Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2042954	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Just Us Kids Pediatrics	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 recertification survey was performed on April 25, 2023 An entrance conference was held with the laboratory representatives. The survey process was discussed, along with review of the survey forms that was sent to the facility, previous to the survey. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficencies, but none were provided. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and testing personnel (TP) interview, the laboratory failed to establish and follow a policy and procedure to assess (TP) competency as required. Findings include: 1. SOP review revealed there was no policy and procedure to assess (TP) competency available at the time of survey. 2. Lack of TP competency documents revealed there was no initial, semiannual, or annual competencies performed for the 8 of 8 TP (refer to CMS 209). 3. Interview with TP #1 (CMS 209) on 4/25/23 at 10:27 a.m. confirmed the lack of a TP competency policy and procedure at the time of survey.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records, policies and procedures, and testing personnel (TP) interview, the laboratory failed to have general laboratory system Quality Assessment (QA) written policies and procedures for the speciality of hematology. Findings : 1. Review of the laboratory's records and the policies and procedures revealed the laboratory failed to define or provide documentation of errors, how the laboratory identifies a potential problem, how the laboratory resolves a problem or error relating to: Patient confidentiality, Specimen identification and integrity, Complaint investigations, Communications, Personnel competency, and Proficiency testing performance. 2. Interview with testing personnel # 1 [see Laboratory Personnel Report (CMS 209)] on April 25, 2023 at 11:00 am, in the providers area, confirmed the laboratory has no documentation of Quality Assessment (QA).
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory records, policy and procedures, and a testing personnel (TP) interview, the laboratory failed to define Quality Assessment (QA) activities, review the effectiveness of corrective actions, or efforts to prevent recurrences in preanalytic systems. Findings include: 1. Review of the laboratory records and the laboratory's policy and procedures revealed no definition or evaluations of preanalytic QA monitors to include: test request, specimen collection/handling/submission. 2. Interview with testing personnel # 1 [see Laboratory Personnel Report (CMS 209)] on April 25, 2023, at 11:00 AM, in the provider's area, confirmed the aforementioned finding.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory records, policy and procedures, and a testing personnel (TP) interview, the laboratory failed to define Quality Assessment (QA) activities, review the effectiveness of corrective actions, or efforts to prevent recurrences. Findings include: 1. Review of the laboratory records and the laboratory's policy and

	procedures revealed no definition or evaluations of analytic QA monitors to include: policy and procedures, test systems, maintenence & function checks, calibration /calibration verification, control procedures, comparison of results, corrective actions, or test records. 2. Interview with testing personnel # 1 [see Laboratory Personnel Report (CMS 209)] on April 25, 2023, at 11:00 AM, in the provider's area, confirmed the aforementioned finding.
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 in-house lab report review and testing personnel (TP) interview, the laboratory failed to include all the required information on the in-house laboratory test reports. Findings: 1. Review of in-house patient test reports revealed 2 of 2 reports did not indicate an idenentification number or unique patient identifier. * sample ND only idnetification was the patient name * sample MY only idnetification was the patient name 2. Interview with TP #1 [see CMS personnel form (209)] on 4/25/23 at 11:30 AM, in the provider's area, confirmed the aforemtioned finding.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory records, policy and procedures, and testing personnel (TP) interview, the laboratory failed to define Quality Assessment (QA) activities, review the effectiveness of corrective actions, or efforts to prevent recurrences in the postanalytical systems. Findings include: 1. Review of the laboratory records and the laboratory's policy and procedures revealed no definition or evaluations of postanalytic QA monitors to include: result reports, record retention, or alert values. 2. Interview with testing personnel # 1 [see Laboratory Personnel Report (CMS 209)] on April 25, 2023, at 11:00 AM, in the provider's area, confirmed the aforementioned finding.
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 the laboratory personnel documents and testing personnel (TP) interview, the laboratory director (LD) failed to ensure that prior to testing patients' specimens, TP receive the appropriate training and demonstrate that they can perform all testing accurately. Findings include: 1. Review of TP documents provided, revealed the lack of training or initial competency doumentation for 8 of 8 TP [see laboratory personnel report form (CMS 209)]. 2. Interview with TP #1 [see laboratory personnel report form (CMS 209)] in the provider's area on 04/25/2023 at 10:27 AM, confirmed the aforementioned finding.
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 test personnel (TP) 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. No written job duties for the LD, Technical Consultant, Clinical Consultant, or TP. 2. Interview with TP #1 (CMS 209) in the providers area on 04/25/23 at 10:27 am confirmed the SOP did not contain a duties and responsibilities policy and procedure. **Repeat deficiency**
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 testing personnel (TP) interview, the technical consultant (TC) failed to perform semiannual competency on testing personnel. Findings: 1. Review of TP documents provided, the TC failed to perform semiannual competency evaluations for 8 of 8 TP (refer to CMS 209 form). 2. Interview with TP #1 (CMS 209) in the providers area on 04/25/23 at 10:27 am confirmed the aforementioned finding.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and testing personnel (TP) interview, the technical consultant (TC) failed to perform annual competency on testing personnel. Findings: 1. Review of TP documents provided, the TC failed to perform annual competency evaluations for 8 of 8 TP (refer to CMS 209 form). 2. Interview with TP #1 (CMS 209) in the providers area on 04/25/23 at 10:27 am confirmed the aforementioned finding.