Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2264561	03/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kidsfirst Childrens Urgent Care	329 Wesley St, Johnson City, TN	

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 laboratory was found not to be in compliance with the following CLIA conditions: D2000: 493.801 Condition: Enrollment and testing of samples D5024: 493.1215 Condition: Hematology D5200: 493.1230 Condition: General laboratory systems D6000: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation of laboratory, lack of documentation, review of patient test records, and interview with the lead testing person, determined the laboratory failed to enroll in proficiency testing (PT) for the complete blood count (CBC) analytes in 2022 and 2023 with 36 patients reported since testing began on 07.15.2022. The findings include: 1. Observation of the laboratory at approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for CBC patient testing. 2. Request for PT records at approximate 1:00 p.m. on 03.14.2023 revealed no PT records were available. The lead testing person stated the laboratory was not enrolled in PT for the CBC analytes. 3. Review of patient test reports revealed patient testing for CBCs began on 07.15.2022 until the date of survey (03.14.2023). 4. Interview with the lead testing person at approximately 2:00 p.m. on

	03.14.2023 confirmed the laboratory was not enrolled in PT for the CBC analytes in 2022 and 2023 with patient testing being performed.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation, lack of documentation, and interview with the lead testing person, the laboratory failed to meet the requirements for the hematology specialty as evidenced by: 1. The laboratory failed to establish written policies and procedures to assess employee competency in 2022 and 2023 for performance of complete blood counts (CBCs) (Refer to D5209) 2. The laboratory failed to establish general quality assessment (QA) policies and procedures in 2022 and 2023 for monitoring of moderately complex complete blood counts(CBCs) (Refer to 5291) 3. The laboratory failed to establish analytic quality assessment (QA) policies and procedures for the complete blood count (CBC) performed on the Abbott Cell Dyn in 2022 and 2023 (Refer to D5791)
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to establish testing personnel competency assessment policies (Refer to D5209) and failed to establish a general laboratory systems quality assessment policy in 2022. (Refer to D5291)
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 request for personnel records, lack of documentation, and interview with the lead testing person, the laboratory failed to establish written policies and procedures to assess employee competency in 2022 and 2023 for performance of complete blood count (CBC), with 36 patients reported since testing began on 07.15.2022. The findings include: 1. Request for testing personnel records revealed no documentation

