2020(令和2)年度厚生労働行政推進調査事業費補助金
(新興・再興感染症及び予防接種政策推進研究事業)

# わが国による入国前結核健診事業精度保証のガイドラインの策定に資する研究（１９HA２００１）

2020年(令和2)度総括研究報告書

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研究要旨：
**[研究目的]** 研究の目的は、わが国で導入する入国前結核健診事業精度保証のあり方について検討し、精度の確保された健診事業が実施されるための「日本版入国前結核健診医療機関査察の手引き」を策定するとともに、「日本版入国前結核健診事業精度保証のガイドライン（案)」をとりまとめることである。
**[研究方法]** 本年度は、昨年度実施した研究により作成された上記２つの成果物のうち「日本版入国前結核健診医療機関査察の手引き」のチェックリスト内容について結核研究所内関係者で検討するとともに、国内外学会で研究成果について発表する。
（倫理面への配慮）本研究においては、個人情報を取り扱うことはなく、調査対象国における入国前結核健診事業に関する情報のみの取り扱いとなるため、研究の実施経過・研究結果の発表により、個人が特定されることはない。
**[研究結果・考察]** 昨年度に作成した「日本版入国前結核健診医療機関査察の手引き（案)」内の査察チェックリスト項目について、結核研究所内関係者とともに検討し、内容の改訂を行った。また、研究結果について国内及び国外の学会で発表するとともに、学術論文に発表した。
**[結論]** 本報告書作成時点で、COVID19 感染症拡大の影響により、わが国による入国前結核健診事業の具体的な開始時期は未定である。入国前結核健診事業が開始となった後の円滑な運営に資するため、今後も厚生労働省他の関係機関担当者間で、本研究によって作成した「入国前結核健診医療機関査察の手引き（案)」と「入国前結核健診事業精度保証体制のガイドライン（案)」内容の更なる検討と改訂を行う必要がある。

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## A. 研究背景

結核は、毎年世界で1000万人以上の患者が発生し、約170万人が死亡している世界最大級の感染症である。わが国の2018年における人口10万対年間新登録結核者数(年間新結核患者登録率)は12.3人であり、近年減少傾向は続いているものの、減少スピードは鈍化している。わが国における年間の結核登録者の傾向としては、65歳以上の高齢者が3分の2を占めていることや、都市部に偏在しつつあることに加えて、外国生まれ結核患者の著しい増加があげられる。2018年の新登録外国生まれ結核患者は1,667人で、10年前と比較して約2倍に増加している。外国生まれ新登録結核患者が全新登録結核患者に占める割合はいまだ1割程であるが、その割合は若年層で特に大きく、20～29歳においては約70%に達している。

多くの欧米諸国においては、外国生まれ新登録結核患者が全新登録結核患者の中で占める割合が50%を超えており、外国生まれ結核患者対策をいかに効率的に実施するかが大きな課題となっている。そのような中、いくつかの工業先進国が、移民を対象とする入国前結核健診事業を導入し、この事業が入国後の移民における結核患者数を減少させるために有用であることが報告されている。一方、入国前結核健診事業の様々な過程において不正のリスクがあるため、その予防策を徹底することや、医療資源の限られる国における結核健診事業に必要とされる医療レベルを確保するために、精度保証体制を確立することが、入国前結核健診事業の成功を左右する要である。

わが国でも入国前結核健診事業導入が決定されているが、この事業に関する精度保証体制は未確立であり、早急に本事業の枠組みに適合した、効果的かつ効率的な精度保証体制確立に向けた方針を固める必要がある。

## B. 研究目的

本研究の目的は、わが国で導入する入国前結核健診事業精度保証のあり方について検討し、精度の確保された健診事業が実施されるための「日本版入国前結核健診医療機関査察の手引き」を策定するとともに、「日本版入国前結核健診事業精度保証のガイドライン（案）」をとりまとめることである。

## C. 研究方法（2年目）

昨年度実施した研究により作成された上記2つの成果物のうち「日本版入国前結核健診医療機関査察の手引き」のチェックリスト内容について結核研究所内関係者で検討するとともに、国内外学会で研究成果について発表する。

