Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2074078	11/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Childrens Urgent Care, The	1260 S Linden Road, Flint, MI	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain for four (#1, #4, #6, and #10) of ten patient charts audited the daily background count for the Medonic M Series hematology analyzer as defined by the manufacturer. Findings include: 1. On November 7, 2018 at 11:14 AM, record review of the daily start-up and quality controls records for the Medonic M Series hematology analyzer revealed the background count for four patient charts audited there was no documentation to show the background count was retained. 2. On November 7, 2018 at 12:30 PM when queried, the laboratory director as listed on the CMS-209 was unable to provide the surveyor the documentation requested. 3. During the interview on November 7, 2018 at 12:30 PM, the laboratory director confirmed the background counts are not consistently retained.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date one ("Procedure Manual") of one procedure manuals for the

	Medonic M Series hematology analyzer. Findings include: 1. On November 7, 2018 at 10:32 AM, procedure manual review revealed there was no documentation to show the laboratory director had approved, signed, and dated the manual prior to being put into use on August 1, 2018. 2. During the interview on November 7, 2018 at approximately 12:30 PM, the laboratory director as listed on the CMS-209 confirmed the manual had not been signed prior to being put into use.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to monitor and document the room temperature and humidity for four (August to November) of four months of operation in 2018 to ensure reliable hematology analyzer operation. Findings include: 1. On November 7, 2018 at 10:44 AM, review of the installation manual for the "Medonic M Series Hematology Analyzer" stated the operating temperature range for "optimal instrument operation is 64 to 90 F (18 to 32 C)" and the "operating maximum relative humidity is less than 80%". 2. On November 7, 2018 at 10:44 AM when queried, the laboratory director was not able to provide documentation to show the room temperature and humidity readings were being monitored. 3. During the interview on November 7, 2018 at 12:30 PM, the laboratory director confirmed the room temperature and humidity readings were not performed and documented.
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 record review and interview, the laboratory failed to perform and document the daily and monthly maintenance for the Medonic M Series hematology analyzer for four (August to November) of four months of operation in 2018. Findings include: 1. On November 7, 2018 at 10:42 AM, record review of the "Medonic M Series Hematology Analyzer" procedure manual revealed the laboratory did not have documentation to show the daily and monthly maintenance had been performed and documented for four months in 2018. 2. During the interview on November 7, 2018 at 12:30 PM, the laboratory director has listed on the CMS-209 confirmed the maintenance had been performed but did not document.
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 record review and interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic laboratory systems for four (August to November) of four months reviewed in 2018. Findings include: 1. On November 7, 2018 at 10:32 AM, record review of the "Procedure Manual" revealed the laboratory did not establish and implement a written quality assurance policy that required the laboratory to monitor, assess, and correct problems when indicated for the analytic laboratory systems. 2. There was no documentation to show the laboratory had established a mechanism to monitor retention of all laboratory phases of testing. 3. There was no documentation to show the laboratory had established a quality assurance mechanism to ensure the established laboratory's procedures were approved by the director prior to being put into use. 4. There was no documentation to show the laboratory had established a quality assurance mechanism to monitor the laboratory room temperature and humidity readings. 5. There was no documentation to show that the laboratory had established a quality assurance mechanism for monitoring the hematology analyzer function checks and maintenance procedures. 6. During the interview on November 7, 2018 at 12:30 PM, the laboratory director as listed on the CMS-209 confirmed the mechanism listed above were not being monitored and documented.
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 record review and interview, the technical consultant as listed on the CMS-209 does not meet the qualification requirements at 493.1411. Findings include: 1. On November 7, 2018 at 11:50 AM, record review of the laboratory directors credentials revealed the qualification requirements for the technical consultant were not met. 2. On November 7, 2018 at approximately 12:30 PM, the laboratory director confirmed he had not worked for one year with his 20 Continuing Medical Education training.
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 record review and interview, the laboratory director failed to ensure the technical consultants (TC) meets the training or experience requirements at 493.1411. Findings include: 1. On November 7, 2018 at 11:50 AM, record review of the laboratory directors Continuing Medical Education (CME) 20 course training revealed the director did not have a year of experience to qualify for the technical consultant (TC) position. 2. During the interview on November 7, 2018 at approximately 12:30 PM, the laboratory director confirmed the qualifications for the TC position was not met.