

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2155580	(X3) Date Survey Completed 08/05/2026
Name of Provider or Supplier Pediatric Associates Of Mobile	Street Address, City, State 740 Museum Drive, Suite E, Mobile, 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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a lack of Calibration-Verification (C-V) records for the Reichert Unistat Bilirubinometer analyzer and an interview with the Technical Consultant (TC) /Testing Personnel 1 (TP1), the laboratory failed to perform C-V procedures at least every six months as per manufacturer's requirement. The surveyor noted no documentation of two of the two possible C-Vs due after the Bilirubin testing was started on 04-16-2025. The findings include: 1. A review of the C-V records for the Reichert Unistat Bilirubinometer analyzer revealed no documentation the C-V performance when it was due October 2025 and April 2026 after the Bilirubin testing was started on 04-16-2025. 2. A review of the Reichert Unistat Bilirubinometer

	manual revealed the following manufacturer's requirement on page 12, Section 6.0 Calibration, 6.1 Calibration Frequency, "The Reichert Unistat Bilirubinometer requires calibration...at least at six-month intervals, ..." 3. TC/TP1 confirmed the above findings during the exit conferenec on 08-05-2026 at 1:23 PM.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on reviews of the personnel records and interview with the Technical Consultant (TC)/Testing Personnel 1 (TP1), the TC failed to ensure Testing Personnel (TP) performing moderate complexity testing had competency assessments which included all six CLIA minimal regulatory requirements. The surveyor noted six of the six requirements were missing from the annual competencies completed in 2025-2026. The findings include: 1. A review of the 2025-2026 personnel records for TP listed on the CMS-209 (Laboratory Personnel Report) revealed competency assessments for the Hematology and Chemistry specialties had no documentation of the six CLIA minimal regulatory requirements, as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. (2) Monitoring the recording and reporting of test results. (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem-solving skills. 2. TC/TP1 confirmed the above findings during the exit conference on 08-05-2026 at 1:23 PM.