

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0661914	(X3) Date Survey Completed 01/13/2021
Name of Provider or Supplier City Of Milwaukee Hlth Dept	Street Address, City, State 841 N Broadway, Milwaukee, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of policies and procedures and interview with a general supervisor, the laboratory has not established policies and procedures to assess general supervisor, technical supervisor, and technical consultant competency. Findings include: 1. Review of policies and procedures showed no evidence of established procedures to assess competency of general supervisors, technical supervisors, and the technical consultant in fulfilling their responsibilities. 2. Interview with a general supervisor, staff A, on January 13, 2021 at 1:15 PM confirmed the laboratory had not established procedures to assess competency for general supervisors, technical supervisors, and the technical consultant.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with a general supervisor, the laboratory did not evaluate the performance specifications of a replacement Leader Luminometer used with the ACCUPROBE Culture Identification Tests for *Blastomyces dermatitidis*, *Coccidioides immitis*, and *Histoplasma capsulatum*. Findings include: 1. Review of laboratory records showed the laboratory received a replacement Leader Luminometer in October 2018. Further review of the records showed no evaluation of the performance of the replacement analyzer beyond the SysCheck calibration check before the laboratory performed patient testing. 2. Interview with a general supervisor, Staff A, on January 13, 2021 at 11:45 AM confirmed the laboratory had not evaluated the accuracy and precision of the replacement Luminometer before reporting ACCUPROBE patient test results for *Blastomyces dermatitidis*, *Coccidioides immitis*, and *Histoplasma capsulatum*.