MDL Form 444 - Mycobacteriology-Drug Susceptibility Testing (DST) of MTBC (CA only) Electronic Submittal Form Instructions

Use Lab Form 444 - Mycobacteriology-Drug Susceptibility Testing (DST) of MTBC (CA only)-444 to submit culture isolates, sediment or miscellaneous specimens for Drug Susceptibility Testing (DST) or Pyrosequencing (PSQ). Use the following steps to enter information for the submission of each specimen.

NOTE: We are unable to process samples with inadequate information.

1. On page one, under "Select Test Requisition", use the pull-down menu to select Lab Form **"Mycobacteriology-Drug Susceptibility Testing (DST) of MTBC (CA only)-444"** Provide all necessary information on page 1. For directions on how to fill out the fields on page 1, please refer to the **"General Human Specimen Submission Page 1 Instructions"** document.

2. For MDL form 444, it is REQUIRED that the following field be filled in:

   2.1. **Field 34 (Material Type Modifier) is a required field.** If "Other" is selected, please specify in "Material Comments" (field #33).

3. This is the instruction for page 2 of the requisition **form 444** for submitting specimens for California patients.

   Contact information: For questions or tests that require approval, please contact the TB laboratory at 510-412-3929 (CDPHTBDST@cdph.ca.gov).

Section	Instructions
1. Sample types submitted	Please select the type of specimen you are submitting. Check one from Culture, Sediment or Miscellaneous.
2. Culture	Please select the **medium** being sent on, such as LJ, 7H10, MGIT, MP, VT, etc.
3. Sediment	A sediment sample resulting from processing a raw specimen can be sent for PSQ, not for DST or genotyping. MDL does not perform DST on a sediment sample. Please select the AFB smear result. PSQ has low sensitivity for testing smear-negative sediments. When Xpert detects MTBC and the Ct values are ≤ 28, PSQ may work. It requires approval before submitting smear-negative sediments.
4. Miscellaneous	On rare occasions, a sample other than a culture or sediment may be submitted. Check one from "**DNA**", "**Raw Specimen**" or "**Other**". Do not send without approval.
5. Test requested	• Multiple tests can be requested. • If MGIT DST is requested on a subsequent culture of the same patient, the collection dates of the two cultures should be at least three months apart.

Section	Instructions
	• If clinical conditions warrant repeat DST in less than 3 months, please provide the reasons in the "Comment" section.
6. First-line DST	First-line drugs are INH, RIF, EMB and PZA. Streptomycin is NOT a first-line drug and is not routinely tested at MDL, because it is rarely used to treat TB patient in the US.
7. Second-line DST	Second-line drugs are moxifloxacin (MFX), amikacin, capreomycin and ethionamide. • The quinolone routinely tested at MDL is MFX. It is tested at 0.25 µg/ml. If an isolate is susceptible to MFX at 0.25 µg/ml, it predicts Levofloxacin (LEV) susceptibility. If resistant to MFX at 0.25 µg/ml, it predicts LEV resistance. When LEV is requested, MFX will be tested instead.
8. Pyrosequencing (PSQ)	• Please check the boxes for reason(s) why PSQ is requested. • If the specimen type is "sediment", please make sure the volume is at least 0.5 ml. Please submit more volume especially when the smear is of low positivity. • PSQ performs well when smear result is ≥ 1+ or ≥ "few AFB". If multiple specimens are available, please submit the one with highest smear positivity and volume. If smear is "rare", it can be accepted but the test sensitivity is reduced. • Do not send smear-negative specimen unless approved. • If PSQ is requested on a subsequent sample, the collection dates must be at least 2 months apart. If less than 2 months, do not send without approval.
9. Other tests	If tests requested are not listed above, please email or call us before sending. • **Genotyping**. Isolates for genotyping should be sent by county laboratories. MDL may accept the request in rare occasions, for example, the county does not have the isolate, but MDL has. Genotyping can be performed on isolates only, not on sediments.
10. Submitting Laboratory's Findings	Enter your laboratory's findings in this section. If the Xpert®MTB/RIF test is performed, please provide the results and include the printout from the Xpert instrument containing Ct values in the specimen package.
11. Comments	Enter comments that are relevant to the requested test(s), such as a brief treatment history, suspicion of *M. bovis* or drug resistance, etc.

4. Print the completed **Lab Form 444** front and back. The document is formatted for 2-sided printing.

5. Packaging and shipping: The submitter is responsible for making sure that all samples are packaged and shipped according to the current federal and state packaging and shipping regulations for "Category A" infectious substances (such as cultures) and/or "Category B" diagnostic samples (such as sediments, raw specimens or DNA samples).

6. Additional considerations when submitting samples:

   6.1. Culture should be pure.

   6.2. Label sample tube with at least two identifiers (i.e. the patient's name, submitter lab number) and the date inoculated.

6.3. For safety, all submitted culture tubes must have a tightened screw cap secured in place using tape. For submitting liquid materials, using a tube with an O-ring cap is preferred.

6.4. Before shipment, insert the completed **Lab Form 444** and all attachments between the inner and outer shipping containers.

6.5. Follow all other submission guidelines as described in the "General Specimen Submission Instructions" and guides located on the MDL Services and Test Catalog website.