Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2173116	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Ivy Creek Family Care Of Troy	101 Hunters Mountain Parkway, Troy, AL	

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
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 a review of the policies and procedures and an interview with the Practice Manager, the surveyor determined the laboratory failed to ensure the Policy and Procedure Manuals specified panic value results and/or ranges, and included a protocol to follow when patients' CBC (Complete Blood Counts) results yielded imminent life threatening results or panic values. The findings include: 1. A review of the laboratory policy and procedure manuals revealed panic value results and/or ranges were not specified, and there was no protocol to follow when testing personnel obtained imminent life threatening results or panic values. 2. During an interview on 2

	/4/2020 at 1:40 PM, the Practice Manager reviewed the manuals with the surveyor, and confirmed the above noted findings. .
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 a review of the policies and procedures and an interview with the Practice Manager, the surveyor determined the Laboratory Director failed to sign his review and approval of the Medonic M Series Hematology Analyzer procedures, before use by the testing personnel for the performance of CBC's (Complete Blood Counts) patient testing on 10/08/2019. The findings include: 1. A review of the general laboratory policy and procedure manual revealed no procedures for Hematology testing. The testing personnel utilized the Medonic M Series Operator's Manual for guidance. 2. A review of the Medonic M Series Hematology Analyzer Operator's Manual revealed the Laboratory Director's reviewed and approved of the procedures on 1/16/2020. However, a review of Hematology records revealed patient CBC testing began on 10/08/2019. 3. During an interview on 2/4/2020 at 1:40 PM, the Practice Manager reviewed the manuals with the surveyor, and confirmed the above noted findings. .
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 a review of temperature records, storage requirements for Hematology controls, and an interview with the Practice Manager, the surveyor determined the laboratory failed to monitor and document refrigerator temperatures for two weeks in December 2019. The findings include: 1. A review of the 2019 temperature charts revealed testing personnel had failed to monitor and document refrigerator temperatures for two weeks in December 2019, from 12/17 thru 12/31/2019. 2. During an interview on 2/4/2020 at 2:30 PM, the Practice Manager reviewed the chart and confirmed the above noted findings. The surveyor then asked what was in the refrigerator, and the Practice Manager stated the Hematology controls with storage requirements of 2-8 degrees Celsius. .
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 a review of quality assurance records and an interview with the Practice Manager, the surveyor determined the laboratory failed to follow the Quality Assessment (QA) procedure, adequately document QA chart reviews, and ensure laboratory staff were trained in QA procedures. The findings include: 1. A review of the Quality Assessment (QA) procedure in the laboratory's Policy and Procedure manual revealed a checklist for an assessment "to be completed no later than the 7th of every month. ...". There was no evidence the checklist had been utilized for QA reviews since the laboratory opened on 10/7/2019. 2. During an interview on 2/4/2020 at approximately 2:45 PM, the surveyor asked if the laboratory had documentation of any QA reviews; the Practice Manager provided the surveyor with the October-December 2019 "Quality Assessment Review Forms". [October and November 2019 listed waived tests only.] The December form listed CBC [Complete Blood Count] Urinalysis" as the "Element Under Review" with "pass/fail" as the "Acceptable Threshold". Various individual parameters of a CBC were listed under the findings. 3. As the interview continued, the surveyor asked the Practice Manager to explain what she was reviewing since the form was unclear; it did not specify if patients were reviewed, or what was actually reviewed on a CBC. The surveyor also asked if the laboratory had a procedure for the review; the Practice Manager stated there was no procedure, however she was checking the accuracy of the results for several patients, but she was not sure she was doing it right. The surveyor then stated it appeared she was doing "Chart Reviews", however the form in use by the laboratory was inadequate for that purpose. The surveyor explained most laboratories utilized a form or procedure that specified how many patients were reviewed, some form of identification of patients reviewed, and elements of the review, such as the collection details (Pre-analytical), a review of the QC on the date of test performance (Analytical), and possibly accuracy of the results in the the EMR (electronic medical record) (Post-analytical). Whatever the Laboratory Director and/or Technical Consultant determined were the most likely sources of error should be included in the periodic assessments of the quality of the laboratory services, and they should ensure testing personnel are trained to understand and correctly follow the QA procedures. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the Medonic M Series Hematology analyzer and an interview with the Practice Manager, the surveyor determined the Laboratory Director failed to document his review and approval of the

	initial validation procedures for precision, accuracy and reportable ranges, as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of Hematology records revealed the initial verification studies for precision, accuracy and reportable ranges were performed on 10/2/2019, and patient CBC (Complete Blood Count) testing on the analyzer began on 10/8/2019. 2. A review of the installation and validation records for the Medonic M Series Hematology analyzer revealed the Laboratory Director dated his review and approval of the initial verification procedures for precision, accuracy and reportable ranges on 1/16/2020, more than three months after the analyzer was utilized for patient CBC testing. 3. During an interview and review of these records on 2/4/2020 at 1:30 PM, the Practice Manager confirmed the above noted findings. SURVEYOR ID #32558 Licensure and Certification Surveyor