its performance in TB screening as identified by audits and evaluations. The Government of Japan can remove the Panel Clinic unless the Panel Clinic responds to its requests or when any fraud actions by the Panel Clinic become apparent.

- If a Panel Clinic has had its designation withdrawn, it must promptly withdraw its publicity as a designated panel clinic, which is publicly displayed at the clinic and on its website. In addition, the Applicant who has already made an appointment should be informed without delay and referred to another designated panel clinic.

Costs

- The Applicant shall be responsible for the cost of pre-entry TB screening, including, but not limited to, the administration, counselling, examination, CXR, and laboratory testing, including bacteriological tests, TST, IGRA, CXR report, CD-ROM for CXR imaging, and, where relevant, the issuance of the Certificate.

- The cost of screening does not include the cost of treatment for active TB or LTBI.

- The Applicant may refuse to undergo the additional tests if additional fees are required. Therefore, the cost of screening, which should include all components described in this Technical Instructions, such as interviews, physical examinations, TST or IGRA including repeat testing due to indeterminate results, CXR including additional different views, sputum tests including repeat testing due to indeterminate results, shall be categorised by age (“general Applicants aged 5 years and above,” and “children aged under 5 years”). The cost may be different for the two age groups, but all examination procedures within the same age group shall cost the same amount.

- The amount charged for screening must be in line with the accepted standards for the specific country.

- The Panel Clinics shall inform the Government of Japan of the full charge they intend to claim from the Applicant, including any disbursements. They shall immediately inform the Government of Japan through the CJPQA of any changes and ensure that the cost is clearly understandable and made visible to Applicants at the reception and/or websites.

- If the Government of Japan determines that a certain panel clinic’s screening fees are significantly higher than those of other Panel Clinics in the same country, the Government of Japan may ask for a correction and the Panel Clinic should respond to the request unless otherwise specified.

Annex B. TB Clearance Certificate

Only the TB Clearance Certificate that is issued from the J-IMS is accepted.

The following items are included on the TB Clearance Certificate:

1) Certificate number
2) Photograph of the Applicant
3) First, middle and family name of the Applicant
4) Date of birth of the Applicant
5) Sex of the Applicant
6) Nationality of the Applicant
7) The passport number, expiry date, and country of issue
8) A check box and a statement: “I certify that all above statements regarding the Applicant are true”.
9) A check box and statement: “I certify that this Applicant has been screened for TB and has not been found to have active TB”.
10) Name of the Panel Clinic
11) Panel Clinic ID
12) Name of the Panel Physician
13) Signature of the Panel Physician
14) Date when the Certificate was issued
15) Expiry date of the Certificate
16) Statement: “IMPORTANT NOTICE TO THE APPLICANT: This Certificate is to be submitted to diplomatic missions abroad or the Regional Immigration Bureau in Japan, together with application forms for the Certificate for Eligibility/visa to Stay. This Certificate contains information in connection with your application to Certificate for Eligibility/visa to Stay for Japan and does NOT constitute a diagnosis or assurance of health. Issuance of the Certificate does not mean that your application for Certificate for Eligibility/visa to Stay will be successful.”

JAPAN Pre-Entry Tuberculosis (TB) Screening Clearance Certificate

結核非発病証明書

Certificate Number: _____
(証明書番号)

Photo	First Name(s)* (名)	Middle Name(s)* (ミドルネーム)	Family Name* (姓)
	Date of Birth *(dd-mmm-yyyy)*: (生年月日)	Sex: ☐ Male (男) ☐ Female (女) ☐ Others (その他) (性別)	Age at the date of application: (申請時における年齢)
	Mode of Personal Identification: ☐ Passport (パスポート) (本人確認書類)	Country of Nationality: (国籍)	*Note:* **As shown in the identification document* (本人確認書類に記載のとおり)

Passport Information (パスポート情報)	Passport Number: (パスポート番号)	Country of Issue: (発行国)	Passport Expiration Date: (有効期限)

☐ I certify that all the above statements regarding the applicant are true.
(申請者に関する上記全項目が真実であることを証明します。)

☐ I certify that this applicant has been screened for TB and has not been found to have active TB.
(申請者が入国前結核健診を受診し、その結果活動性結核が診断されなかったことを証明します。)

QR code

Name of Panel Clinic: (指定医療機関名) _____
Panel Clinic ID: (指定医療機関 ID) _____
This Certificate was issued on *(dd-mmm-yyyy)* (証明書の発行日) _____

Name of Panel Physician: (医師の氏名) _____
Signature (署名): _____
and is valid until *(dd-mmm-yyyy)* (証明書の有効期限) _____

IMPORTANT NOTICE TO THE APPLICANT:
This certificate is to be submitted to the diplomatic missions abroad or the Regional Immigration Bureau, together with application forms for visa/Certificate for Eligibility. This certificate contains information in connection with your application for visa/Certificate for Eligibility to stay for Japan and does not constitute a diagnosis or assurance of health. Issuance of the certificate does not mean that your application for visa/Certificate for Eligibility will be successful.

