Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473674	07/27/2021
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 on 07/27/2021. The findings were reviewed with the laboratory director and lead tech during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the lead tech, the laboratory failed to use materials that had not expired. Findings include: (1) On 07/27 /2021 at 09:50 am, the lead tech stated to surveyor #1 manual differential testing and slide reviews were performed in the laboratory; (2) On 07/27/2021 at 10:00 am, surveyor #1 observed the bottle of Wright's stain stored in the laboratory cabinet, and identified Healthlink Wright's Stain, lot #0043, with an expiration date of 05/12/2021; (3) Surveyor #1 showed the bottle of Wright's stain to the lead tech and asked if it was currently being used for patient testing. The lead tech stated the stain was currently in use and was not aware it had expired; (4) The surveyor reviewed patient testing records and identified patient manual differential and or slide reviews had been performed using the expired stain on 05/24,28/2021; 06/04,09,11,30/2021; and 07/16, 21,22/2021.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the lead tech, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 4 of 14 months. Findings include: (1) On 07/27/2021 at 09:50 am, the lead tech stated to surveyor #1 that CBC (Complete Blood Count) testing was performed on the Medonic M-Series analyzer; (2) Surveyor #2 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for monthly maintenance were as follows: (a) Fill a cup with 10 ml 2% hypochlorite (bleach), certified by Boule, and one cup with 18 ml diluent; (b) Aspirate the hypochlorite as a pre-diluted sample and then repeat; (c) Run 2 blank samples by aspirating diluent as a pre-diluted sample; (d) Perform a background check, in pre-dilute mode, to verify all values are with range. (3) Surveyor #2 then reviewed maintenance records for 14 months (January 2020 through February 2021). There was no evidence the monthly maintenance had been performed: (a) Between 05/28/2020 and 08/08/2020 (b) Between 09/26/2020 and 11 /20/2020 (c) Between 12/28/2020 and 02/14/2021 (4) Surveyor #2 reviewed the records with the lead tech, who stated on 07/27/20201 at 01:50 pm the monthly maintenance had not been performed as required.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the lead tech, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for hematology testing for 18 of 18 months. Findings include: (1) On 07/27 /2021 at 10:00 am, the lead tech stated to surveyor #1 CBC (Complete Blood Count) testing was performed on the Medonic M-Series analyzer; (2) On 07/27/2021 at 01:45 pm, the lead tech stated to surveyor #2 that three levels of QC (quality control) materials were performed each day of patient testing; (3) Surveyor #2 requested QC records (i.e., Levey-Jennings data) for the above testing performed from January 2020 though June 2021 to ensure QC had been monitored for variances (i.e. shifts, trends, biases). The lead tech stated on 07/27/2021 at 02:20 pm, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period because data had not been printed and maintained. Surveyor

	#2 was able to verify that QC had been performed each day of patient testing, however, there was no documentation the data had been reviewed for variances by the laboratory.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the lead tech, the laboratory failed to verify the stated value of control materials before they were put into use. Findings include: (1) On 07/27/2021 at 09:50 am, the lead tech stated the following to surveyor #1: (a) The laboratory performed routine CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (b) Three levels of manufacturer control materials were analyzed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) Surveyor #2 reviewed records for 6 control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 6 of 6 lot numbers as follows: (a) Low control lot #22012-21, Normal control lot # 22102-22 and High control lot #22102-23 used from 01/21/2021 through 04/26/2021; (b) Low control lot # 22102-31, Normal control lot #22102-32, and High control lot #22102-33 used from 04/27/2021 through 07/13/2021. (3) The findings were reviewed with the lead tech who stated on 07/27/2021 at 01:15 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the lead tech, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.

D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the lead tech, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 1 of 1 competency evaluations performed. Findings include: (1) On 07/27/2021 at 09:45 am, surveyor #2 reviewed records for 2 persons performing moderate complexity testing in 2019, 2020 and to date in 2021. The records showed the evaluations for 1 of 1 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 07/31/2020 and 07/20/2021 evaluations had been performed by the lead tech (this person had earned an Associates Degree in Science); (2) Surveyor #2 reviewed the records with the lead tech on 07/27/2021 at 11: 00 am, and explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The lead tech stated to surveyor #2 on 07/27/2021 at 11:

	10 am, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.