

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0709813	(X3) Date Survey Completed 02/06/2025
Name of Provider or Supplier Obgyn Associates Montgomery	Street Address, City, State 495 Taylor Road, Montgomery, AL	
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 the review of the Policy and Procedure manual, and an interview with Testing Personnel 4 (TP4), the laboratory failed to establish a policy to monitor and assess competency of physicians who performed Provider Performed Microscopy (PPM). The surveyor noted no documentation of physician assessments from the date of the last survey, 12-13-2022 to the date of the current survey, 02-06-2025. The findings include: 1. A review of the Policy and Procedure manual revealed no procedure on how to monitor and assess the competency of physicians who performed PPM, and reported results utilized in the diagnosis and treatment of patients. 2. During the exit conference on 02-06-2025 at 4:38 PM, TP4 confirmed the above findings.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the policy and procedure manual, and an interview with Testing Personnel 4 (TP), the laboratory failed to establish a maintenance and function checks policy for the four microscopes used in the performance of Provider Performed Microscopy (PPM). The surveyor noted the missing policy was from the last survey date of 12-13-2022 through the current survey date of 02-06-2025. Findings are: 1. A review of the laboratory's policy and procedure manual revealed no written procedure on the maintenance and function checks required for the four PPM microscopes. 2. The TP4 confirmed the above findings during the exit conference on 02-06-2025 at 4:38 PM.

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 Testing Personnel 4 (TP4), the Technical Consultant failed to ensure eight of the eight Testing Personnel (TP) who performed Provider Performed Microscopy (PPM) had annual competency assessments documented from 2023-2025. The findings include: 1. A review of the personnel records revealed eight of the TP listed on the CMS-209 (Laboratory Personnel Report) performing PPM had no annual competency assessments from the date of the previous survey, 12-13-2022 to the date of the current survey, 02-06-2025. 2. The TP4 confirmed the above findings during the exit conference on 02-06-2025 at 4:38 PM.