Annex C. Informed Consent Form

JAPAN PRE-ENTRY TUBERCULOSIS SCREENING PROGRAMME
Informed Consent Form

Photo	BIOGRAPHIC INFORMATION		
	Applicant's Name: *[First Name(s)]* *[Middle Name(s)]* *[Family Name]*		
	Date of Birth *(dd/mm/yyyy):*	**Sex:** ☐ Male	☐ Female ☐ Others
	Nationality:		
	Passport # :		
	Panel Clinic Name:		

Applicant's Declaration:

I understand that:

1. I am required to undergo screening for active tuberculosis (TB), involving an interview, physical examinations, chest X-ray and, possibly, sputum tests, before applying for the Certificate of Eligibility or visa for mid to long-term stay in Japan;
2. if my chest X-ray is abnormal, I will be required to receive individual counselling and an explanation of the further screening procedures;
3. if my chest X-ray is abnormal and the changes are suggestive of pulmonary TB, regardless of whether these changes are old or new, or if there are other clinical reasons to suspect pulmonary TB, I will be required to provide three sputum samples, which will be tested for TB with smear, culture, and, if available, other World Health Organization (WHO)-recommended nucleic acid amplification tests (NAATs), such as Xpert MTB/RIF or Xpert MTB/RIF Ultra or TB-LAMP;
4. if sputum testing is indicated, I will be required to submit three sputum specimens on each day for three consecutive working days, taken in the early morning (e.g., by 10 a.m.) within seven days of my chest X-ray. I may, however, submit the first sputum specimen on the spot on the first day. If I fail to submit three sputum samples on three consecutive days within seven days, I must re-start sputum collection. I will be responsible for paying an additional fee if I am required to restart sputum collection for reasons attributable to myself. If I further fail to return within the next seven days, except in cases of unpredictable and unavoidable circumstances, will forfeit the opportunity to obtain the TB Clearance Certificate. If I am forced to interrupt the sputum collection due to such unpredictable and unavoidable circumstances, I understand that as soon as those circumstances are resolved, I will immediately resume the sputum collection;
5. it may take up to ten weeks to receive the results of sputum culture tests;
6. if any of the bacteriological tests show the presence of TB bacteria and/or the physician makes an active TB diagnosis, I will be counselled and referred for TB treatment. TB treatment shall be at my own expense; I will inform the TB treatment medical facility of any close family contacts, who may need evaluation for TB;
7. I have the right to refuse to undergo the TB screening procedure and/or TB treatment if indicated, or to withdraw my consent at any time, but I understand that such action of refusal or withdrawal may adversely affect my application for the Certificate of Eligibility or visa for mid-to long-term stay in Japan;
8. the personal identification document used during the screening process must be a valid passport;
9. the Panel Physician has the final decision about whether I receive the TB Clearance Certificate;
10. if the results of the TB screening process show that I have TB, the Panel Clinic may be required by law to report these results to the relevant public health authority in the country where the TB screening occurred. My results may also be shared with external healthcare providers for the purpose of facilitating treatment and follow-up;
11. by consenting to this form, I authorize the Panel Clinic and its designated laboratory to enter all relevant personal information collected during the assessment process, including health records in the JPETS Information Management System (J-IMS), an electronic platform developed, hosted and maintained by IOM. The information collected which pertains to my TB screening will be processed in J-IMS for the purpose of providing the TB screening service (the Purpose) and transferred to the Japanese immigration authorities, namely the Immigration Service Agency, for the Certificate of Eligibility or Consulate for visa and the Centre for JPETS Quality Assessment (CJPQA) (https://jata.or.jp/english/jpets.html). IOM, as the host of J-IMS, will preserve and keep confidential any information in relation to my TB screening that is processed within J-IMS, in line with the IOM Data Protection Principles[1], and will not use or disclose the information for any other purpose unless required

[1] The IOM Data Protection Principle is available at: https://publications.iom.int/books/iom-data-protection-manual

by the Government of Japan;

12. my de-identified and aggregated data (including health data in J-IMS) may be transferred to and used by CJPQA or IOM for research for the purposes of analysis of migration health issues to inform policy and/or for reporting programme evaluation;
13. if I develop active tuberculosis after entering Japan, my personal information collected under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Japan's Infectious Disease Law) may be provided to CJPQA, IOM, and MHLW and used for purposes for the quality control of this tuberculosis screening program;
14. by consenting to this form, I acknowledge that I have a chance to ask questions to the Panel Physician and the Panel Clinic regarding matters related to TB assessment procedures and that such questions were answered to my satisfaction;
15. I have the right to request clarifications and additional information from the Panel Clinic staff or CJPQA if any of the above is unclear;
16. by consenting this form, I release and hold harmless the Government of Japan, the Panel Physician, the Panel Clinic, CJPQA and the International Organization for Migration (IOM) from any liability for loss, any injury or other harm suffered during, or as a result of, the TB assessment procedures or the processing of my personal data, except where such loss, injury or harm are caused directly by gross negligence or misconduct of the Government of Japan, the Panel Physician, the Panel Clinic, CJPQA and IOM; and
17. by consenting to this form, I declare that I have read and fully understood the contents of this form and the procedures involved in the TB screening performed by the Panel Clinic and the processing of my personal data, and I hereby provide my consent and sign the form of my own free will.

Additional Declaration by Female Applicants:

I understand that:

- all female applicants will be asked about the date of their last menstrual period to identify applicants who may be pregnant;
- a chest X-ray can carry a risk of radiation for the unborn child, but this risk is relatively small in the second and third trimester;
- if I am or could be pregnant, I will be offered two options: 1) to postpone the chest X-ray (and TB clearance) until after delivery or 2) to proceed with a chest X-ray with double protective shielding;
- I am therefore advised to consult the Panel Physician and may wish to consult my gynecologist to ensure that I fully understand the risks before I proceed with a chest X-ray; and
- if I decide to submit to a chest X-ray, it shall be at my own risk.

Signatory	Print name	Signature	Date (dd/mm/yyyy)
Applicant			
Legal guardian for children or mentally incapacitated adult (*Relationship to the Applicant*)	( )		
Witness for adults unable to physically sign (*Relationship to the Applicant*)	( )		

Statement by the Panel Physician

I have explained the content of this document to the Applicant and confirm that

- ☐ the Applicant has agreed to go ahead with the assessment.
- ☐ the Applicant has declined to go ahead with the assessment.

