Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2136800	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
First Point Urgent Care Inc Mo	8144 Nw Prairie View Rd, Kansas City, MO	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of hematology procedure, quality control (QC), patient reports and interview with the laboratory director the laboratory failed to follow hematology quality control procedure. Findings: 1. Review of laboratory hematology procedure states "Three commercial controls are run each morning". 2. Review of QC and patient reports shows on 3/14/18 and 3/22/18 laboratory reported out patient results and failed to run QC. 3. Interview with the laboratory director on April 11, 2018 at 3: 00 PM confirmed the laboratory failed to follow hematology quality control procedure.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of Medonic hematology analyzer validation and interview with the laboratory director on April 11, 2018 at 3:00 PM confirmed the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.
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 review of patient test reports and interview with the laboratory director the laboratory failed to include positive patient identification on patient test reports. Findings: 1. The laboratory scans complete blood count (CBC) results (a print out from analyzer) into patient charts. 2. Review of patient CBC result's test report from 3 /22/18 from the patient's chart shows only the last name of the patient is on the test report. 3. Interview with the laboratory director on April 11, 2018 at 3:00 PM confirmed the laboratory failed to include positive patient identification on laboratory reports.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test report , Medonic hematology procedure and interview with the laboratory director the complete blood count (CBC) normal values on the patient report did not match the normal values in the procedure. Findings: 1. Review of patient test report shows normal range of CBC: WBC: 3.5-10 Gra%: 35-80 Mid%: 2-15 Lym%: 15-50 RBC: 3.5-5-5 HGB: 11.5-16.5 MCV: 75-100 HCT: 35-55 MCH: 25-35 MCHC: 31-38 PLT: 100-400 MPV: 8-11 2. Review of Medonic hematology procedure shows: WBC: 4.6-10.2 LYM%: 10-50 GRAN%: 37-80 MID%: 0-12 RBC: males 4.69-6.13 female 4.04-5.48 HGB: males 14.1-18.1 female 12.2-16.2 HCT: males 43.5-53.7 female 37.7-47.9 MCV: males 80-97 female 80-97 MCH: 27-31.2 MCHC: 31.8-35.4 PLT: 142-424 3. Interview with the laboratory director on April 11, 2018 at 3:00 PM confirmed the laboratories CBC normal values for patient test reports did not match the procedure.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of Medonic hematology analyzer quality control (QC), hematology procedure and interview with the laboratory director the technical consultant failed to establish parameters for acceptable levels of analytic performance and ensure these levels were maintained. Findings: 1. Review of QC for complete blood counts (CBC) for April 2018 showed on 4/3/18, 4/4/18 and 4/5/18 hemoglobin was not within acceptable limits for the normal and high controls. Laboratory performed no corrective action. 2. Laboratory procedure states "Results that are not within the expected range will be flagged "Red". Take appropriate corrective action for flagged results." 3. Review of QC showed no review documented by technical consultant. 4. Interview with the laboratory director on April 11, 2018 at 3:00 PM confirmed the technical consultant failed to establish parameters for acceptable levels of analytic performance and ensure they were maintained.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, the laboratory did not have academic credentials required to qualify three of three testing personnel for the speciality of hematology for moderate complexity testing (refer to tag #6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by:

	Based on review of personnel records and interview with the laboratory director, the laboratory failed to have documentation of academic credentials to qualify three of three testing personnel for moderate complexity testing. Findings: 1. Review of the personnel records for three of three testing personnel for the speciality of hematology revealed the laboratory failed to have academic credentials to qualify these individuals. 2. Interview with the laboratory director on April 11, 2018 at 3:00 PM confirmed, the laboratory failed to have the required documentation to qualify three of three testing personnel of moderate complexity.