

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0643851	<b>(X3) Date Survey Completed</b>  04/24/2018
<b>Name of Provider or Supplier</b>  Microbial Diseases Laboratory (Mdl)	<b>Street Address, City, State</b>  850 Marina Bay Pkwy Ste E164, Richmond, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2006</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency testing records on April 24, 2018, the laboratory failed to perform the internal proficiency testing blind samples the in the same manner as it tests patient specimens. Findings Include: a. The laboratory performed internal PT for laboratory developed testing for molecular testing of Brucella, Botulism, and Parasitology pathogens (Ehistocytes, Giardia, Cryptospridium), due to lack of PT program availability in 2017. b. The laboratory created five blind specimens for each of the samples, and all three testing personnel tested the same five samples. For Brucella internal PT event 1, 2017: Testing Person 3. performed samples on 3/24/2017- A1, A2, A3, A4, A5 Testing Person 2. performed samples on 3/27/2017- A1, A2, A3, A4, A5 Testing Person 1. Performed samples on 3/23/2017- A1, A2, A3, A4, A5 All results were reviewed for evaluation on 03/27/2017. For Brucella internal PT event 2, 2017: Testing Person 3. performed samples on 12/01/2017- B1, B2, B3, B4, B5 Testing Person 2. performed samples on 11/14/2017- B1, B2, B3, B4, B5 Testing Person 1. Performed samples on 11/29/2017- B1, B2, B3, B4, B5 All results were received for evaluation on 12/06/2017. For Botulinum Enterotoxin Event 2, 2017: the three testing personnel were provided instructions to run three tubes to identify Clostridium Botulinum by culture, by gram</p>

stain, and by CMGS: Testing Person 3. performed samples on 12/01/2017- tube 1, tube 2, tube 3, Testing Person 2. performed samples on 11/13/2017- tube 1, tube 2, tube 3, Testing Person 1. Performed samples on 11/13/2017- tube 1, tube 2, tube 3, All results were received for evaluation on 01/04/2018 For Parasitology Stool pathogens, Event 1 of 2017: Testing Person 3. performed samples on 12/01/2017- tube 1, tube 2, tube 3, Testing Person 2. performed samples on 11/13/2017- tube 1, tube 2, tube 3, Testing Person 1. Performed samples on 11/13/2017- tube 1, tube 2, tube 3, All results were received for evaluation on 01/04/2018 c. The laboratory department Technical Supervisor affirmed this testing process by interview on, April 24, 2018 at approximately 1:47 pm, and is not the process used to test patients samples. d. The laboratory reports testing approximately 19,438 patient samples annually.

**D5473**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of control logs and interviews with the laboratory director and department staff on April 23 rd and 24th, 2018, the laboratory failed to test staining materials each day of use for intended reactivity. Findings include: a. For immunohistochemical and florescent stains the laboratory reportedly do not perform quality control testing on day of use. b. For mycology specimens, the laboratory did not perform or document quality controls to test the procedure with known positive and negative organisms. c. For biochemical testing and antimicrobial testing the laboratory did not perform or document quality control testing with know positive and negative organisms. d. These deficient practices were affirmed by interview on April 24th, 2018 at approximately 0900 am, by the laboratory Director and the laboratory staff. e. The laboratory reports performing approximately 19, 438 patient samples annually.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's personnel competency records, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the

preanalytic, analytic, and postanalytic phases of testing, and resulting of patient specimens. Findings include: a. The personnel training and competency records do not identify the duties and responsibilities of the consultants, supervisors and testing personnel in the laboratory. b. The laboratory proficiency reports are signed off by the laboratory supervisor no designation of authority provided. c. Testing personnels semi- annual and annual competency records are signed by the general supervisors, no designation of authority provided. d. This lack of documentation of authority was affirmed by interview with the laboratory director on April 24th, 2018 at approximately 3:00 pm.

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory quality control records and policy's on April 23 and, 2018, the technical supervisor failed to establish a quality control program appropriate for the testing performed. Findings include: a. The laboratory performs Mycobacterium testing. The laboratory did not perform daily QC with positive and negative organisms each time of use for immunoflorescent stains. b. The laboratory did not perform or document quality control testing for lactophenol blue staining on each day of use for mycology testing. c. The laboratory did not perform or document quality control testing in bacteriology for antimicrobial reagents each day of testing. d. This lack of documentation of quality control for acceptable levels of analytic performance throughout the testing processes were affirmed by interview of laboratory staff, records review and interview with the laboratory director on April 23 and 24th of 2018 at approximately 3:00 pm. e. The laboratory reports performing approximately 19,438 patient specimens annually.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory testing personnel training and competency records on April 23rd, 2018, the technical supervisors failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually after the first year, and when test methodology or instrumentation changes, prior to reporting patient test results, reevaluate the testing personnel to include the use of the new test methodology or instrumentation. Findings Include: a. The laboratory has multiple testing departments and staff are periodically reassigned from one to another

department. During those times of reassignment the Technical Supervisors did not perform reevaluation on the testing personnel for 6 month competency or for a general annual competency. Out of 39 testing personnel- 4 were missing an annual competency for 2016 and 4 were missing annual or initial competency for-2017. b. The laboratory director affirmed this deficient practice by interview on April 24th, 2018. c. The laboratory reports performing approximately 19,438 specimens annually.