Print name	Signature	Date (dd/mm/yyyy)

Annex D. Pre-Entry Tuberculosis Screening Results Report

JAPAN PRE-ENTRY TUBERCULOSIS SCREENING PROGRAMME

Pre-Entry Tuberculosis Screening Results Report
申請者の入国前結核健診結果に関する情報提供書

Photo

BIOGRAPHIC INFORMATION		
Reference ID:		
Applicant's Name: *[First Name(s)]*	*[Middle Name(s)]*	*[Family Name]*
Date of Birth *(dd-mmm-yyyy):*	Sex: o Male	o Female o Others
Nationality:		
Passport Number:		

Dear Colleague, ご担当者様

I write to inform you of the test results for the above-mentioned Applicant, who underwent Japan pre-entry TB screening as part of the application process of the Certificate of Eligibility / visa for mid- to long-term stay in Japan.
上記の申請者は、日本入国前結核健診を受けました。結果の詳細を以下の通りお知らせいたします。

HISTORY & PHYSICAL EXAMINATION			
Exam Date:			
Cough	o No o Yes	**Sputum Expectoration**	o No o Yes
Night Sweats	o No o Yes	**Hemoptysis**	o No o Yes
Weight Loss	o No o Yes	**Fever**	o No o Yes
History of TB	o No o Yes o Unknown		
Anyone in the household diagnosed with active pulmonary TB	o No o Yes (If yes, in the last 2 years? o No o Yes) o Unknown		
History of contact with active pulmonary TB, if known	o No o Yes (If yes, in the last 2 years? o No o Yes) o Unknown		
History of or currently immune compromised	o No o Yes o Unknown		
History of or currently using immunosuppressant agents	o No o Yes o Unknown		
History of chronic disease, history of previous thoracic surgery/cyanosis, respiratory insufficiency that limits activity? (5 to below 15 years only)	o No o Yes		
Chest Auscultation	o Normal o Abnormal (specify,) o Not Done		
Examination of the Neck	o Normal o Abnormal (specify,) o Not Done		
Remarks			

TST/IGRA TEST (< 5 years only) o Not done o Done o Pending									
TST	**Date Applied** *(dd-mmm-yyyy):* **Date Read** *(dd-mmm-yyyy):* **Result** *(mm):* **Interpretation:** o Negative o Positive								
IGRA	**Date of Blood Drawn** *(dd-mmm-yyyy):* **Interpretation:** o Negative o Positive o Indeterminate or Invalid								
	QFT	Nil (IU/ml)		**T-SPOT**	Nil (spots)		**Wantai TB-IGRA**	N (Background Control, pg/ml)	
		TB1 (IU/ml)			A-Nil (spots)			P (Positive Control, pg/ml)	
		TB2 (IU/ml)			B-Nil (spots)			T (Testing, pg/ml)	
		Mitogen (IU/ml)			Positive Control (Spots)				

CHEST X-RAY: o Not done o Done o Pending	
Date of Chest X-ray *(dd-mmm-yyyy):*	**Name of Radiologist:**
Chest X-ray Interpretation	**Findings:** o Normal o Abnormal o Pending **Details:**

BACTERIOLOGICAL TEST: o Not done o Done o Pending				
Collection Date	**Report Date**	**Smear Results**	**Culture Results**	**Molecular Tests, if done**

PANEL PHYSICIAN		
Panel Physician Name:	**Signature:**	**Date** *(dd-mmm-yyyy)*:
Name of Panel Clinic:	**Address:**	

Annex E. Sputum collection

Administrative arrangements

- Confirm the identity of the Applicant.
- Ensure accurate specimen identification using non-removable labels.
- Explain the collection procedure to the Applicant.
- Use appropriate disposable equipment.
- Safe storage and disposal of clinical waste.

Sputum collection

- Collect a sufficient amount of sputum specimen (4 mL at least).

- Preferably collect the specimens early in the morning.

- Three specimens must be collected at least 24 hours apart, preferably on consecutive days. The first spot specimen out of three specimens can be collected under supervision in the laboratory on the day when the Panel Physician requests the Applicant to submit sputum specimens.

- Sample collection must be directly supervised in a Panel Clinic or a Panel Laboratory. A screw-cap container must be used for sputum collection.

- Must be collected in a safe environment and not at the Applicant's home.

- Applicants should rinse their mouths with purified water before providing sputum specimens. Check that sputum, not just saliva, is collected.

- The collector or supervisor of the laboratory or the laboratory technician preparing the specimen can discard any specimen that is saliva and not sputum. In this case, the Applicant must return the following day for collection.

- All Applicants must be instructed to take three deep breaths and cough on the fourth deep breath. The cough should involve an abdominal contraction, not just the upper chest or throat.

- The collector needs to listen to the Applicants coughing to ensure that a cough comes from the stomach and not from the chest or throat. If an Applicant continues to cough from the throat or is unable to cough from the stomach, the Applicant should be asked to return the following day.

- Applicants must not submit their nasal passages into the back of their throat as a sputum specimen.

- Specimens must never be pooled.

Use of induced and aspirated sputum

- If Applicants find it difficult to produce sputum, the following method can be used to obtain specimens: inhalation of an aerosol of sterile hypertonic saline (3–6%), usually produced by an ultrasonic nebuliser, can be used to stimulate the production of sputum, followed by expectoration of sputum. Sputum induction and aspiration can be used for children as young as 3 years of age.

- A gastric aspirate can be collected from Applicants of all ages and may be especially helpful for young children who find it difficult to provide a sputum specimen.

Specimen handling

- The collector should wear an appropriate mask not a surgical mask, but N95 and well-fitting gloves during the collection process.

