

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0305645	<b>(X3) Date Survey Completed</b>  01/15/2025
<b>Name of Provider or Supplier</b>  Mobile Bay Ob/Gyn	<b>Street Address, City, State</b>  3 Mobile Infirmiry Circle, Suite 201, Mobile, AL	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of the Policies and Procedure Manual, and an interview with the Technical Consultant (TC), the laboratory failed to establish a policy to monitor and assess competency of physicians who performed Provider Performed Microscopy (PPM). This was noted from the date of the last survey, 09-20-2022, to the date of the current survey, 01-15-2025. The findings include: 1. A review of the Policies and Procedures Manual revealed a lack of policy to monitor and assess the competency of physicians who performed PPM and were responsible in reporting PPM patient results. 2. During the exit conference on 01-15-2025 at 2:45 PM, the TC confirmed the above findings.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC), the Laboratory failed to implement a mechanism to verify the accuracy of the Provider Performed Microscopy (PPM) on the Urine Sediments</p>

PT, a non-regulated test. The surveyor noted the laboratory failed two out of the three consecutive events from 2022-2023. The findings include: 1. A review of the AAB-MLE PT records revealed the laboratory evaluation scores were 50 percent on the PPM-Urine Sediments PT for the following events: a) 2022 MLE M3 b) 2023 MLE M1 2. A further review of the laboratory's PT Failure log revealed the TC's corrective action was "reviewed slide (physician)" for the two events. There was no documented investigation during the second failed event whether the physicians who performed PPM needed retraining and competency evaluations. 3. The TC confirmed the above findings during the exit conference on 01-15-2025 at 2:45 PM.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on reviews of the Quality Assessment (QA) policies and procedure manual, Testing Personnel (TP) records, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC), the TC failed to establish and implement a policy to assess physicians who performed Provider Performed Microscopy (PPM). The surveyor noted the lack of policy occurred from the date of the last survey, 09-20-2022 to the date of the current survey, 01-14-2025. The findings include: 1. A review of QA policies and procedures revealed no policy was established to assess the competency of physicians who performed PPM. (Refer to D5209) 2. A review of the TP records revealed no documentation of annual competency assessments for physicians who performed Urine Sediment examination. (Refer to D6054) 3. A review of the AAB-MLE PT revealed two consecutive failures for Urine Sediment Examination, a non-regulated analyte performed by the physicians. The only corrective action documented for both events was, "reviewed slide (physician)". (Refer to D5217) 4. During the exit conference on 01-15-2025 at 2:45 PM, the TC confirmed there were no competency evaluations performed on physicians to ensure the urine sediments results were reported accurately.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:  
Based on a review of the personnel records and an interview with the Technical Consultant (TC) and the Testing Personnel (TP), the TC failed to ensure five of the five Testing Personnel (TP) who performed Provider Performed Microscopy (PPM) had annual competency assessment documentation from 2022-2025. The findings include: 1. A review of the personnel records revealed five of the TP listed on the

CMS-209 (Laboratory Personnel Report) performing PPM had no annual competency assessments completed and documented from 2022-2025. 2. The TC confirmed the above findings during the exit conference on 01-15-2025 at 2:45 PM.