| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number

11D2042954 | (X3) Date Survey Completed

02/20/2019 |
|---|---|---|
| **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 February 20, 2019. 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:
D5805	TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient reports and interview with the office manager, the laboratory failed to include all required components on the facility's result reports. Findings include: 1. Review of patient reports (performed at the on site laboratory) revealed the units of measure were not included on the report. 2. Interview with the office manager at approximately 12 noon on 2/20/19 in the back office area, confirmed the reports did not contain the units of measurement. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of testing personnel(TP) documents and an interview with the office manager, the lab director failed to ensure proper documented training was given to all new testing personnel. Findings include: 1. Review of personnel documents revealed the lab director failed to ensure proper training was documented/given to 3 of 3 new testing personnel (TP#5, 6, & 7 CMS 209 form). 2. Interview with the office manager at approximately 11:15 AM on 2/20/19 in her office area, confirmed the aforementioned training documents were not available.

| D6053 | TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of testing personnel(TP) documents and an interview with the office manager, the technical consultant (TC)(lab director) failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of competency documents revealed the TC (lab director) failed to perform 6 month competencies on 5 of 5 testing personnel (TP#1,2,3,4,5 CMS 209 form) in 2018. 2. Interview with the office manager at approximately 11:15 AM on 2/20/19 in her office area, confirmed the 2018 semiannual competencies were not available. |