

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0271087	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Pensacola Pediatrics Pa	Street Address, City, State 4951 Grande Dr, Pensacola, FL	
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
D0000	An on - site announced CLIA recertification survey was conducted at Pensacola Pediatrics PA on 02/14/2024 - 02/20/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 competency assessment (CA) records, the laboratory's Quality Assurance Plan dated 10/04/23, and staff interview, the laboratory failed to perform 6 month CA for 3 of 3 Testing Personnel (TP). Findings included: 1. Review of CA records revealed TP # H and N received an initial CA on 03/16/23, but did not receive the follow-up 6 month CA. 2. Review of CA records revealed TP #O received an initial CA on 03/21/23, but did not receive the follow-up 6 month CA. 3. Review of the Quality Assurance Plan revealed that the plan does not list the 6 month CA as a requirement for TP. 4. At 11:00 a.m. on 02/14/24, the Lab Manager stated that she did not know a 6 month CA was required for TP.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
 Based on review of College of American Pathologists (CAP) proficiency testing results and interview with Testing Person #B, the laboratory failed to have corrective action for unsatisfactory test scores for Hematology Auto Differentials for 3 (2nd testing event of 2022, 2nd and 3rd event of 2023) out of 6 (1st, 2nd, and 3rd testing events in 2022 and 2023) testing events reviewed. Findings included: Review of CAP proficiency results for 2nd testing event of 2022 revealed that the laboratory scored 80% in Red Blood Cell Count (RBC) and Hematocrit (Hct), 2nd testing event of 2023 revealed that the laboratory scored 80% in RBC, Hemoglobin (Hgb) and Hct, and 3rd testing event of 2023 revealed that the laboratory scored 80% in White Blood Cell Count (WBC), Neutrophil Absolute, and Lymphocytes. No corrective action was performed. During an interview on 2/14/24 at 11:00 a.m. Testing Person #B confirmed the laboratory did not perform corrective action for the testing events that received an 80%.

D6023

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(6)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
 Based on review of Interlaboratory Quality Assurance Program (IQAP) records, the laboratory's Quality Assurance Plan, and interview, the Laboratory Director failed to review IQAP from 4/22 to 01/24 (22 out of 22 months). Findings included: 1. Review of IQAP records revealed logs for months 04/22; 05/22; 06/22; 08/22; 09/22; 10/22; 11/22; 12/22; 01/23; 02/23; 04/23; 05/23; 06/23; 07/23; 08/23; 10/23; 11/23; 12/23; and 01/24 were not reviewed by the Laboratory Director. 2. Review of IQAP records revealed missing logs for months 07/22; 03/23; and 09/23. 3. Interview via email on 02/19/2024 at 3:44 PM, the Lab Manager confirmed that the IQAP for 07/22, 09/23, and 01/24 were missing.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(14)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review, the laboratory's Quality Assurance Plan, and interview the Laboratory Director (LD) failed to specify in writing the responsibilities and duties for the positions Technical Consultant (TC) and Clinical Consultant (CC) . Findings included: 1. Form 209 (02/2021) signed and dated by the LD on 02/12/24 lists the following personnel: 1 LD, 1 CC, 2 TC, and 21 Testing Personnel (TP). The LD and the TC are both listed as TP. 2. The Quality Assurance Plan signed and dated by the LD on 10/04/23 lists responsibilities and duties for the LD and TP. The Quality Assurance Plan does not list the responsibilities and duties for CC or TC. 3. Interview on 02/14/2024 at 11:45 AM the Lab Manager confirmed the CC and TC responsibilities and duties were not included in the job descriptions.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (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.

This STANDARD is not met as evidenced by:
Based on Competency Assessment (CA) record review and interview, the Technical Consultant (TC) failed to perform or evaluate CA for 21 of 21 Testing Personnel (TP) listed on Form 209 (02/2021) for 2023 and 2024. Findings included: 1. Form 209 signed and dated by the Lab Director (LD) on 02/12/24, lists the TC as TP. There are no CA records for the TC. 2. CA records revealed that CA for TP #A-C and TP #E-S were signed by TP#D. 3. CA records revealed that CA for TP#D was signed by TP #B. 4. CA records revealed that the TC did not sign CA for TP #A-S in 2023 and 2024. 5. TP#B and TP#D do not qualify to perform CA. 6. Interview on 02/14/2024 at 11:00 AM the Lab Manager confirmed the missing competencies.