Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2039505	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Our Town Family Care, Llc	1025 Medical Center Parkway, Selma, 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
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 calibration records, a review of operations manual, and an interview with test personnel (TP) #1 and the office manager, the laboratory failed to perform and document calibrations on the Emerald Cell-Dyn at least once every six months, as required by the laboratory's policy, between March 2018 to March 2019. This affected one of five opportunities to perform the calibration. The findings include: 1) A review of the calibration records in March for the Cell-Dyn Hematology analyzer revealed data from one calibration performed on March 6, 2018 and the next was performed on June 10, 2019. The laboratory did not perform a calibration for a whole year. 2) During an interview on 11/04/2020 at 2:25 PM, when asked what was the calibration policy for the Emerald, TP#1 and the office manager stated it should be done every six months. At this time, the surveyor and the laboratory staff reviewed the operator's manual, which indicated the calibration should be performed every six months. The surveyor asked TP#1, why a calibration was not performed for a whole year between 3/06/2018 to 6/10/2019, TP#1 stated she was not sure, because she was not there at the time it occurred.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the 2018-2020 temperature logs for the laboratory, a review of the operator's manual and the policies and procedures, and an interview with Testing Personnel (TP) #1 and the office manager, the surveyor determined the laboratory failed to document corrective actions when the room temperature exceeded acceptable ranges. This affected 7 random months (February, April, and December of 2019; January, March, June, and September of 2020). The Findings Include: 1) A review of the temperature logs revealed the following: a) On the 2019 temperature logs, the laboratory indicated acceptable room temperature range as 18-25 degrees Celsius (C). The laboratory documented temperatures less than 18 degrees C on 8 days in February and April. The laboratory failed to document corrective actions for these temperatures outside of acceptable range. b) In December, 2019 up to 11/04/202, the laboratory indicated acceptable room temperature range as 20-25 degrees C. The laboratory documented temperatures less than 20 degrees C on 23 days in December 2019 and January, March, June, and September of 2020. The laboratory failed to document corrective actions for these temperatures outside of acceptable range. 2) A review of the laboratory's policy and procedure manual revealed the room temperature should be 20-25 degrees C. 3) A review of the Emerald operators' manual revealed the following: "Note: To ensure the instrument and reagents function properly, it is important to maintain the temperature between 64-90 degrees Fahrenheit (F) (18-32 degrees C) relative humidity 80%..." 4) In an interview on 11/04/2020 at 2:25 PM, the surveyor discussed with TP#1 and office manager, the varying environmental factors associated with the Emerald, as indicated in the operators' manual and policy and procedure manual verus the temperature charts. The surveyor further discussed the laboratory's failure to document corrective actions for out of range temperatures. TP#1 confirmed the above noted findings and voiced understanding.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on a review of the 2018-2020 American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel (TP) #1 and the office manger, the surveyor determined the Laboratory Director or designee failed to sign the performance review evaluation for one of the nine proficiency testing events reviewed by the surveyor. The findings include: 1) A review of the API proficiency testing records revealed the Laboratory Director failed to sign the performance review evaluation for Hematology Event #3 2019. 2) In an interview on 11/04/2020 at 2:19 PM, when asked why was the 2019 Hematology Event #3 performance review evaluation signed by TP #1 and not by the laboratory director/designee, TP#1 stated it should have been the laboratory director and it was her error. TP #1 was not listed on the personnel form as a qualified designee.
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 a review of policies and procedures, a lack of quality assurance (QA) documentation and interviews with the Testing Personnel (TP) #1 and the office manager, the surveyor determined the Laboratory Director failed to establish and maintain an effective quality assessment program to assure quality assessments were performed and documented. This affected the survey review period from June 2018 to September 2020. The finding include: 1) A review of the policies and procedures revealed a QA statement the following would be monitored: specimen collection and handling, patient test management, record keeping, quality control, laboratory safety, proficiency testing, patient test results, and record retention. 2) A review of the monthly laboratory quality control (QC) report, item #15 indicated chart reviews were completed twice monthly. The laboratory staff documented two days each month indicating a chart was reviewed. However, the staff failed to document which charts were reviewed or what was monitored. All QA activities must be documented, according to the CLIA regulations. 3) During an interview on 11/04/2020 at 2:19 PM, the surveyor asked TP#1 to explain the monthly QC reports. TP#1 stated the reports were end-of-month control checks. When asked how QA and chart reviews were performed, TP#1 stated the physician reviewed random charts pulled by the testing personnel. When the surveyor asked how the QA monitoring was documented, TP#1 stated staff only documented the chart review dates. The office manager was present during the interview.