- The specimens must be sent to the laboratory in a plastic or polystyrene cool box with a sealed lid.

- If the laboratory is on the same premises as the sputum collection site, all specimens must arrive at the Panel Laboratory within 4 hours of collection. If sputum specimens cannot be sent to the Panel Laboratory within 1 hour, they must be refrigerated (i.e., from 4 to 10 degrees Celsius, but not frozen).

- If sputum specimens need to be transported to another site, they must be transported to the Panel Laboratory in a cold container containing ice packs within 24 hours after specimen collection. Do not transport sputum specimens collected on different days together. Sputum specimens should be collected between Monday and Thursday (or Friday if difficult) and be transported on a weekday, not stored over the weekend.

- When transportation requires more than 24 hours after sputum collection as an exceptional situation, the specimens must be refrigerated (i.e., from 4 to 10 degrees Celsius, but not frozen) with temperature data monitoring and transported to the Panel Laboratory as soon as possible.

- The specimens should be placed in a rack to prevent spillage and should be protected from heat at all times. The specimens must not be frozen.

- The Panel Laboratory should process and examine the specimens within 24 hours of receipt.

Safety measures

- Preferably, collection should take place outside in a sunny, well-ventilated area. To protect the privacy of the Applicant, the collection location should be private and free of passers-by and onlookers.

- The waiting area should be separated from the collection area, and Applicants should be allowed to sit before collection and read the collection technique instructions.

- All collectors must wear an appropriate mask (not a surgical mask, but N95) and well-fitting gloves for the process.

- If specimens must be collected inside, they must be collected in a booth or room with negative airflow. There should be 12–18 complete room air changes per hour. A small strip of single-layer tissue paper can be placed on the door of the booth at least once a day, and if the paper moves 45 ° toward the door, it means adequate ventilation is provided.

- Phenol- or alcohol-based disinfectant solutions can be used to disinfect surfaces.

- Ultraviolet (UV) light can also be used provided that the lamp is cleaned once a week to prevent dust build-up and it emits light at wave-lengths of 254 nm. The UV light must be on for 1 hour after work has finished in the booth. It must be noted that this only disinfects the surfaces in the booth so benches should be kept to a minimum in the area, and the booth must be free of all other materials. The UV light should be replaced regularly in accordance with the manufacturer's instructions.

Sputum specimen processing

- Smear and culture examinations should be performed in the same laboratory.

- Quality assurance (QA) activities for TB testing should be conducted according to the WHO guidelines ("Practical manual on tuberculosis laboratory strengthening, 2022 update", pp.55-64

and pp.120-140)[2]. The quality of all examinations, i.e., smear examinations, culture tests, drug susceptibility tests, IGRA, and NAATs if performed, should be monitored monthly.

- Sputum specimens should be centrifuged before the smears are performed. Standard preparation methods for decontaminated-concentrated specimens using N-acetyl L-cysteine–Sodium hydroxide [NALC-NaOH] according to the guidelines ("Mycobacteriology Laboratory Manual")[3] should be applied.

- Results of microscopic examination of the smear should be judged according to the modified WHO guideline in the table below ("LABORATORY DIAGNOSIS OF TUBERCULOSIS BY SPUTUM MICROSCOPY: THE HANDBOOK")[4].

Table: AFB smear reading (modified WHO guideline)

Brightfield Microscopy (x1000)	Fluorescence Microscopy		Report
	(x200)	(x400)	
0 AFB/ 100 field	0 AFB/ One length	0 AFB/ One length	Negative
	1-4 AFB/ One length	1-2 AFB/ One length	Confirmation required*
1-9 AFB/ 100 field	5-49 AFB/ One length	3-24 AFB/ One length	Scanty
10-99 AFB/ 100 field	3-24 AFB/ One field	1-6 AFB/ One field	1+
1-10 AFB/ One field, check 50 fields	25-250 AFB/ One field	7-60 AFB/ One field	2+
>10 AFB/ One field, check 20 fields	>250 AFB/ One field	>60 AFB/ One field	3+

*Confirmation required by another technician or preparation and reading of another smear with Ziehl–Neelsen stain.

- Liquid and solid cultures should be observed at least for 6 and 8 weeks, respectively, under suitable conditions.

- A combination of liquid and solid cultures is preferred. Two tubes should be applied to each specimen when only solid culture is used.

- Either of the following three combination patterns is preferable:
  - One liquid culture tube and one or two solid culture tube(s) can be applied to each of the three sputum specimens, i.e., three liquid culture tubes and three or six solid culture tubes will be used altogether.

[2] https://www.who.int/publications/i/item/9789240061507
[3] https://npin.cdc.gov/publication/mycobacteriology-laboratory-manual
[4] https://www.stoptb.org/sites/default/files/imported/document/TB_MICROSCOPY_HANDBOOK_FINAL.pdf

- One liquid culture tube can be applied to two (two of the first, second, or third) sputum specimens; then, two solid culture tubes can be applied to the other sputum specimen, i.e., two liquid culture tubes and two solid culture tubes will be used altogether.
- One liquid culture tube can be applied to one (either the first, second, or third) sputum specimen, and two solid culture tubes can be applied to each of the two other sputum specimens, i.e., one liquid culture tube and four solid culture tubes will be used altogether.

- Any of the following combination patterns are acceptable:
  - Two solid culture tubes can be applied to each of the three sputum specimens, i.e., six solid culture tubes will be used altogether.
  - One liquid culture tube can be applied to each of the three sputum specimens, i.e., three liquid culture tubes will be used altogether.

Annex F. Tuberculosis Treatment Certificate

To: Health Officer or Physician
Upon completion of TB treatment, please fill out the form and provide it to the patient with investigation reports, images or relevant documents if available.

