Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473674	08/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric & Adolescent Care	2000 S Wheeling Ave, Suite 300, Tulsa, OK	

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	The recertification survey was performed 08/19/19. The findings were reviewed with the laboratory lead and the clinic manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory lead and the clinic manager, the laboratory failed to ensure proficiency testing samples were tested by personnel who routinely performed patient testing. Findings include: (1) At the beginning of the survey, the surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed prior to the survey. The form listed 4 testing persons (Laboratory lead, clinic manager, testing person #3, and testing person #4) as performing the moderate complexity testing in the laboratory; (2) The laboratory lead stated to the surveyor the laboratory performed the following moderate complexity testing: (a) CBC (Complete Blood Count)(i.e. WBC-White Blood Count; RBC-Red Blood Count; Hemoglobin, Hematocrit, Platelet, etc.) testing using the Medonic M Series hematology analyzer; (b) Neonatal bilirubin testing using the Reichert Unistat Bilirubinometer. (3) The surveyor then reviewed proficiency testing records for the Third 2017 Event; the First, Second, and Third 2018 Events; and the First and Second 2019 Events and identified the clinic manager had not performed proficiency testing in 6 of the 6 Hematology proficiency testing events reviewed and 4 of the 4 proficiency testing events for neonatal bilirubin; (4) The surveyor asked the laboratory lead if the clinic manager had been trained to perform CBC and neonatal bilirubin testing. The laboratory lead stated to the surveyor, the clinic manager had been trained

	and would fill in and perform patient testing if necessary; (5) The surveyor reviewed the findings with the laboratory lead and the clinic manager and explained all testing persons who perform, or would perform the moderate complexity patient testing must participate in proficiency testing.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the laboratory lead, the laboratory failed to verify the accuracy of KOH prep and urine sediment examinations at least twice annually. Findings include: (1) At the beginning of the survey, the laboratory lead stated to the surveyor KOH preps (for presence/absence of fungal elements) and microscopic urine sediment examinations were performed in the laboratory; (2) The surveyor reviewed proficiency testing records for the Third 2017 Event; First, Second, and Third 2018 Events; and the First and Second 2019 Events. The surveyor identified the laboratory had not participated in proficiency testing during the proficiency testing events reviewed; (3) Since the laboratory had not enrolled in proficiency testing (enrollment and participation in a proficiency testing program is not required for KOH preps and microscopic urine sediment examinations; they are not regulated analytes), the surveyor asked the laboratory lead how the testing was verified for accuracy during 2017 through the date of the survey; (4) The laboratory lead stated 2 patient KOH and 2 urine sediment examinations were performed in office and the results documented. The samples were then sent to a reference laboratory for testing and the results compared. The laboratory director reviewed the results for acceptability; (5) The surveyor then reviewed the accuracy testing for 2017 through the date of the survey and identified during 2018 and 2019, the comparison testing had not been performed twice annually as required: (a) KOH prep comparison testing was performed on 07/19/18 and on 07/19/19; (b) Microscopic urinalysis examination testing comparison was performed on 05/05/18 and on 01/11/19. (6) The surveyor reviewed the findings with the laboratory lead who stated to the surveyor, the laboratory failed to verify the accuracy of KOH prep and urine sediment examinations at least twice annually in 2018 and 2019.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the laboratory lead and clinic manager, the laboratory failed to have complete written quality control policies. Findings include: (1) At the beginning of the survey, the laboratory lead stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count; RBC-Red Blood Count; Hemoglobin, Hematocrit, Platelet, etc.) using the Medonic M Series hematology analyzer and 3 levels of Boule Con-Diff QC (Quality Control) materials were analyzed each day of patient testing; (2) The surveyor reviewed QC records for 21 QC lot numbers used from January 2017 through August 2019 and identified the laboratory submitted the results each month to the manufacturer's quality assurance "CDS eQCAP" program. The results were printed and the data reviewed; (3) The surveyor then reviewed the laboratory's written policies and procedures. The following was not located: (a) A policy which explained how the eQCAP reports were evaluated for acceptability; (b) A policy which explained the corrective actions to take if the results were unacceptable. (4) The surveyor reviewed the findings with the laboratory lead and clinic manager who stated to the surveyor the laboratory's written policies and procedures did not include the items listed above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory lead and clinic manager, the laboratory failed to take corrective action for quality control results which did not meet established criteria for acceptability. Findings include: (1) At the beginning of the survey, the laboratory lead stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count; RBC-Red Blood Count; Hemoglobin, MCV (Mean Corpuscular Volume), automated WBC differential in percentages and numbers (Lymphocytes, Mids/Monocytes, Granulocytes), Platelet, etc.) using the Medonic M Series hematology analyzer and the laboratory analyzed 3 levels (Low, Normal, and High) of Boule Con-Diff QC (Quality Control) materials each day of patient testing. In addition, the laboratory lead stated to the surveyor each month the laboratory submitted the results to the manufacturer's "CDS eQCAP" program. The results were printed and reviewed; (2) The surveyor reviewed QC records from January 2017 through August 2019 and identified QC lot numbers had been flagged by the manufacturer. The surveyor