## D. 研究結果・考察

昨年度に作成した「日本版入国前結核健診医療機関査察の手引き（案）」内の査察チェックリスト項目について、結核研究所内関係者とともに検討し、内容の改訂を行った（添付資料１）。また、研究結果について国内及び国外の学会で発表するとともに、学術論文に発表した。

## E. 結論

COVID19感染症拡大の影響により、わが国による入国前結核健診事業の具体的な開始時期は未定である。入国前結核健診事業が開始となった後の円滑な運営に資するため、今後も厚生労働省他の関係機関関係者間で、本研究によって作成した「入国前結核健診医療機関査察の手引き（案）」と「入国前結核健診事業精度保証体制のガイドライン（案）」内容の更なる検討と改訂を行う必要がある。

## F. 健康危険情報

なし。

## G. 研究発表

１． 論文発表

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２． 学会発表

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（３） 河津里沙、大角晃弘、内村和広、濱口由子、吉山崇、高木明子. 入国前結核健診における健診実施医療機関の現地査察に関する検討. グローバルヘルス合同大会 2020, 大阪, 2020 年 11 月 2 日. 一般口演 抄録 O14-02 p.31.

（４） 河津里沙、大角晃弘、内村和広. 入国前結核健診対象国出生患者の臨床・疫学的な属性について. 第 178 回日本結核・非結核抗酸菌症学会関東支部学会、2020 年 9 月 12 日. 一般口演. 演題番号 71. 抄録 p.32.

（５） Kawatsu L, Uchimura K, Hamaguchi Y, Ohkado A, and Yoshiyama T. Characteristics of migrants to Japan with TB and implications for pre-migration TB screening. The 16th World Conference on Public Health 2020.10. No. DP4.

## H. 知的財産権の出願・登録状況

1. 特許取得

なし。

2. 実用新案登録

なし。

3. その他

なし。

## I. 健康危険情報

なし。

J. 添付資料１
日本の入国前結核健診医療機関査察チェックリスト（案）（2020 年 7 月改訂版）

# Quality Assessment for Japan Pre-Entry Tuberculosis Screening Programme

Tool for Panel Site Evaluation (DRAFT ver. 1.2)
2020.07.15

COMPONENTS
1. Facilities, infrastructure and general client services
2. Personnel
3. Identity verification and document security
4. Past medical history and physical examination
5. Radiography
6. Sputum collection
7. TB smear
8. TB culture

Instructions:
1) Enter Y for Yes, N for No, NE for not evaluated, NA for not applicable or number
2) In principle, all the items must be seen in person, and not simply asked

| | |
|---|---|
| **Country** | **City** |
| **Clinic name** **tele-radiography available** □ | |
| **Laboratory name (if applicable)** | |
| **Other countries to which the clinic conduct TB screening, if any** | |
| **Approx. number of examinations for Japan per year** | |
| **Date of visit** | **Date of prior visit (if applicable)** |
| **Name(s) of assessor(s)** | |
| **Name(s) of lead panel physician** | |
| **Name(s) of radiologist(s)** | |
| **Name(s) of laboratory director(s)** | |

## 1) Facilities, infrastructure and general client services

| Item no. | Description | Y/N/NE/NA or number | Comments |
|---|---|---|---|
| | Clean and tidy facility | | |
| | Adequate lighting | | |
| | Waiting room of sufficient capacity | | |
| | Handwashing facility with soap/sanitizer | | |
| | Clean and well-sized examination gowns | | |
| | Changing area and secure lockers | | |
| | Chaperon available when requested | | |
| | IEC materials in appropriate language(s) readily available (by Japanese government) | | |
| | Client appointment processed within 5 days | | |
| | Displays transparent fee structure and itemized receipt | | |
| | Communicates effectively in English | | |
| | Most updated TI (JPETS) and SOP (general - OPD) readily available | | |

## 2) Personnel

| Item no. | Description | Y/N/NE/NA or number | Comments |
|---|---|---|---|
| | No. panel physicians at site | | |
| | No. panel physicians assessed this visit | | |
| | No. panel physicians with two years or more experience in pre-entry TB screening | | |
| | No. panel physicians who have attended IPPA or other similar training | | |
| | No. radiologists at site | | |
| | CV, license status/legal right to practice for all physicians and radiologists readily available | | |
| | All staff are familiar with the latest JPET TI | | |
| | Good communication with the local health authority | | NTP、local health dept との連絡打ち合わせ等？ |
| | Referral support available (paediatrician) | | |
| | Referral support available (chest physician) | | |
| | Referral support available (oncologist) | | |
| | Referral support available (OB-GY) | | |
| | Referral support available (other specialists) | | |

## 3) Identity verification and document security

| Item no. | Description | Y/N/NE/NA or number | Comments |
|---|---|---|---|
| | Identity of client is verified at reception by passport photograph (or other official document with facial photo) and signature | | |
| | Has other ID been previously used for verification? If yes, give details. | | |
| | Client forms, records and CXRs are kept in secure document storage | | |
| | Client forms, and records are kept electronically | | |
| | Client forms, records and CXRs are kept for XX years | | |

### 4) Past medical history and physical examination

| Item no. | Description | Y/N/NE/NA or number | Comments |
|---|---|---|---|
| | Clients disrobed appropriately | | |
| | Vital sign measurement | | |
| | Past history acquired | | |
| | Pulmonary examination | | |
| | Neck examination | | |
| | TB symptoms asked | | |

### 5) Radiography

| Item no. | Description | Y/N/NE/NA or number | Comments |
|---|---|---|---|
| a. Fraud prevention(KQ: Key question) | | | |
| | Identity of client is verified by comparing facial appearance and photograph of XXXX | | |
| | Patient ID entry and film labelling is correct and appropriate | | |
| b. Process quality | | | |
| | Explains about risks for **pregnant women**(KQ) | | |
| | Explains procedures to client(KQ) | | |
| | Clothing and accessories removed as appropriate, with gowns provided(KQ) | | |
| | Appropriate lead shielding provided and used (for men and non-pregnant women, and adult sized children) | | |
| | Appropriate lead shielding provided and used (for pregnant women) (e.g., double shielding through minimizing exposure area and covering abdominal~pelvic site with a lead shield) (KQ) | | |
| | Appropriate lead shielding provided and used (for children) (KQ) | | |
| | Adequate beam distance (e.g., 140~200cm) (KQ) | | 200cm がベター。距離があった方が被爆が少ない。 |
| | Appropriate focal spot size used (i.e., small focal spot size used, i.e., =<1~1.3 mm) (KQ) | | 大きいと焦点があわず機器に負担がかかる。0.6 か 1.2mm で設定。胸部の場合は 0.6mm にセット |
| | Appropriate current set? (e.g., Automatically set as 100mA (200mA or less) when set to small focal spot size) (KQ) | | |
| | Appropriate exposure time set (e.g., auto exposure time mode used? If manual mode, <30~50msec?) (KQ) | | 照射時間 0.03-0.05 秒 |
| | Appropriate mAs set? (e.g., =<4mAs) (KQ) | | 体厚を測定して計算する（オートマ・マニュアル)。<br>装置の容量によるので難しい？ |
| | Appropriate voltage set? (e.g., 100~140kV) (KQ) | | だいたい 125kV にセット。<br>縦隔なら up。肺は透過率が良いので down。 |
| | Correct X-ray exposure field size (as minimum required size for CXP) (KQ) | | |
| | Grid is used? If yes, what is the grid ratio? (e.g., >=8~12:1), what is the strip density? (i.e., >=40~50 | | 原則として Yes。12:1 か 10:1 アルミ板の枚数のことを指 |

| | | | |
|---|---|---|---|
| | lines per cm) | | す。<br>focused・paralleled どちらでも OK。Strip density は複十字では 60<br>胸部用のグリッド↓<br>  |
| | Generator type? (e.g., inverter type or not?) | | ビームを生成するデバイス。通常は inverter だが古いものは mono phase(single phase)。 |
| | Appropriate geometrical X-ray beam alignment with detector? (e.g., appropriate correct light collimation positioning) | | 設置時にあわせ、後は半年に一回業者のメンテナンス。beam の精度が落ちると画像の陰影が偏ってくる。 |
| | Patient remains until image quality is checked? (KQ) | | |
| | Urgent findings are immediately notified to Panel Physicians (PP) (KQ) | | |
| c) Image quality　（フィルム現物をみせてもらう）　医師がいない場合は、写真をデジカメでとって遠隔で評価。5 枚程度連続して | | | |
| | Side marker correctly present(KQ) | | 左右立位か臥位または腹臥位か仰臥位かを判断するマーカーを張って一緒に撮影するか、デバイスで入力する方法がある。<br>  |
| | Image includes entire thorax(KQ) | | |
| | Correct patient positioning(KQ) | | |
| | Full inspiration (e.g., the posterior 10th rib is visible above the diaphragm) (KQ) | | |
| | Artifacts absent(KQ) | | |
| | Appropriate sharpness *1 | | 画像を作る時に変更する。<br>院内のフィルム評価会の基準があって A 評価の写真を standard にデフォルト設定して比べる。<br>デバイス毎のデフォルト設定もオファーされる。 |
| | Adequate contrast *2 | | |
| | Appropriate penetration / density | | |
| | Digital re-take rate data available, if yes, give details *3 (KQ) | | デジタルではほとんどリテイクがない（一桁程度）のでモニタリングはしていない。 |
| | | | |

| | | | |
|---|---|---|---|
| | | | |
| d) Supplies and equipment maintenance(KQ) | | | |
| If CR used, | | | |
| | CR cassettes stored upright to prevent damage | | 上向き保管で（ノッチのへたりの原因となるため）。  |
| | CR cassette and plate cleaned regularly (e.g., once per week or per two weeks) | | 画像を見ることで確認。 |
| | CR plate inspection and quality assessment done | | 経年変化で変色（黄色）<br>写真をとる。 |
| If DDR used, | | | |
| | DDR sensor calibration needed to control exposure | | Calibration とは感度調整のこと。メーカーが数年に一回のメンテナンス。メンテナンスの契約内容の確認。y/n, 頻度。 |
| CXR machine | | | |
| | X-ray machine (generator) checked annually and certified, if yes, by whom? | | 撮影する機械のメンテナンス。<br>地元の技師？会社？メーカ？ |
| e) Reading, reporting, and data saving | | | |
| | Image is read within the same day(KQ)? If no, how long does it take? | | 2 日以内 |
| | At least 1 MP monitor located in a quiet area, and checked monthly using QC monitor test pattern - looking at geometric distortions, luminance, reflection, noise and glare. | | MP：メガピクセル<br>2MP 胸部（3MP が最適）<br>高精細モニターの画面のちらつきや輝度の異常がないか y/n。<br>半年から１年に１回 calibration にて輝度・コントラストを確認する。<br>確認方法はデバイスによる<br>１）ソフトウェア<br>２）モニター付属の設定ボタン<br>３）別のデバイスを画面に取り付ける |
| | Dictated report used?<br><br>書いているところを見せてもらう | | 結果の記載は放射線科医師本人が行うこと（口頭での結果報告を、他の人が代理で記載しないこと） |
| | No. of reading radiologists per day during opening hours (including off-site) | | |
| | Data compression ratio --- reversible or irreversible? If irreversible, less than 1/10 compression ratio? (i.e., 1/2 ~ 1/4 compression ratio) | | データの保存方法。<br>圧縮方法が可逆的 or 非可逆的<br>可逆的がベターだがサーバー |

| | | | |
|---|---|---|---|
| | | | の容量による。 |
| | | | |
| f) Safety(KQ) | | | |
| | Walls and doors have appropriate radiation shielding | | 半年に 1 回漏洩線量を測定。 |
| | Red light to alert during exposure | | デバイスに電源を入れたら使用中ランプが点灯。 |
| | Radiological technologist shielded during exposure | | |
| | Badge reading documentation | | 線量バッジを頭部と胸部（女性なら腹部）の 2 カ所に装着。<br>毎月業者に送ると測定結果が返ってくる。 |
| | Annual lead shield check whether crack exists? If yes, how? | | 透視で(目視のみでもやらないよりは良い)。 |
| | Radiation safety officer designated, if yes, who is it? | | 1 人。 |
| | Annual health check for RT | | 年 2 回。 |

Notes:
*1: Reference for “**Sharpness**” (TBCTA Handbook, 2007):
“Good”: the pulmonary vessels are clearly visible in the entire left lung fields, especially around the left part of the cardiac shadow.
“Fair”: the pulmonary vessels are clearly visible in the upper left lung fields, but obscure around the left part of the cardiac shadow.
“Poor”: the pulmonary vessels are obscure in the entire left lung fields.
*2: Reference for “**Contrast**” (TBCTA Handbook, 2007):
1) Lung field:
“Good”: the pulmonary vessels can be easily traced at the lung fields.
“Fair”: not good but not poor.
“Poor”: it is impossible to trace the pulmonary vessels in the lung fields.
2) Lung periphery:
“Good”: the pulmonary vessels can be easily traced to lung periphery, and also the border line between the chest wall and the lung field is clearly visible.
“Fair”: not good but not poor.
“Poor”: it is impossible to trace the pulmonary vessels in the peripheral part of the lung, or the border line between the chest wall and the lung field is obscure.
3) Mediastinum:
“Good”: the trachea and both main bronchi are clearly visible.
“Fair”: not good but not poor.
“Poor”: it is impossible to identify the trachea or main bronchus.
4) Cardiac shadow:
“Good”: the pulmonary vessels can be easily traced behind the cardiac shadow.
“Fair”: not good but not poor.
“Poor”: it is impossible to trace the pulmonary vessels behind the cardiac shadow.
*3: 4-8% and investigate if 10% for adults, 3-5% and investigate if 7% for children (by US CDC)

## 6) Sputum collection

Collection facility:_____(circle one: panel site /lab /other)

| Item no. | Description | Y/N/NE/NA or number | Comments |
|---|---|---|---|
| a. Fraud prevention | | | |
| | Identity of client is verified by comparing facial appearance and photograph of XXXX | | |
| | Coded labelling for specimens (no personal identifiers) | | |
| | Uses difficult-to-remove label on the cup (not lid) | | |
| | Supervised collection with adequate and trained staff | | |
| | Restricted access to sputum collection area (companies not allowed in principle) | | |
| | Takes measures to minimize specimen substitution/contamination (bags not allowed or closely monitored) | | |
| b. Facilities and infrastructure: sputum collection area | | | |
| | Clean and tidy | | |
| | Inside: negative pressure | | |
| | Inside: observation window | | |
| | Inside: adequate air exchange/flow takes place (e.g., 100 air cycles per hr.) | | Give detail, use tissue<br>換気回数は 100 回/h 程度。相対的陰圧を要確認。 |
| | Inside: UV light | | 換気されていれば UV はマストではない。 |
| | Outside: well ventilated | | |
| | Outside: exposed to UV sunlight | | 写真とる。 |
| | Adequate equipment of the staff: N95 masks | | |
| | Adequate equipment of the staff: Gloves | | |
| | Adequate equipment used: Tissues | | |
| | Adequate equipment used: Fridge or cool box | | |
| | Adequate equipment for applicants: Drinking water for rinsing mouth (preferably filtered bottled water, if not, no breakfast taken before the sputum collection) | | |
| | Adequate equipment: Sink | | |
| | Adequate equipment: Aerosol nebulizer using 3%saline | | 3%生理食塩水。 |
| | Instructive illustration/video displaced in collection area | | |
| c. Collection method　実際のプロセスを見れるように調整が必要 | | | |
| | Latest SOP on sputum collection available and understood by staff | | |
| | Provides clear counselling/instruction to the applicants | | |
| | Collects three specimens over three consecutive working days | | |
| | Collects early morning fasting specimens under direct observation | | |
| | Uses clean, disposable, and clear container | | |
| | Uses container 25 ml – 50 ml in volume | | |
| | Uses contained with wide mouth screw-cap | | |
| d. Specimen quality | | | |
| 1 | Quality is visually checked by trained technician before client leaves | | y/n |
| 2 | Rejects specimen if inferior quality, i.e., purely saliva-like specimen | | 現場で reject するために上記を行っているか。 |
| 3 | Obtains at least 5 ml of specimen | | |

| | | | |
|---|---|---|---|
| 4 | Sputum quality is classified according to Miller & Jones sputum classification | | 表現を変える。淡の性状を評価し記録しているか（通常はラボで評価するもの）。 |
| | Refrigerates or transports specimen to laboratory in timely manner, e.g., within one hour unless refrigerated, within one day if refrigerated | | |
| | Monitors and keeps record of temperature of refrigierator/ cool box | | |
| e. Safety | | | |
| | Risk of contamination/infection minimized by limiting access to collection area | | |
| | Ensures continuous ventilation during opening hours | | |
| | Technicians wear N95 mask and gloves | | |
| | Client provided tissues | | |
| | Contaminated materials are appropriately disposed (dedicated trash bag and receptable with lid to discard infectious and contaminated biological materials) | | |
| | Maintain adequate separation between clients | | |

## 7) TB smear

Testing Laboratory:_____ Country:_____

Laboratory in-Charge:_____ Date of filling out:_____

| Item no. | Description | Y/N/NE/NA or number | Comments >>> |
|---|---|---|---|
| a. Fraud prevention | | | |
| | Labels slides permanently with ID number | | |
| | Uses result form per applicant, and labels form with ID number | | |
| | Storage period of smear slides: at least _____ month / year for all slides | | |
| | Stores results in logbook/computer for at least 2 years | | |
| b. Facilities and infrastructure: microscopy work area | | | |
| | Separate area for TB work | | |
| | Microscope area: Clean and tidy | | |
| | Microscope area: Adequate lighting and seating | | |
| | Microscope area: Vibration and distraction-free | | |
| | Method: ☐ Light microscope ☐ Fluorescent microscope | | |
| | Microscope: Clean body and lens | | |
| | Microscope: Mechanical stage moves freely in both axes | | |
| | Microscope: Magnification: _____ x for reading | | |
| | Smearing and staining area: Clean and tidy | | |
| | Smearing area: Biosafety cabinet (BSC) □ None □ Class I □ Class IIa □ Class IIb □ Class III □ Other _____ | | |
| | Type of specimen for smearing: □ Non-centrifuge specimen □ Centrifuge specimen (concentration method used) | | |
| | Smearing area: Explosion-free centrifuge, if centrifuge specimen used for smear microscopy | | |
| c. Smearing and stain/reagent preparation | | | |
| | Validated SOP: □ None □ Available in the local language □ Available in English □ Other _____ | | |
| | Smearing and Staining SOP understood by all staff | | |
| | Smearing and Staining SOP is displayed in the room | | |
| | Uses for smearing: □ New clean slides □ Smear size (1 x 2 cm) | | |

| | | | |
|---|---|---|---|
| | □ Appropriate sterile applicator (e.g., stick, loop or pipet) | | |
| | Air dried slides | | |
| | Fixed slides with flame, slide warmer or ethanol | | |
| | Uses for staining:<br>□ Reagent-grade stains (□ Commercial □ on-site prepared)<br>□ Clear stain bottles □ Stains without precipitates<br>□ Stains stored at room temperature<br>□ Stains stored away from bright light or by using shading bottle<br>□ On-site prepared stains within 6 months of preparing<br>□ Commercial stains within expiration and 6 months of opening | | |
| | Uses approved staining procedures in line with SOP | | |
| | Uses appropriate staining times measured by timer | | |
| | Includes control slides in each staining batch | | |
| d. Microscopy and Reading | | | |
| | Validated SOP: □ None □ Available in the local language<br>□ Available in English □ Other _____ | | |
| | Microscopy SOP understood by all staff | | |
| | Light microscope used: □ Use clean oil<br>□ Reads 300 fields by slide □ Reads each slide for 15 min<br>□ Remove oil from microscopy and slide with xylene/kerosene | | |
| | Fluorescent microscope used:<br>□ Reads 30 fields by slide □ Reads each slide for 5 min<br>□ Keep logbook of cumulative time lap is on | | |
| | Reporting with internationally accepted grating system (e.g., WHO/IUATLD or CDC-US) | | |
| | Uses: □ positive control smear □ negative control smear | | |
| | Perform second reading: □ on all positive slides<br>□ on a sample of negative slides | | |
| | Results available within 24 hours | | |
| | Keeps and monitors statistics of numbers of specimens and positives using quality performance indicators* as quality assurance (QA) activities *; e.g., GLI Practical Guide to Tb Laboratory Strengthening (http://www.stoptb.org/wg/gli/assets/documents/GLI_practical_guide.pdf) or local NTP laboratory guideline | | |
| | Performs external quality assurance (EQA): ☐ Yes ☐ No<br>If yes, who conducts: ☐ National reference laboratory (NRL)<br>☐ Other _____<br>how often: ☐ Quarterly ☐ Annually<br>☐ Other _____<br>Method: ☐ On-site supervision ☐ Proficiency testing<br>☐ Blinded re-checking<br>☐ Other _____ | | |
| | No of specimens processed per technician:<br>each day _____, each week _____ | | |
| e. Safety | | | |
| | Restricted access to laboratory | | |
| | Well ventilated airflow through laboratory from less contaminated to more contaminated area | | |
| | Uses regularly certified BSC | | |
| | Wears appropriate protective clothing and equipment | | |
| | Appropriate disposal of contaminated material | | |
| | Spill kit available | | |
| | Has continuous surface bench | | |

| | | | |
|---|---|---|---|
| | Performs administrative laboratory work in separate room from processing | | |
| | Provides health check for lab personnel: ☐ Yes ☐ No<br>If yes, method and frequency (per year): ☐ CXR, _____ time<br>☐ TST/IGRA, _____ time ☐ Other _____, _____ time | | |
| | Assign safety officer: ☐ Yes _____ ☐ No | | |

## 9) TB culture

Laboratory:_____
District/Country:_____
Laboratory in-Charge:_____ Date of filling out:_____

| Item no. | Description | Y/N/NE/NA or number | Comments |
|---|---|---|---|
| a. Fraud prevention | | | |
| | Culture tubes barcoded with printed labels or other ID methods used | | |
| | Uses result form per applicant, and labels form with ID number instead of name of applicant | | |
| | Uses computerized tracking system | | |
| b. Facilities and infrastructure: culture work area | | | |
| | Year of laboratory established: _____<br>Year of culture work started: _____ for solid, _____ for liquid | | |
| | Liquid culture method and No of instruments:<br>□ MGIT960 ____ □ BACTEC460 ____ □ Manual MGIT ____<br>□ MB/BacT ____ □ Other _____<br>No of liquid cultures (tubes) per month: _____ | | |
| | Solid culture media:<br>□ Löwenstein–Jensen (□ In-house □ Commercial)<br>□ Ogawa (□ In-house □ Commercial)<br>□ Other _____ (□ In-house □ Commercial)<br>No of incubators for solid culture: _____<br>No of solid cultures (tubes) per month: _____ | | |
| | Clean and tidy | | |
| | Incubator with temperature display | | |
| | Monitoring thermometer inside incubator | | |
| | Temperature monitored and recorded daily with monitoring thermometer | | |
| | Type of biosafety level (BSL) for culture and DST work area:<br>□ BSL ____ □ Other _____ | | |
| | Type and No of Biosafety cabinet (BSC) for culture and DST:<br>□ Class I ___ □ Class IIa ___ □ Class IIb ___ □ Class III ___<br>□ Other _____ | | |
| | Correct BSC position, i.e., BSCs should be sited away from thoroughfares and out of cross-currents from doorways and air-inlet systems. | | |
| | Autoclave accessible from negative pressure area | | |
| | Refrigerated explosion-free centrifuge | | |
| c. Process control: culture | | | |
| | Validated SOP: □ None □ Available in the local language<br>□ Available in English □ Other _____ | | |
| | Culture SOP understood by all staff | | |
| | Coded specimen labelling | | |
| | Type and No of cultures conducted per specimen, e.g., 1 (tube) liquid and 2 solid:<br>1st_____, 2nd_____, 3rd_____ | | |

| | | | |
|---|---|---|---|
| | All specimens cultured are also smeared from sediment directly | | |
| | Positive and negative control specimens included regularly | | |
| | Standardised register of results maintained | | |
| | Identification tests: □ Nitrate □ Catalase □ Niacin<br>□ AFB cording □ Capilia □ GenProbe □ Other _____<br>Register of species identification maintained: □ Yes □ No | | |
| | Positive results notified directly to requesting personnel | | |
| | MTB isolates stored in locked freezer long-term | | |
| | Keeps and monitors statistics of numbers of specimens, positives, culture recovery rate, contamination rate, and so on using quality performance indicators* as quality assurance (QA) activities<br>*e.g., GLI Practical Guide to TB Laboratory Strengthening (http://www.stoptb.org/wg/gli/assets/documents/GLI_practical_guide.pdf) or local NTP laboratory guideline | | |
| | Routine lab servicing occurs outside processing times | | |
| d. Decontamination method for culture | | | |
| | Method: □ NALC-NaOH □ Na-L-Cysteine □ Petroff<br>□ Other _____<br>Final concentration of decontamination agent: _____<br>Time of exposure to decontamination agent: _____<br>Ensures exposure time with timer: □ Yes □ No<br>Volume of pH 6.8 buffer used to neutralize decontamination agent: _____ volume of specimen (sputum)<br>If centrifuge, time and speed: _____ g, _____ min<br>No (max.) of samples proceed per batch: _____ for Liquid<br>No (max.) of samples proceed per batch: _____ for Solid | | |
| | Decontamination agent added slowly without container contact and vortex mixed | | |
| | Each Decontamination buffer batch tested for NTM contamination | | |
| | Centrifuge buckets handled in BSC | | |
| | Supernatant decanted into splash-proof container that has sufficient volume capacity | | |
| | Leftover sediment stored until final culture result is available | | |
| | No of culture specimens processed per technician:<br>each day _____, each week _____<br>No of culture specimens processed at laboratory:<br>each day _____, each week _____ | | |
| e. Solid culture | | | |
| | Quality-assured media used | | |
| | Media incubated prior to use | | |
| | Incubator trays labelled with date of inoculation | | |
| | Tubes stored as horizontal inoculation area in incubator for first 24 - 72 hours to ensure the inoculation surface becomes dry | | |
| | Tube caps loose during above period | | |
| | Contamination check conducted at 48 hours, culture should continue if contaminated partially | | |
| | Recognizes contamination appearance, including media colour | | |

| | | | |
|---|---|---|---|
| | ZN staining conducted on all growth resembling mycobacteria | | |
| | Weekly readings of all tubes up to 8 weeks of incubation | | |
| | Negative results also recorded on register | | |
| | Positive isolates stored until final results available | | |
| f. Liquid culture | | | |
| | Daily check of temperature and test indicators | | |
| | Monthly air filter cleaning | | |
| | Yearly service by BD technicians or authorized distributors | | |
| | Regular data back-up | | |
| | Inoculum tubes wiped with alcohol before placing in machine | | |
| | Negative tubes checked visually for growth before disposal | | |
| | Z-N staining conducted on all positive tubes | | |
| | Positive tubes kept in incubator for 1-2 days to concentrate | | |
| | Samples correctly extracted from positive growth tubes | | |
| g. Safety | | | |
| | Restricted access to laboratory | | |
| | Well ventilated airflow through laboratory from less contaminated to more contaminated area | | |
| | Negative pressure work area with air pressure differential at least -12.5 Pa | | |
| | Negative pressure monitored with alert system | | |
| | Negative pressure anteroom | | |
| | SOPs for BSC understood and followed | | |
| | Uses regularly certified BSC | | |
| | Adequate PPE available and used | | |
| | Mask fit testing undertaken at least when technician starts her/his work | | |
| | Well ventilated airflow through laboratory | | |
| | Appropriate disposal of contaminated material | | |
| | All waste autoclaved prior to disposal | | |
| | Has continuous surface bench | | |
| | Spill kit available | | |
| | Performs administrative laboratory work in separate room from processing | | |
| | Provides health check for lab personnel: □ Yes □ No<br>If yes, method and frequency (per year): □ CXR, _____ time<br>□ TST/IGRA, _____ time □ Other _____, _____ time | | |
| | Assign safety officer: □ Yes _____ □ No | | |