JAPAN PRE-ENTRY TUBERCULOSIS SCREENING PROGRAMME
Tuberculosis Treatment Certificate

Photo	BIOGRAPHIC INFORMATION	
	Reference ID:	
	Patient's Name: *[First Name(s)]* *[Middle Name(s)]* *[Family Name]*	
	Date of Birth *(dd-mmm-yyyy):*	**Sex:** o Male o Female o Others
	Address:	

PRE-TREATMENT DIAGNOSIS

TB Type: o Pulmonary TB o Pulmonary TB with extrapulmonary involvement
o Extrapulmonary TB only (specify:)

Reason for Treatment: o Positive smear for AFB o Abnormal CXR consistent with TB
o Positive culture for MTB o Transfer in
o Sign or symptom consistent with TB o Other (Specify:)

TB Classification: o New o Relapse o Treatment after default
o Treatment failure o Transfer in o Other (Specify:)

Symptoms: o No o Yes (specify:)

History: o No o Yes (specify:)

Physical Examination: o Normal o Abnormal (specify:)
o Not Done

Remarks:

DRUG SUSCEPTIBILITY TEST RESULTS: *R = Resistant, S = Susceptible, ID = Indeterminate/Intermediate*

DST	Drug List*													
	H	R	E	S	Z	Lfx	Mfx							
Phenotypic														
Genotypic														

Result: **Report Date** *(dd-mmm-yyyy):*

*H – Isoniazid R – Rifampicin E – Ethambutol S – Streptomycin Z – Pyrazinamide Lfx – Levofloxacin Mfx – Moxifloxacin

TREATMENT REGIMEN

Drug	Dose	Start Date	End Date	Status	Comments

Treatment Commenced *(dd-mmm-yyyy):* **Treatment Completed** *(dd-mmm-yyyy):*

MONITORING SUMMARY, if available						
Month	Weight (kg)	Collection Date	Smear Results	Culture Results	CXR Date	CXR Results
0						

Remarks:

TREATMENT OUTCOMES

o Cure o Complete o Lost to follow up o Failure o Transfer-out o Death
o Discontinued due to change of diagnosis

TB TREATMENT FACILITY & PHYSICIAN

Name of Treating Physician:	Signature:	Date *(dd-mmm-yyyy):*
Name of Treatment Facility:	Address:	Tel:

Annex G. Tuberculosis Treatment Report

JAPAN PRE-ENTRY TUBERCULOSIS SCREENING PROGRAMME

Tuberculosis Treatment Report

日本入国前結核健診において活動性結核と診断された申請者の結核治療歴に関する情報提供書

Photo	BIOGRAPHIC INFORMATION	
	Reference ID:	
	Applicant's Name: *[First Name(s)] [Middle Name(s)] [Family Name]*	
	Date of Birth *(dd-mmm-yyyy):*	Sex: o Male o Female o Others
	Nationality:	
	Passport Number:	

Dear Colleague,
ご担当者様

I write to inform you that the above-mentioned Applicant, who underwent tuberculosis testing as part of the application process of the Certificate of Eligibility / Visa for mid- to long-term stay in Japan, has been diagnosed as active tuberculosis and has completed a full course of TB treatment prior to being issued the TB Clearance Certificate. The details of her/his TB diagnosis and treatment are as follows:
上記の申請者は、日本入国前結核健診において活動性結核と診断され、日本入国前に結核の治療を終了しました。結核の診断および治療の詳細について以下の通りお知らせ致します。

PRE-TREATMENT DIAGNOSIS
TB Type: o Pulmonary TB o Pulmonary TB with extrapulmonary involvement o Extrapulmonary TB only (specify:)
Reason for Treatment: o Positive smear for AFB o Abnormal CXR consistent with TB o Positive culture for MTB o Transfer in o Sign or symptom consistent with TB o Other (Specify:)
TB Classification: o New o Relapse o Treatment after default o Treatment failure o Transfer in o Other (Specify:)
Symptoms: o No o Yes (specify:)
History: o No o Yes (specify:)
Physical Examination: o Normal o Abnormal (specify:) o Not Done
Remarks:

TST/IGRA TEST (< 5 years only) o Not done o Done o Pending									
TST	**Date Applied** *(dd-mmm-yyyy):* **Date Read** *(dd-mmm-yyyy):*								
	Result *(mm):* Interpretation: o Negative o Positive								
IGRA	**Date of Blood Drawn** *(dd-mmm-yyyy):* **Interpretation:** o Negative o Positive o Indeterminate or Invalid								
	QFT	Nil (IU/ml)		T-SPOT	Nil (Spots)		Wantai TB-IGRA	N (Background Control, pg/ml)	
		TB1 (IU/ml)			A- Nil (Spots)			P (Positive Control, pg/ml)	
		TB2 (IU/ml)			B-Nil (Spots)			T (Testing, pg/ml)	
		Mitogen (IU/ml)			Positive Control (Spots)				

CHEST X-RAY o Not done o Done o Pending	
Date of Chest X-ray *(dd-mmm-yyyy):*	Name of Radiologist:
Chest X-ray Interpretation	Findings: o Normal o Abnormal o Pending Details:

BACTERIOLOGICAL TEST o Not done o Done o Pending

Collection Date	Report Date	Smear Results	Culture Results	Molecular Test Results, if done

DRUG SUSCEPTIBILITY TEST RESULTS: *R = Resistant, S = Susceptible, ID = Indeterminate/Intermediate*

DST	Drug List*													
	H	R	E	S	Z	Lfx	Mfx							
Phenotypic														
Genotypic														

Result: Report Date *(dd-mmm-yyyy):*

*H – Isoniazid R – Rifampicin E – Ethambutol S – Streptomycin Z – Pyrazinamide Lfx – Levofloxacin Mfx – Moxifloxacin