	of competency for all testing persons. 2. The testing personnel competency policies and procedures were requested from the lead testing person at approximately 2:00 p. m. on 03.14.2023. The lead testing person stated the laboratory did not have policies or procedures for assessing testing personnel competency. 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory failed to establish written policies and procedures to assess employee competency since patient testing began 07.15.2022 through the survey date of 03.14.2023 with 36 patients had been reported since testing began on 07.15.2022.
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 observation of the laboratory, lack of documentation, and interview with lead testing person, the laboratory failed to establish general quality assessment (QA) policies and procedures in 2022 and 2023 for monitoring of moderately complex complete blood counts(CBCs), with 36 patients reported since testing began on 07.15.2022. The findings include: 1. Observation of the laboratory at approximately 1: 00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter for CBC patient testing. 2. Request for QA policies and procedures from the lead testing person on 03.14.2023 at 1:00 p.m. revealed the laboratory had no general QA policies or procedures. 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory did not have any general QA policies or procedures in 2022 and 2023, with 36 patient CBCs reported since testing began on 07.15.2022 through the date of survey (03.14.2023).
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 observation of the laboratory, lack of documentation, and interview with the lead testing person, determined the laboratory failed to have a manual that included requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection for the Complete Blood Count (CBC) instrument in use for patient testing since patient testing began 07.15.2022 through the survey date of 03.14.2023. The findings include: 1. Observation of the laboratory at approximately 1: 00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for CBC patient testing. 2. Request for a written and approved procedure for use of the Abbott Cell Dyn CBC instrument in use for patient testing revealed the testing personnel were using the Abbott Cell Dyn quick reference card as the procedure, therefore, no written and approved procedures were available. 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023, confirmed the laboratory failed to have a manual that included requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection for the Abbott Cell Dyn Complete Blood Count (CBC) instrument in use for CBC patient testing since patient testing began 07.15.2022 through the survey date of 03.14.2023.
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 observation of the laboratory, document review, and interview with the lead testing person, determined the laboratory director failed to approve the Abbott Cell Dyn quick reference card being used as the procedure for the Complete Blood Count (CBC) instrument prior to patient testing that began 07.15.2022. The findings include: 1. Observation of the laboratory at approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for CBC patient testing. 2. Review of the Abbott Cell Dyn quick reference card, being used as the procedure, revealed it had not been approved by the laboratory director. 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed that the Abbott Cell Dyn quick reference card being used as the procedure for the Abbott Cell Dyn Complete Blood Count (CBC) instrument had not been approved by the laboratory director prior to patient testing that began 07.15.2022.
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: Citation #1 Based on observation of the laboratory, review of manufacturers' instructions, lack of documentation, and interview with the lead testing person, determined the laboratory failed to monitor and document room temperature and humidity in the area where the Abbott Cell Dyn instrument was in use for Complete Blood Count (CBC) patient testing since patient testing began 07.15.2022 through the survey date of 03.14.2023. Findings include: 1. Observation of the laboratory at approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for performing CBC patient testing. No devices for monitoring temperature or humidity were noted in the laboratory. 2. Review of the laboratory's Abbott Cell Dyn System Installation checklist stated, "Temperature range: 64-90 degrees Fahrenheit (F) or 18-32 degrees Celsius (C). Maximum relative humidity 80% for temperatures up to 88 F (31 C)" 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory failed to monitor and document room temperature and humidity in the area where the Abbott Cell Dyn instrument was in use for Complete Blood Count (CBC) patient testing since patient testing began 07.15.2022 through the survey date of 03.14.2023. Citation #2 Based on observation of the laboratory, review of manufacturer's instructions, lack of documentation, and interview with the lead testing person, determined the laboratory failed to document refrigerator temperature for the Quality Control (QC) of the Abbott Cell Dyn instrument in use for Complete Blood Count (CBC) patient testing since patient testing began 07.15.2022 through the survey date of 03.14.2023. Findings include: 1. Observation of the laboratory at approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for performing CBC patient testing. 2. Observation of the laboratory at approximately 1: 00 p.m. on 03.14.2023 revealed Abbott Cell Dyn instrument QC in the refrigerator. 3. Review of the laboratory's Abbott Cell Dyn 18 Plus Control package stated, "Temperature range: 2-10 degrees Celsius (C)." 4. Request for laboratory environmental logs of the CBC QC refrigerator revealed none available for surveyor review. 5. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory failed to document refrigerator temperature where the Abbott Cell Dyn QC was being stored .
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 observation of the laboratory, lack of documentation, and interview with the lead testing person, determined the laboratory failed to establish analytic quality assessment (QA) policies and procedures for the complete blood count (CBC) performed on the Abbott Cell Dyn in 2022 and 2023, with 36 patients reported since testing began on 07.15.2022. The findings include: 1. Observation of the laboratory at approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for CBC patient testing. 2. Request for QA policies and procedures for the Abbott Cell Dyn CBC instrument from the lead testing person on

