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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D1094654 | (X3) Date Survey Completed 03/23/2021 |
| Name of Provider or Supplier All Ages Pediatrics, Pc | Street Address, City, State 301 W 2nd Street, Suite 1, Ottumwa, IA | |
| 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 |
|---------------------------|---|
| D2000 | <p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of proficiency testing records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:20 pm on 03/23/2021, the laboratory failed to enroll in an approved proficiency testing program for the subspecialties, bacteriology and virology (respiratory pathogen panel), for two out of two years from 2020- 2021. The findings include: 1. Interview with laboratory personnel identifier #1 confirmed the laboratory began performing respiratory pathogen panel testing on the BioFire instrument in August 2020. 2. At the time of the survey, personnel identifier #1 confirmed the laboratory did not enroll in an approved proficiency testing program for the subspecialties, bacteriology and virology (respiratory pathogen panel) for 2020 or 2021.</p> |
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for</p> |

specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at approximately 3:30 pm on 03/23/2021, the laboratory failed to have the following written procedures: assessment of personnel competency and training; interpretation and reporting of test results; corrective action to take when test systems become inoperable; and the system for entering test results into patient records.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:20 pm on 03/23/2021, the laboratory failed to perform two levels of QC each day of patient testing for the BioFire test system (respiratory pathogen panel) from 11/09/2020- 03/23/2021. The findings include: 1. The laboratory installed and began using the BioFire test system (respiratory pathogen panel) in August 2020. 2. The laboratory began using respiratory panel cartridge lot number 915620 on 11/09/2020; lot number 11LK20 on 11/23/2020; and lot number 128Y20 on 01/11/2021. The laboratory did not perform QC on lot numbers 915620, 11LK20, or 128Y20. 3. Laboratory personnel identifier #1 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. The manufacturer stated positive and negative controls should be performed with each new lot number and/or shipment of cartridges. 5. At the time of

the survey, the laboratory did not have QC records for respiratory panel cartridge lot numbers 915620, 11LK20, or 128Y20 nor did it have an IQCP for the BioFire test system (respiratory pathogen panel).

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 03/23/2021, the laboratory director failed to ensure the laboratory established and maintained a quality assessment program which covered the four quality systems: general, pre-analytic, analytic, and post-analytic. At the time of the survey the laboratory did not have a quality assessment procedure and the laboratory did not have documented quality assessment activities.