TREATMENT REGIMEN

Drug	Dose	Start Date	End Date	Status	Comments

Treatment Commenced *(dd-mmm-yyyy):* Treatment Completed *(dd-mmm-yyyy):*

MONITORING SUMMARY, if available						
Month	Weight (kg)	Collection Date	Smear Results	Culture Results	CXR Date	CXR Results
0						

Remarks:

TREATMENT OUTCOMES
o Cure o Complete o Lost to follow up o Failure o Transfer-out o Death o Discontinued due to change of diagnosis

TB TREATMENT FACILITY & PHYSICIAN:	
Name of Treatment Facility:	Name of Treating Physician:
Address:	

PANEL PHYSICIAN		
Panel Physician Name:	Signature:	Date *(dd-mmm-yyyy)*:
Name of Panel Clinic:	Address:	Tel:

Annex H. Technical details of radiographic exams

1. Radiographic techniques

- All CXRs should be taken in postero-anterior (PA) projections to reduce cardiac magnification. In a correctly exposed film, the penetration should be such that one should be able to see the first four (4) vertebral bodies well (T1-T4), and the ribs, while the rest of the vertebrae should be visible through the heart shadow.

- Routine CXRs should be taken in full inspiration.

- All CXRs should include the costophrenic angles. Apices should be clearly visible (without overlying clavicles).

- Chest rotation should be avoided. The scapulae should be clearly demarcated from the lung fields.

- The distance from the CXR tube to the film must be 4.5–6.5 feet (140–200 cm).

- Artefacts must be excluded.

2. Special views

- CXR should be performed in apical lordotic view and lateral decubitus view, if necessary.

- Antero-posterior CXR can be performed if the Applicant is unable to stay in the position for standard postero-anterior CXR.

- For children aged under 15 years, CXR should be performed in the lateral and postero-anterior views.

3. Radiation safety

Ensure the following:

- Routine use of lead shielding for all Applicants and double-layer lead shielding for children and pregnant women.

- Selection of correct collimation.

- Additional CXRs must not be performed unless clinically indicated.

4. CXR image identification

- The CXR image must bear the Applicant's name in English, the name of the clinic, the date of the CXR in Gregorian calendar, and anatomical side markers.

5. Women

- The Panel Physician must explain to all female Applicants that appropriate radiation safety is secured. Physicians have an ethical obligation to ensure that these Applicants are adequately protected. Be vigilant in avoiding unnecessary radiation exposure. For considerations of pregnant women, see Section 3. "2) Screening categories and processes".

6. Children

- Radiation exposure should be maintained at a minimum level. Collimation should include only the chest, and abdominal shielding should be used.

7. Quality assessment of chest radiography

- The quality of the CXR images obtained at the Panel Clinics must be assessed by the IOM Teleradiology Quality Control Center, Manila, in accordance with the standard procedures set by the IOM.

8. Others

- Abdominal shielding should be properly used.

- Privacy of the Applicants should be respected.

- Belongings should be properly managed to avoid the loss of valuables.

- The CXR image should be digitally captured, and the image data should be digitally managed.

Annex I. Radiological interpretations of CXRs

1. CXR image and reports

- The CXR image must bear the Applicant's name in English, the name of the clinic, the date of the CXR in Gregorian calendar, and anatomical side markers.

- Examine the so-called hidden areas in the postero-anterior view:
  - behind the heart,
  - the apices,
  - costophrenic angles,
  - both the hila,
  - paratracheal regions, and
  - below the diaphragms.

- If a nodule in the lower zones is difficult to differentiate from nipple shadow, the CXR must be repeated with nipple markers for confirmation.

2. Requirements for examining radiologists

Panel Radiologists must ensure the following:

- They should accurately record the date and place of examination, name of the Applicants, and results of their radiological examination, along with the results of any additional investigations. The Panel Radiologist's name should also appear clearly. This information must be either handwritten or printed in a manner such that it cannot be tampered.

- When reading the CXR on a monitor screen, the Panel Radiologists and Physicians must also use a high-resolution diagnostic monitor (≥2 MP of approximately 21 inches in size and at least 350cd/m^2 of maximum brightness).

- The extent and likely activity of any disease should be described, and further investigations must be recommended.

- The initial interpretation of a CXR imaging performed by Panel Radiologists is referred to as a primary reading. The Panel Radiologists share their findings and interpretations with the Panel Physicians who conduct the secondary reading. Additionally, if the Panel Radiologists identify significant abnormalities, such as changes suggestive of active TB, they must promptly communicate these to the Panel Physicians.

- If the panel clinics are unable to conduct primary readings due to the absence of Panel Radiologists or other reasons, they may request external radiologists to perform these readings.

- Based on the results of the primary reading, the Panel Physicians conduct the secondary reading. The Panel Physicians review the Panel Radiologists' interpretation and choose either to 'agree' or 'disagree.' In cases of disagreement, it is recommended to discuss the interpretation with the Panel Radiologists before finalization. If the Panel Physicians opt to disagree after this discussion, they must seek a final opinion from a radiologist at the IOM Teleradiology Quality Control Center as a second opinion (See Figure and Section 6).

- The Panel Radiologist assumes responsibility for the integrity and quality of the radiological examination process.

- The Government of Japan, or CJPQA may audit all or part of radiological examinations, and any evidence of failure to maintain the integrity and quality of the examination will result in revocation of registration of the Panel Radiologist.