	03.14.2023 at 1:00 p.m. revealed no procedures were available. 3. Interview with the lead testing person at approximately 1:00 p.m. on 03.14.2023 confirmed the laboratory failed to establish QA policies and procedures for use of the Abbott Cell Dyn in 2022 and 2023. 4. Interview with the lead testing person at approximately 1:00 p.m. on 03.14.2023 revealed the laboratory reported 36 patient CBCs since testing began on 07.15.2022 until the date of the survey on 03.14.2023
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to ensure the laboratory was enrolled in proficiency testing in 2022 (Refer to D6015), failed to establish a quality assessment plan (Refer to D6021), failed to ensure policies for maintaining employee competency (Refer to D6030) , failed to ensure an approved procedure manual was available for use (Refer to D6031), and failed to ensure job descriptions were present for the laboratory director, technical consultant, clinical consultant, and testing personnel (Refer to D6032) .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on observation of laboratory, lack of documentation, review of patient test records, and interview with the lead testing person, determined the laboratory director failed to ensure the laboratory was enrolled in proficiency testing (PT) for the complete blood count (CBC) analytes in 2022 and 2023 with with 36 patients reported since testing began on 07.15.2022. (Refer to D2000) The findings include: 1. Observation of the laboratory at approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for CBC patient testing. 2. Request for PT records at approximately 1:00 p.m. on 03.14.2023 revealed no PT records were available. The lead testing person stated the laboratory was not enrolled in PT for the CBC analytes. 3. Review of patient test reports revealed patient testing for CBCs began on 07.15.2022 until the date of survey (03.14.2023). 4. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory director failed to ensure the laboratory was enrolled in PT for the CBC analytes in 2022 and 2023.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with lead testing person, the laboratory director failed to ensure the establishment of a quality assessment (QA) program in 2022 and 2023. (Refer to D5291) The findings include: 1. Observation of the laboratory approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter for CBC patient testing. 2. Request for QA policies and procedures from the lead testing person on 03.14.2023 at 1:00 p.m. for the Abbott Cell Dyn CBC instrument revealed no QA policies or procedures were available. 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory director failed to ensure the establishment of a quality assessment (QA) program in 2022 and 2023.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the lead testing person, determined the laboratory director failed to ensure written policies and procedures were established to assess employee personnel competency in 2022 and 2023 for the performance of complete blood count (CBC), with 36 patients reported since testing began on 07.15.2022. (Refer to D5209) The findings include: 1. Request for testing personnel competency assessment policy from the lead testing person at approximately 2:00 p.m. on 03.14.2023 revealed the laboratory did have not have competency assessment policies or procedures. 2. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory director failed to ensure established written policies and procedures to assess employee competency.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on observation of the laboratory, document review, document request ,and interview with the lead testing person, determined the laboratory director failed to approve the Abbott Cell Dyn quick reference card being used as the procedure for the Complete Blood Count (CBC) instrument prior to patient testing that began 07.15.2022. (Refer to D5403 and D5407) The findings include: 1. Observation of the laboratory at approximately 1:00 p.m. on 03.14.2023 revealed an Abbott Cell Dyn instrument on the laboratory counter in use for CBC patient testing. 2. Request for a written and approved procedure for use of the Abbott Cell Dyn CBC instrument in use for patient testing revealed the testing personnel were using the Abbott Cell Dyn quick reference card as the procedure, therefore, no written and approved procedures were available. (Refer to D5403 and D5407) 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the above findings.
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 document request and interview with the lead testing person, the laboratory director failed to ensure job descriptions were present that outlined the duties and responsibilities of the laboratory director, technical consultant, clinical consultant, and testing personnel. The findings include: 1) Request for written job descriptions for the laboratory director, technical consultant, clinical consultant, and testing personnel from the lead testing person on 03.14.2023 at 2:00 p.m. revealed no job descriptions were present. 2. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory director failed to ensure job descriptions were present for the laboratory director, technical consultant, clinical consultant, and testing personnel.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

	This STANDARD is not met as evidenced by: Based on request for personnel records, lack of documentation, and interview with the lead testing person, the laboratory failed to ensure training was completed for the testing personnel in 2022 prior to analyzing complete blood counts (CBCs) which began on 07.15.2022. The findings include: 1. Request for testing personnel records revealed no documentation of training for all testing persons. 2. The testing personnel training/competency policies and procedures were requested from the lead testing person at approximately 2:00 p.m. on 03.14.2023. The lead testing person stated the laboratory did not have policies or procedures for assessing testing personnel competency. 3. Interview with the lead testing person at approximately 2:00 p.m. on 03.14.2023 confirmed the laboratory failed to ensure training was completed for the testing personnel in 2022 prior to analyzing complete blood counts (CBCs) which began on 07.15.2022.