	identified that 15 of the laboratory's 21 QC lot numbers used during the review period obtained "S1" flags, which indicated the SDI was greater than +/- 2.0 and outside the defined reference limits. There was no documentation in the laboratory's records the S1 flags were identified, evaluated, and corrective action taken. The findings follow: (a) July 2017: (i) Normal, Lot #2170532: WBC, Lymph%, and Mid% obtained an S1 flag (ii) High, Lot #2170533: MCV obtained an S1 flag (b) June 2018: (i) Low, Lot #2180301: Platelet obtained an S1 flag (ii) Normal, Lot #2180302: Hemoglobin and Platelet obtained an S1 flag (iii) High, Lot 32180303: Hemoglobin obtained an S1 flag (c) September 2018: (i) Low, Lot #2180621: Hemoglobin, Mid%, and Platelet obtained an S1 flag (ii) High, Lot #2180623: Lymph%, Mids%, Mids#, and Platelet obtained an S1 flag (d) January 2019: (i) Normal, Lot #2170922: Mids%, Gran%, and Lymph# obtained an S1 flag (ii) High, Lot #2170923: Lymph% obtained an S1 flag (e) February 2019: (i) Low, Lot #2181131: Mids% obtained an S1 flag (ii) Normal, Lot #2181132: Mids% and Lymph# obtained an S1 flag (iii) High, Lot #2181133: Lymph% and Mids% obtained an S1 flag (f) July 2019: (i) Low, Lot #2190521: Mids% obtained an S1 flag (ii) Normal, Lot #2190522: Mids% obtained an S1 flag (iii) High, Lot 2190522: Lymphs% and Mids% obtained an S1 flag (3) The surveyor reviewed the findings with the laboratory lead and clinic manager and asked if the eQCAP reports listed above had been reviewed by the technical consultant for acceptability and if corrective had been taken for the flagged analytes. The laboratory lead and clinic manager stated to the surveyor, the technical consultant had reviewed the monthly eQCAP reports but had not documented the review, and corrective action had not been taken for the S1 flags.
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 a review of records and interview with the laboratory lead and the clinic manager, the technical consultant failed to ensure that testing persons performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) At the beginning of the survey, the laboratory lead stated to the surveyor the laboratory performed the following moderate complexity testing: (a) CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count; RBC-Red Blood Count; Hemoglobin, Hematocrit, Platelet, etc.) using the Medonic M Series hematology analyzer; (b) Microscopic testing (i.e., urinalysis, WBC differentials, KOH exams for fungal elements); (c) Neonatal Bilirubin testing using the Reichert Unistat Bilirubinometer. (2) The surveyor reviewed personnel records for the 4 individuals (laboratory lead, clinic manager, testing person #3, and testing person #4) who performed the moderate complexity testing. The surveyor identified the semiannual competency assessment had not been performed for testing person #4, hired after the previous recertification survey performed on 08/07/17: (a) The initial training for testing person #4 was completed on 09/04/18. There was no evidence a semiannual evaluation had been performed. (3) The surveyor reviewed the records with the laboratory lead and clinic manager, who both stated there were no records available to prove testing person #4 had been evaluated semiannually.