

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2042954	(X3) Date Survey Completed 06/29/2021
Name of Provider or Supplier Just Us Kids Pediatrics	Street Address, City, State 105 Oakhill Boulevard, Newnan, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 29, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual (SOP) review and staff interview, the laboratory failed to include all required procedures in the SOP. Findings include: 1. SOP review reveals the laboratory does not have written procedures for panic/critical result values,</p>

downtime procedure, or corrective actions. 2. Interview with staff #1 (CMS 209) on 6/29/2021 at approximately 12:20 p.m. in the breakroom, confirmed the lack of the aforementioned procedures.

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 review of the laboratory's American Academy of Family Physicians (AAFP) Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were reviewed upon receipt from the PT agency. Findings include: 1. Review of PT records for 2019 event #3, 2020 events #1, #2, #3, and 2021 event #1 revealed the laboratory director failed to review the results received from the AAFP PT program. 2. Interview with TP # 1(CMS 209) on 6/29/21 at 12 pm in the break room confirmed results were not reviewed by the LD when received from the PT provider.

D6020

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 the quality control program is 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 quality control (QC) and staff interview, the laboratory director failed to ensure that the quality control program is maintained to identify failures in quality. Findings include: 1. Review of levy jennings charts and eCQAP QC documents revealed the lack of review by qualified personnel (lab director /technical consultant). 2. Interview with staff #1 (CMS 209) on 6/29/21 in the break room at approximately 12 PM, confirmed the lack of QC review by the lab director /technical consultant.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual (SOP), and staff interview, the laboratory director failed to ensure an approved procedure manual is available to testing staff. Findings include: 1. Review of the SOP reveals the lack of signed procedures by the lab director. 2. Interview with Staff #1 (CMS 209) in the break room on 6/29/21 at approximately 11:43 a.m. confirmed the SOP was not signed by the lab director.

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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with Staff #1 (CMS 209) in the break room on 6/29/21 at approximately 11:43 a.m. confirmed the SOP did not contain a duties and responsibilities policy and procedure.