

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0914265	(X3) Date Survey Completed 05/30/2024
Name of Provider or Supplier Pensacola Pediatrics Pa - Tiger Point	Street Address, City, State 1368 Country Club Rd, Gulf Breeze, 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 announced CLIA recertification survey was conducted at Pensacola Pediatrics PA-Tiger Point on 05/23/2024-05/30/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400-Analytic Systems D6000-Moderate Complexity Laboratory Director
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Proficiency Testing (PT) records and interview, it was determined the laboratory failed to maintain documentation of each step in the testing for bacteriology testing, and attestation statement signed by the the laboratory director for hematology and bacteriology testing for 2 of 2 years (2022-2024) reviewed. Findings: Review of 2022-3rd event, 2023-1st, 2nd, and 3rd event for Bacteriology CAP records failed to include documentation of examination records and each step of testing. Review of 2022-3rd event, 2023-1st, 2nd, and 3rd event for Bacteriology and Hematology, and 2024-1st event for Hematology CAP records failed to include attestation statement signed by the the laboratory director. On 5/23/2024 at 10:45 AM, Testing Personnel A (TP-A)</p>

	<p>confirmed there was no documentation available for review of each step of testing for the above listed proficiency bacteriology samples and the Laboratory Director had not signed the listed attestation statements.</p>
<p>D5311</p>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to follow written procedure for specimen labeling 3 of 3 patients (# 57, 58, and 59). Findings: During a tour of the laboratory on 05/23/2024 at 09:20 AM inoculated patient samples #57, 58, and 59 for throat cultures were only labeled with patient names. Review of procedure for throat culture signed by the Laboratory Director on 09/13/2023, stated inoculated plates were to be labeled with patient name, chart number, and date. Testing Personnel confirmed on 05/23/2024 at 09:40 AM the inoculated patient samples were only labeled with patient names.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the Laboratory failed to ensure bacteriology procedures were followed (D5411) and failed to ensure bacteriology expired media was not used (D5417).</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure testing was performed following the laboratory's approved procedure for 12 of 12 daily urine and</p>

	<p>throat culture logs reviewed. Findings: The Laboratory's procedure manual was approved by the Laboratory Director 09/13/2023. The procedure for throat cultures stated inoculated patient samples were to be incubated for 24 hours. The procedure for urine cultures stated inoculated patient samples were to be incubated for 18-24 hours. Patient culture logs for 05/8/2024 to 05/22/24 (12 testing days) did not indicate time of inoculation or incubation time. Testing Personnel A on 5/23/2024 at 12:15 PM confirmed there was no method to monitor inoculated plates to ensure incubation times followed laboratory procedures.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure the bacteriology media for throat cultures testing was not expired prior to testing 59 patient tests from 5/8/2024 to 5/23/2024. Findings: On 5/23/2024 at 9:20 AM, 9 unopened sleeves, one opened sleeve with 2 remaining plates and there were 2 inoculated plates with 3 patient samples with Lot # 3361456 and the 05/08/2024 expiration date observed in the incubator of media Lot # 3361456 with expiration date 5/8/2024 were observed in the laboratory refrigerator. On 5/23/2024 at 9:40 AM, Testing Personnel A (TP-A) confirmed the expired media was available for use and had been used for patient testing. TP-A stated since 5/8/2024 no media which had not expired had been available for patient testing. Review of the laboratory patient culture log documented 59 patients had been tested from 5/8/2024 to 5/23/2024. Review of the media check showed quality control had been performed on expired media on 05/10/2024, 05/15/2024, and 05/20/2024.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on observation, review of records, and interviews, the Laboratory Director failed to provide overall management of the laboratory for 2 of 2 (2022-2024) years. Findings: The laboratory director failed to ensure the laboratory maintained documentation of each step in the testing for bacteriology testing, and attestation statements were signed by the the laboratory director. (See D2015) The Laboratory Director failed to ensure competency of testing personnel. (See D6004) The laboratory director failed to ensure testing was performed as required for accurate and reliable results for Bacteriology patient testing. (See D6014) The Laboratory Director failed to review the laboratory's performance of proficiency testing. (See D6018)</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p>

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on records review, and interview the Laboratory Director failed to ensure competency of testing personnel for 2 of 2 years (2022-2024) reviewed. Findings: The laboratory director failed to ensure the Technical Consultant had evaluated the competency of all testing personnel. (See D6046)

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview the laboratory director failed to ensure testing was performed as required for accurate and reliable results for 2 of 2 years (2022-2024) of Bacteriology patient testing. Findings: The laboratory director failed to ensure the laboratory followed written procedure for specimen labeling. (See D5311) The laboratory director failed to ensure the laboratory followed the laboratory's approved procedure for urine and throat cultures. (See D5411) The laboratory director failed to ensure the laboratory did not use expired bacteriology media. (See D5417)

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to review the

laboratory's performance of proficiency testing results for 10 of 10 proficiency events. Findings: Review of proficiency results for 2022-2nd event Hematology, 3rd events for Hematology and Bacteriology, 2023-1st, 2nd, and 3rd events for Hematology and Bacteriology, and 2024-1st event for Hematology did not show review of the laboratory's performance of proficiency results. On 5/23/2024 at 10:45 AM, Testing Personnel A confirmed there was no evidence of Laboratory Director reviewing of proficiency results.

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 record review, and interview it was determined the Technical Consultant failed to be responsible for evaluating the competency of all testing personnel for 2 of 2 years (2022-2024) reviewed. Findings: Review of the Laboratory Personnel Report signed by the Laboratory Director on 05/20/2024 showed there were 6 employees listed on the form, including the Laboratory Director who was also listed as Clinical Consultant and Technical Consultant. The Laboratory Procedure manual signed by the Laboratory Director on 9/13/2023 included the Quality Assurance Plan which documents "At least annually, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency." Review of Annual Evaluations 2023 and 2024 of testing Personnel Competency for Testing Personnel B, C, and D showed they were signed by Testing Personnel A and for Testing Personnel A showed were signed by Testing Personnel B on 07/28/2023 and 5/14/2023. There was no Annual Evaluation for 2023 or 2024 provided for review for Testing Personnel F. Testing Personnel A confirmed on 05/23/2024 at 10AM the Laboratory Director/Technical Consultant had not perform testing personnel competencies and there was no competency available for review for Testing Personnel F.