3. Recording of radiological findings

If any of the following abnormalities are present, radiologists are required to annotate their reports using the following numerical codes:

A. Findings likely to suggest active TB:

A-1 Cavitary lesions
A-2 Consolidation or ill-defined soft tissue infiltration
A-3 Miliary lesions
A-4 Multiple / single ill-defined nodules or masses
A-5 Soft-tissue hilar or mediastinal mass / lymphadenopathy
A-6 Pleural effusion

B. Findings sometimes seen in active TB:

B-1 Fibronodular / fibrocalcific / fibrocystic lesions or localised multiple calcific nodules with or without volume loss
B-2 Multiple / single well-defined pulmonary nodules or masses (non-calcified)
B-3 Notable apical pleural capping (rough or ragged inferior border) and / or pleural thickening ≥1 cm at any point

C. Minor findings which may be associated with old / healed TB:

C-1 Solitary calcified nodule

C-2 Calcified hilar lymph node(s)

C-3 Multiple calcified pulmonary nodules with distinct borders (scattered)

C-4 Calcified pleural lesions

C-5 Costophrenic angle blunting (either side above the horizontal)*

*Note: Conduct lateral decubitus CXR if effusion is suspected.

D. Minor findings likely not associated with TB:

D-1 Single linear streak

D-2 Smooth pleural thickening, apical and / or lateral (<1-cm thickness at all points)

D-3 Unilateral or bilateral costophrenic angle blunting (below the horizontal)*

D-4 Others, specify ( )

*Note: Conduct lateral decubitus CXR if effusion is suspected.

E. Suggestive of significant non-TB findings:

(Choose the applicable anatomical part(s) below and describe the findings in the remarks.)

E-1 Soft tissue and bones

E-2 Heart and great vessels

E-3 Diaphragm, costophrenic angles, and pleura

E-4 Hilar and mediastinum

E-5 Lung fields

E-6 Others, specify ( )

*Note: The cut-off point for cardiomegaly is CTR of ≥55% for adults and ≥60% for children.
Specific chamber enlargement should also be considered abnormal even if the CTR is normal.

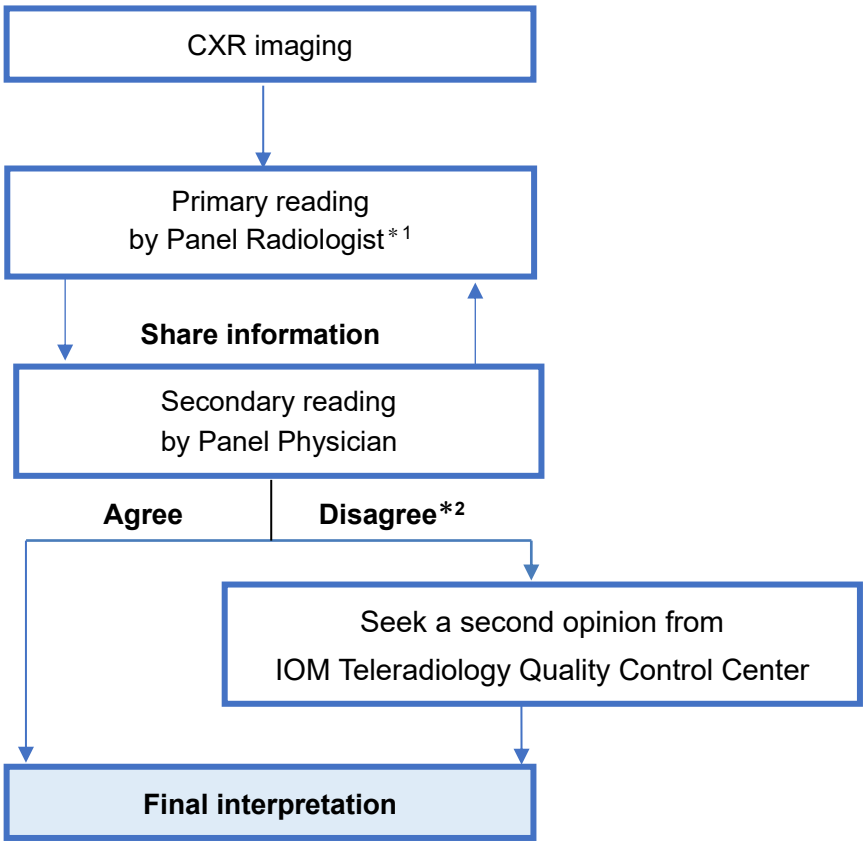
Remarks (Describe all abnormal findings in the chest X-ray film)**:**

INSTRUCTIONS TO PANEL PHYSICIANS:

The Panel Physician should request the Applicant to submit a set of three sputum specimens in the following scenarios:

1. If any CXR findings under A or B are identified.
2. If any CXR findings under C are identified and the Applicant shows clinical signs and symptoms suggestive of pulmonary TB irrespective of the duration or if the Applicant has a history of active TB.
3. If any CXR findings under D, E, or normal CXR findings are identified and the Applicant shows typical signs and symptoms suggestive of pulmonary TB such as prolonged cough for 2 weeks or more or if the Applicant has a history of active TB.

Figure. The flow of radiological interpretations of CXRs



*1 Panel clinics can request external radiologists if Panel Radiologists are absent.

*2 It is recommended that Panel Physicians discuss the interpretation with Panel Radiologists before finalization.

Annex J. CXR Report

JAPAN PRE-ENTRY TUBERCULOSIS SCREENING PROGRAMME

Chest X-ray Report

Photo	REGISTRATION DETAILS	
	Reference ID	
	Exam Date	
	City of TB Assessment	
	Country of TB Assessment	
	Panel Clinic Name	
	Panel Clinic ID	

BIOGRAPHIC INFORMATION	
Applicant's Name: *[First Name(s)] [Middle Name(s)] [Family Name]*	
Date of Birth *(dd-mmm-yyyy):*	Sex: o Male o Female o Others
Nationality:	
Passport Number:	

CHEST X-RAY DETAILS		
Date of Chest X-ray *(dd-mmm-yyyy):*	Radiologic Technologist Name:	
Chest X-ray View	Standard View(s):	
	Additional View(s), specify:	
Other details, if applicable	☐ With pelvic shielding	☐ Other *(specify)*: .....

