Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2173116	03/15/2022
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
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 a review of the Medonic M Series Hematology analyzer records, and an interview with Testing Personnel #4 (the Office Manager), the surveyor determined the laboratory failed to retain the manufacturer's calibration assay sheets (package inserts) in 2020 and the first half of 2021, as per CLIA regulatory requirements. The findings include: 1. A review of the Medonic M Series Hematology analyzer records revealed no retention of the manufacturer's calibration assay sheets for any calibrations performed in 2020 or the first half of 2021. 2. In an interview on 3/15 /2022 at 2:05 PM, Testing Personnel #4 confirmed she was unable to find the missing calibration assay sheets. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration

	verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Medonic Hematology analyzer calibration records, the Medonic Procedure Manual and an interview with Testing Personnel #4 (the Office Manager), the laboratory failed to perform a calibration at least every six months as per manufacturer's instructions. The laboratory failed to provide documentation of the two Hematology calibrations due in 2020. The findings include: 1. A review of the Medonic Hematology records revealed a calibration was performed on 10/2/2019 during the installation of the instrument; this documentation was reviewed during the previous survey. 2. The next "calibration" was performed on 4/15/2020 by a previous testing personnel who had run three levels of quality control times five runs each in the calibration mode. The surveyor reviewed instructions for a manual calibration in the User's Manual with Testing Personnel #4 who confirmed the previous testing personnel had not followed the instructions. Testing Personnel #4 was unsure what the previous testing personnel "was doing" because she was not hired until August 2020. 3. The next valid calibration was not performed until 4/27/2021, a year and a half after the 10/2/2019 installation calibration. 4. A review of the Medonic Procedure Manual on page 7 of 9 revealed, "Calibration must be performed upon set up of the instrument and then at a minimum of every six months. ..." 5. In an interview on 3/15/2022 at 2: 05 PM, the surveyor asked how often the Medonic should be calibrated; Testing Personnel #4 stated every six months, and confirmed the above noted findings. .
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 (QA) records and an interview with Testing Personnel #4 (the Office Manager), the laboratory failed to implement and document additional QA procedures to ensure proficiency testing (PT) results were submitted within the timeframes required by the PT provider, and ensure the frequency of Hematology calibrations was performed as per the manufacturer's requirements. The findings include: 1. A review of QA records revealed the laboratory performed monthly patient record reviews, and monthly quality control, maintenance and environmental records included a monthly QA review sheet. However, there was no indication the laboratory had implemented additional QA procedures to ensure Hematology calibrations were performed at least every six month [Refer to D5437], or PT results were submitted within the timeframes required by API (American Proficiency Institute) [Refer to D6017]. 2. In an interview on 3/15/2022 at 3:35 PM, Testing Personnel #4 reviewed and confirmed the above noted findings. .
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with the Testing Personnel #4 (the Office Manager), the Laboratory Director failed to ensure results were submitted before the PT provider's cutoff date. This affected one of three 2021 PT surveys. The findings include: 1. A review of the API PT records for the 2021 Event #1 Hematology survey revealed the survey samples were run on 3/29/2021, and the laboratory was required to submit their results by 11:59 PM on 3/31/2021. However, a review of the CMS (Center for Medicare and Medicaid Services) CASPER Report 0096D revealed the laboratory received a 0% score for the first survey event in 2021, due to "Failure to Participate". 2. During an interview on 3/15/2022 at 12:45 PM, Testing Personnel #4 confirmed the laboratory had missed the submission date because "a lot was going on" during that period. SURVEYOR ID#32558 Licensure and Certification Surveyor