Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0655411	08/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Firsthealth Of The Carolinas, Inc Dba	925 Long Drive, Rockingham, NC	

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 review of 2018 and 2019 coagulation records, the absence of documentation, and interview with TS (technical supervisor) #1 on 8/15/2019, the laboratory failed to retain required ACL Top 300 and ACL Top 500 coagulation maintenance records for at least 2 years. Findings: Review of the coagulation maintenance records revealed electronic printouts from the ACL Top 300 and ACL Top 500 analyzers for daily, weekly, and monthly maintenance from April 1, 2018 to July 31, 2019. The review revealed no maintenance records available for the ACL Top 300 and ACL Top 500 analyzers prior to April 1, 2018. During interview at approximately 10:15 a.m. on 8/15/2019, TS #1 stated the laboratory discontinued manual coagulation maintenance logs in 2016 or 2017. He confirmed the laboratory began printing electronic maintenance records from the ACL Top 300 and ACL Top 500 analyzers in May 2018. At the request of the surveyor during time of interview, the TS attempted to print maintenance records for March 2018, but the records were no longer available.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with TS (technical supervisor) #1 on 8/14/19 - 8/15/19, the laboratory's procedures were not complete and current. Findings: Review of the laboratory's policies and procedures revealed the laboratory did not have a written step-by-step policy or procedure describing the process for reporting Troponin I patient test results. During interview 8 /15/19 at approximately 2:15 p.m., TS #1 confirmed that the laboratory did not have a procedure which described the laboratory's process for reporting patient Troponin I test results.
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 review of the laboratory's policies and procedures, review of manufacturers' instructions, and review of 2018 and 2019 DXH 600, DXH 800, and Aerospray Stainer maintenance records 8/14/19- 8/15/19, the laboratory failed to perform and document maintenance for the hematology analyzers and stainer at the frequency specified by the manufacturer. Findings: The laboratory's "Hematology Maintenance" policy states "All maintenance in the Hematology department is performed daily, weekly, and/or monthly. Document all maintenance in the Hematology Maintenance Notebook. ..." The laboratory's "Clinical Laboratory Quality Management Plan" states on page 98 "... Instrument Maintenance Routine preventive maintenance as recommended by the manufacturer will be completed and documented by assigned personnel. ... Instrument function checks will be performed with frequency and procedure as directed by the manufacturer. Instrument maintenance is documented. ..." Review of 2018 and 2019 maintenance records revealed the laboratory failed to perform and document the following maintenance procedures as specified by manufacturers' instructions: 1. DXH 800 hematology analyzer monthly maintenance not documented 10 of 12 months in 2018 (January, February, March, May, June, July, September, October, November, December). 2. DXH 600 hematology analyzer monthly maintenance not documented 1 of 12 months in 2018 (June). 3. Aerospray stainer (Model 7122) monthly maintenance not documented 5 of 12 months in 2018 (January, February, March, May, October); 4. Aerospray stainer (Model 7122) weekly "Drain Line Flush" not documented: a. weeks 1, 2, 3, 4 in February 2018; b. week 1 in March 2018; c. weeks 1, 3, 4 in April 2018; d. weeks 1, 2 in May 2018; e. week 2 in July 2018; f. week 4 in August 2018; g. weeks 3, 4 in October 2018; h. weeks 1, 3 in December 2018.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the absence of documentation, and interview with TS (technical supervisor) #1 on 8/14/19 at 9:30 a. m., the laboratory failed to establish a system for BNP (Brain natriuretic peptide) comparison testing between the Beckman Coulter Access 2 and the DxC 600/600i chemistry analyzers at least twice a year. Findings: Review of the laboratory's policies and procedures revealed the laboratory did not have a procedure for bi-yearly method comparison testing between the two instruments performing BNP testing, including how the comparisons are performed, the frequency, the criteria for acceptability, and the steps to take if the results are unacceptable. The Beckman Coulter DxC 600/600i is used as the primary analyzer and the Access 2 is used as the backup. TS #1 confirmed during interview that the laboratory did not have a procedure for method comparison and the comparison had not been performed twice a year.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with staff 8/14/19 - 8/15/19, the laboratory failed to establish policies and procedures for evaluating the performance of duties delegated by the laboratory director to personnel designated as "technical consultant", "technical supervisor", and "general supervisor". Findings: The "... Clinical Laboratories Scope of Services" policy states "... Organizational Management Medical Directors The Medical Directors are responsible for the oversight and management of the Clinical Laboratories. ... The Medical Directors delegate responsibilities of daily laboratory oversight, management and patient testing to qualified individuals designated as Administrative/Clinical Directors, Assistant Directors, Supervisors, Team Leaders, Medical Technologists and Medical Laboratory Technicians. ..." Review of the "Laboratory Director Responsibilities and Delegations" document updated and approved by the laboratory director 7/23/19 revealed the laboratory director delegated duties to other personnel, but there was no documentation that the laboratory director evaluated the personnel to ensure the delegated duties were performed as required. Examples: 1. Review of the "Laboratory Director Responsibilities and Delegations" document updated and approved by the laboratory director 7/23/19 revealed the laboratory director delegated the following duties to TS (technical supervisor) #1 and GS (general supervisor) #1, GS #2, GS #3, and GS #4: "Assess competency for personnel performing high complexity testing on the appropriate schedule". In

	addition, the laboratory director delegated the duty "Assess competency for personnel performing moderate complexity testing on the appropriate schedule" to TS #1, GS #1, GS #2, GS #3, GS #4, and TC (technical consultant) #1. Review of personnel records revealed there was no documentation that the laboratory director had evaluated TS #1, GS #1, GS #2, GS #3, GS #4, and TC #1 on their performance of this delegated duty. During interview 8/14/19 at approximately 1:25 p.m., the Laboratory Administrative Director confirmed that the laboratory's competency evaluation process did not include an evaluation of duties delegated by the laboratory director. 2. Review of the "Laboratory Director Responsibilities and Delegations" document updated and approved by the laboratory director 7/23/19 revealed the laboratory director delegated the following duties to the blood gas supervisor, GS #5: " Ensure that a quality control and quality assurance program is established and maintained"; "Ensure that execution of the PT program is in accordance with CLIA requirements"; "Ensure review of daily test results or worksheets, QC, associated corrective actions, PT results, and preventive maintenance and function records". Review of personnel records revealed there was no documentation that the laboratory director had evaluated GS #5 on the performance of these delegated duties. During interview 8/15/19 at approximately 10:30 a.m., GS #5 stated that he reviews blood gas quality control but the reviews are not documented. He also stated that TS #1 receives and distributes the proficiency testing samples and reviews proficiency testing results.