

Guidelines for Submission of Sputum Specimens for TB Testing

A key role of the public health laboratory is to provide specialized testing for low incidence, high risk diseases such as tuberculosis (TB). This would include testing of specimens from suspect cases of tuberculosis to identify *M. tuberculosis* infections, to determine drug susceptibilities to guide treatment, and to genotype isolates to identify clusters of infections¹.

Background

Public health laboratories throughout the country perform diagnostic and reference services in support of the National Plan for elimination of TB in the United States. These services vary among states as to the levels of service provided to their clientele and the frequency for which these services are provided. This statement provides guidance to assist laboratories in the development of institutional policies to ensure proper collection and submission of sputum specimens for TB testing.

In an MMWR article dated April 15, 2005, the CDC reported on the Models of Network Collaboration in six states². The report stipulated that laboratorians and TB Control officials should work together to design a system to prioritize testing and maximize resources to obtain prompt, reliable test results. Recommended benchmarks were offered to improve laboratory TB services and TB control. The article discussed strategic planning to help jurisdictions select appropriate resources and testing algorithms to serve their population and public health system. Capacity, capability, and cost analysis are factors which must be evaluated in the maintenance and improvement of TB services.

Sputum Specimen Collection

The diagnosis of TB, management of patients with the disease, and public health TB control services rely on accurate and timely laboratory tests. Laboratory services are an essential component of effective TB control, providing key information to clinicians and public health agencies.

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Sputum Specimen Collection (continued)

Quality specimens are vital for the laboratory diagnosis of TB and sputum is the most frequent specimen collected for TB testing. Sputum is a respiratory secretion originating from deep within the lungs. Patients should be instructed on the difference between sputum and saliva or nasopharyngeal secretions and the necessity for a deep, productive cough. Sputum specimens are preferably collected under the direction of a trained health care professional.

Sputum induction with hypertonic saline may be necessary to obtain specimens and bronchoscopy may be considered for patients who are unable to produce sputum. Specimens should be collected in containers that are sterile, clear, plastic, and leak-proof, for example a 50-ml screw-cap centrifuge tube. Sputum collection devices and wide-mouth sterile collection containers are commercially available. It is recommended that specimens be delivered to the public health laboratory within 24 hours of collection. Samples that cannot immediately be transported to the laboratory should be refrigerated to reduce growth of contaminating endogenous respiratory organisms.

TB Testing for Initial Diagnosis

For initial diagnosis of pulmonary TB collect a series of three sputum specimens, 8-24 hours apart, at least one of which is an early morning specimen³. Optimally, specimens should be collected before drug therapy is started, as even a few days of treatment may inhibit growth and prevent isolation of *M. tuberculosis* complex (MTBC). Certain commercial nucleic acid amplification (NAA) tests cannot be performed if patients have been on anti-tuberculous therapy for seven or more days⁴.

Samples submitted for the initial diagnosis of TB should be tested by both concentrated smear and culture. Reports of AFB smears should be made to the submitting agency within 24 hours. Cultures should be held for a period of at least 6 weeks before being reported as negative.

It is recommended that NAA testing be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management and TB control activities⁵.

TB Testing for Release from Isolation

A patient may be released from isolation if the following criteria are met:

- 1.) an adequate course of chemotherapy has been administered for a minimum of two weeks and there is clinical evidence of improvement such as a decrease in symptom severity, radiographic findings indicating improvement, or other medical determination of improvement,
- 2.) sputum or bronchial secretions are free of acid fast bacilli as determined by 3 consecutive negative smear results documented from different days.

Therefore, daily acid fast smears are desirable after 2 weeks of treatment until 3 consecutive negative sputum smears have been documented³. The specimens should be collected at 8-24 hour intervals, with at least one being an early morning specimen. It is not necessary to perform cultures on these specimens.

TB Testing to Monitor the Course of Treatment

For patients whose sputum cultures are positive before treatment, the best way to measure the effectiveness of therapy is to obtain specimens for culture at least monthly until the cultures convert to negative⁶. If a sputum culture becomes contaminated, laboratories should request resubmission of a new sputum specimen to avoid gaps in patient monitoring. Patients with multidrug-resistant tuberculosis (MDR-TB) should have cultures performed monthly for the entire course of treatment. In some cases, a patient may not be able to produce a sputum specimen after two months of treatment.

Patients whose cultures have not become negative or whose symptoms do not resolve despite three months of therapy should be reevaluated for potential drug-resistant disease, as well as for potential failure to adhere to the regimen. Laboratories should consider consultation with their Regional Training and Medical Consultation Center (RTMCC).

TB Testing and Follow-up for Drug Resistance

Patients with (MDR-TB) should have cultures performed monthly for the entire course of treatment. Second line drug susceptibility testing should be considered for patients who have had prior therapy, who are contacts of patients with drug resistant TB, who have demonstrated resistance to rifampin or to other first-line drugs, or who have positive cultures after three or more months of treatment⁶. If drug susceptibility test results show resistance to rifampin or any other first line drugs, or if the patient remains symptomatic or smear/culture positive after three months, a tuberculosis medical expert should be consulted. Consider consultation with the RTMCC.

References

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