CHEST X-RAY INTERPRETATION

Chest X-ray Findings: ☐ Normal ☐ Abnormal

A. Findings likely to suggest active TB: ☐ No ☐ Yes *(Choose below)*
- ☐ A-1 Cavitary lesions
- ☐ A-2 Consolidation or ill-defined soft tissue infiltration
- ☐ A-3 Miliary lesions
- ☐ A-4 Multiple / single ill-defined soft tissue nodules or masses
- ☐ A-5 Soft tissue hilar or mediastinal mass / lymphadenopathy
- ☐ A-6 Pleural effusion

B. Findings sometimes seen in active TB: ☐ No ☐ Yes *(Choose below)*
- ☐ B-1 Fibronodular / fibrocalcific / fibrocystic lesions or localized multiple calcific nodules with or without volume loss
- ☐ B-2 Multiple / single well-defined pulmonary nodules or masses (non-calcified)
- ☐ B-3 Notable apical pleural capping (rough or ragged inferior border) and/or pleural thickening ≥ 1cm thickness at any point

C. Minor findings which may be associated with old / healed TB: ☐ No ☐ Yes *(Choose below)*
- ☐ C-1 Solitary calcified nodule
- ☐ C-2 Calcified hilar lymph node(s)
- ☐ C-3 Multiple calcified pulmonary nodules with distinct borders (scattered)
- ☐ C-4 Calcified pleural lesions
- ☐ C-5 Costophrenic angle blunting (either side above the horizontal)*

**Note: Take lateral decubitus CXR, if effusion is suspected.*

D. Minor findings, likely not associated with TB: ☐ No ☐ Yes *(Choose below)*
- ☐ D-1 Single linear streak
- ☐ D-2 Smooth pleural thickening, apical and/or lateral (< 1cm thickness at all points)
- ☐ D-3 Unilateral or bilateral costophrenic angle blunting (below the horizontal)*
- ☐ D-4 Others, *specify*: .....

**Note: Take lateral decubitus CXR, if effusion is suspected.*

Reference ID: Applicant's Name *(First | Middle | FAMILY NAME)*:

E. Suggestive of significant non-TB findings: ☐ No ☐ Yes *(Choose the applicable anatomical part(s) below and describe the findings in the remarks.)*

- ☐ E-1 Soft tissue and bones
- ☐ E-2 Heart and great vessels
- ☐ E-3 Diaphragm, costophrenic angles and pleura
- ☐ E-4 Hilar and mediastinum
- ☐ E-5 Lung fields
- ☐ E-6 Others, specify .....

**Note: The cut off point for cardiomegaly: CTR ≥ 55% for adults and ≥ 60% for children. Specific chamber enlargement should also be checked as abnormal even if normal CTR.*

Remarks *(Describe all abnormal findings in the Chest X-ray)*:

RADIOLOGIST DETAILS
Radiologist Name:
Radiologist Signature:
Date of Chest X-ray Reading *(dd-mmm-yyyy)*:
CHEST X-RAY REVIEW BY PANEL PHYSICIAN
Panel Physician Remarks
Panel Physician Name:
Panel Physician Signature:
Review Date *(dd-mmm-yyyy)*:

INSTRUCTION TO PANEL PHYSICIANS:

The Panel Physician should request the applicant to submit a set of 3 sputum specimens in the following scenarios:

1. If any of the CXR findings under A or B is identified.
2. If any of the CXR findings under C is identified and the applicant shows any signs and symptoms suggestive of pulmonary TB, irrespective of the duration.
3. If any of the CXR findings under D, E or Normal CXR finding is identified and the applicant shows typical signs and symptoms suggestive of pulmonary TB, e.g., prolonged cough for 2 weeks or more.

Annex K. Referral letter for TB treatment

JAPAN PRE-ENTRY TUBERCULOSIS SCREENING PROGRAMME

Referral Letter for TB Treatment

Photo	BIOGRAPHIC INFORMATION	
	Reference ID:	
	Applicant's Name: *[First Name(s)]* *[Middle Name(s)]* *[Family Name]*	
	Date of Birth *(dd-mmm-yyyy):*	Sex: ☐ Male ☐ Female ☐ Others
	Nationality:	
	Passport Number:	

Dear Ms/Mr/Dr,

I refer to you the above-mentioned Applicant who underwent tuberculosis testing as part of application process of the Certificate of Eligibility / Visa for mid- to long-stay in Japan and was found to have active infectious / non-infectious TB. We would appreciate your assistance in providing anti-TB therapy for this patient. Please find related documents and information attached.

ATTACHMENTS: *(Tick as appropriate)*	
1. TB Treatment Certificate form *(Upon completion of TB treatment, please fill out the form and provide it to the patient)*	☐
2. Medical exam form with photo for identification	☐
3. Sputum results	☐
4. CXR report	☐
5. CXR image in CD-ROM	☐
6. DST results	☐
7. Any other relevant information:	☐

Please notify us once treatment has begun, and in the event of treatment failure, default, or completion, kindly fill out the TB Treatment Certificate, which is required for future applications for the Certificate of Eligibility/Visa for Japan. Thank you for your kind cooperation.

Sincerely,

PANEL PHYSICIAN		
Physician Name:	Signature:	Date *(dd-mmm-yyyy)*:
Name of Panel Clinic	Address:	Tel: