

## Recommendations for the microbiological diagnosis of *Mycobacterium tuberculosis* (TB) infection

Produced by the Greater Manchester Microbiology Network Advisory Group

### 1. Laboratory testing

**Good laboratory practice requires CPA accreditation for the Mycobacterium diagnostic services provided.**

#### 1.1 Microscopy

- At least a six day service should be available for the routine processing of samples for acid-fast bacilli (AFBs).
- Microscopy results should be available within one working day.
- A molecular test, either Nucleic Acid Amplification Test (NAAT) or hybridisation gene probe, for *M. tuberculosis* should be performed on all samples **positive** on microscopy for acid-fast bacilli (AFBs) that are from previously undiagnosed patients (first specimen from a new case). The result should be available within three working days of receipt of the sample by the testing site laboratory.
- A molecular test to detect rifampicin resistance should be performed on all samples from new patients that are **positive** on microscopy for AFBs.
- Currently molecular tests are not recommended for direct testing of specimens that are AFB negative because of the low sensitivity of the tests with specimens containing small numbers of organisms. However there may be rare exceptions when this test is requested by a Respiratory Physician to support a clinical diagnosis eg. a patient with a high risk of drug resistance, who is of East European origin and/or a previous incomplete therapy.
- All samples processed for TB diagnosis should be cultured (whether positive or negative on microscopy).
- AFB microscopy should not be provided out of core routine hours.

**Note: Any changes to these recommendations for microscopy because of local service requirements should only be introduced following a risk assessment of the procedures.**

#### 1.2 Culture

- Samples sent to the microbiology laboratory for TB culture should be processed and cultured within one working day of receipt in the local laboratory.
- At least a six day service should be available for the routine processing of samples for TB culture.

- All samples for TB culture should be inoculated into automated liquid culture media.
- At least one sample of the specimen type for each patient should be inoculated onto Lowenstein Jensen (LJ) solid medium.
- AFB microscopy should be performed within one working day on bottles which flag **positive** on the automated liquid culture system.
- Molecular tests for confirmation of Mycobacterium species and to detect rifampicin resistance should be performed on cultures which are **AFB positive** on microscopy and are from previously undiagnosed patients. ( first culture positive specimen from a new case)
- Samples which flag **positive** on automated culture should be sub-cultured onto chocolate agar/blood agar. The laboratory should have clear instructions for the interpretation of AFB positive specimens and chocolate agar/blood agar culture results.

**Note: Additional molecular testing may be necessary on a subsequent specimen from a patient when possible treatment failure is suspected. Retesting by molecular tests should be done following discussion with the clinical team.**

## **2. Testing of clinically relevant specimens**

### **2.1 Microscopy**

The following specimen types should receive routine microscopy for AFBs whether requested or not:

- Broncho-alveolar lavages (BALs)

**Note: Sputum specimens are only examined by microscopy when requested.**

### **2.2 Culture**

The following specimen types should receive culture for TB whether requested or not:

- Broncho-alveolar lavages (BALs)
- Lymph nodes / lymph node aspirates
- Spinal biopsy
- Pleural biopsy

**NB:** See NICE TB recommendations 1.1.2.2. It may be appropriate to append a comment such as “sample not cultured for TB” on additional samples listed by NICE if culture is not requested and not routinely performed.

- Investigation of urine for *Mycobacterium species* requires that three consecutive early morning samples are submitted.

### **3. Communicating positive results**

#### **3.1 Microscopy**

Positive results from new cases should be reported by telephone to the clinical team, the local TB nurse service and to the Greater Manchester Health Protection Unit (GMHPU) within one working day of the result becoming available.

#### **3.2 Rifampicin resistance**

A positive molecular test indicating rifampicin resistance should be reported to the clinical team, the local TB nurse service and the GMHPU within one working day of the result becoming available.

#### **3.3 Culture**

Report any new Mycobacterium culture positive result from a previously undiagnosed patient, by telephone, to the clinical team and the local TB nurse service within one working day. Report any new Mycobacterium isolate confirmed as MTB complex by molecular tests or likely to be MTB complex based on morphology and/or clinical presentation (while awaiting the result of molecular confirmation) to the GMHPU within one working day.

#### **3.4 Antimicrobial Drug Susceptibility Testing**

Any drug resistances should be telephoned to the clinical team within one working day of the results being available, following either local testing or a report from the Mycobacterium reference laboratory. Isolates that are multi-drug resistant should be telephoned to both the clinical team and the GMHPU.

#### **3.5 Communicable Diseases Report (CDR) Reporting**

The laboratory that first isolates *M. tuberculosis* from a sample should report this to the Health Protection Agency as part of CoSURV reporting to the Communicable Diseases Report (CDR).

### **4. Reference Tests**

Send all Mycobacterium isolates from new cases to the Mycobacterium Reference Laboratory (Newcastle) for susceptibility testing and molecular typing.

**Note: It may be necessary to send additional isolates if treatment failure is suspected.**