Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0303490	12/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gadsden Medical Clinic	601 South 3rd Street, Gadsden, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2020 CAP (College of American Pathologists) proficiency testing (PT) records and interview with the Testing Personnel #1 (listed on Form CMS-209), the laboratory failed to ensure attestation statements for two out of eight surveys were signed by the Laboratory Director (LD) and Testing Personnel (TP). The findings include: 1. A review of the CAP PT records revealed no signatures of the Laboratory Director and Testing Personnel on the attestation statements for the following surveys: A) 2019-FH2-B Hematology Event: No LD or TP B) 2020-FH2-A Hematology Event: No LD or TP 2. In an interview on 12/8/2020 at 12:43 PM, TP #1 reviewed the PT records with the surveyor, and confirmed the above noted findings. .
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

	This STANDARD is not met as evidenced by: Based on a review of CAP (College of American Pathologists) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to participate in one out of three proficiency testing events in 2019. The findings include: 1) A review of the CAP PT records for the 2019 FH2-B Hematology survey event revealed results were due on or before 5/28/2019. However the laboratory failed to submit the PT results within this timeframe, and received a score of 0% due to "failure to participate". 2) In an interview on 12/8/2020 at 12:45 PM, TP #1 stated that she had run the CAP samples on 5/16/2019 at 10:06 AM, however she had failed to submit the results on time. .
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2020 CAP (College of American Pathologists) proficiency testing (PT) records and an interview with Testing Personnel #1 and #2, the surveyor determined the laboratory failed to document reviews of eight of eight of the returned survey evaluations results, and further failed to document corrective action for two of eight surveys with results less than 100% (percent). The findings include: 1. A review of the CAP PT records revealed no documentation of review (as indicated by the date and signature of the Laboratory Director) of the returned evaluations for eight Hematology surveys in 2018 - 2020. 2. A review of the survey results revealed no documentation of investigation or corrective action for two surveys with results less than 100%, as follows: A) 2018 FH2-C Hematology: Lymphocytes Absolute Count with a score of 80%. B) 2019 FH2-B Hematology: Failure to submit PT results within the established timeframe which resulted in a score of 0% for non-participation [Refer to D2123], and no internal evaluation of the laboratory's results for this survey to determine if corrective actions were needed. 3. In an interview on 12/8/2020 at approximately 12:45 PM, the surveyor reviewed the above records with TP #1 and TP #2. When asked if the Laboratory Director reviewed the returned proficiency testing results, and if the laboratory performed corrective actions for CAP PT with scores less than 100%, TP #1 and TP #2 stated the Director does review the survey evaluations, however he was not documenting his reviews with a signature. TP #1 further stated they had not noticed the 80% score on the Lymphocyte Count on the 2018 FH2-C event, and did not know a self-evaluation was required for the 2019 FH2-B event. 4. This is a repeat deficiency. .
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 lack written policies and procedures, and interviews with Testing Personnel #1 and the Laboratory Director, the surveyor determined the laboratory failed to have written policies and procedures for the testing personnel to reference. The findings include: 1. A review of the laboratory processes revealed a lack of written policies and procedures for the testing personnel to reference were contributing factors in the following deficiencies: A) No proficiency testing policies (Refer to D2009, D2123, D5221) B) No policy specifying expiration dates should be checked, and expired calibrators (and other items) should not be utilized beyond expiry (Refer to D5417.) C) No policy specifying the performance frequency of Beckman Coulter AcT diff 2 calibrations (Refer to D5437.) D) No policy specifying the frequency and method of documenting and monitoring QC shifts and trends (Refer to D5441.) 2. During an interview on 12/8/2020 at 2:30 PM, TP #1 confirmed there were no written policies for the testing personnel. TP #1 stated several years ago the laboratory had lost the tech who knew the most about the lab. She had left a list of "things that needed to be done" in the lab. The surveyor stated the laboratory must have written procedures, and these should also include a policy specifying panic (or alert) values with a protocol for the testing personnel to follow when patient samples have critical results. TP #1 and the Laboratory Director both confirmed the laboratory did not have a critical values list or policy; they stated since all Complete Blood Count (CBC) reports were given directly to the doctor, they did not think a written policy was required. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter (B-C) AcT diff 2 Hematology analyzer calibration records and an interview with Testing Personnel #1, the laboratory failed to ensure the April 2020 calibrator was used before its expiration date. This was observed on one of three 2018 - 2020 calibrations reviewed. The findings include: 1. A review of records for the B-C AcT diff 2 Hematology analyzer, revealed a calibration was performed on 4/8/2020, using an expired S-CAL Calibrator, lot number 4790 and expiry date of 4/4/2020. 2. During an interview on 12/8/2020 at 1: 05 PM, the surveyor reviewed and confirmed the above noted findings with Testing Personnel #1. .

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 reviews of the Beckman Coulter AcT diff 2 Hematology analyzer Operator's Manual, calibration records, quality control (QC) records and interviews with Testing Personnel (TP) #1 and #2, the surveyor determined the laboratory failed to implement and follow a policy in the performance frequency of calibrations in 2018-2020, and failed to follow the manufacturer's instructions to confirm the instrument calibration by monitoring QC for shifts and trends. The instrument had not had a valid calibration since 3/27/2019 (approximately twenty months earlier). The findings include: 1. A review of the Beckman Coulter AcT diff 2 Hematology analyzer records revealed the following: A) Two calibrations in 2017 on 3/22/2017 and 9/20/2017 B) Two calibrations in 2018 on 4/05/2018 and 10/04/2018 C) One 2019 calibration on 3/27/2019, and D) One calibration performed on 4/8/2020 with an expired calibrator (Lot number 4790; Expiry 4/4/2020) (Refer to D5417.) 2. A review of the Beckman Coulter AcT diff 2 Hematology analyzer Operator's Guide on page 5-1 revealed the following: "... Beckman Coulter recommends that you calibrate your instrument according to the regulations required by your inspecting agency. ..." [CLIA regulations specify a laboratory must follow the manufacturer's instructions or specify the calibration frequency in a policy if the manufacturer does not.] (Refer to D5403.) "...Your laboratory's quality control program should continually monitor and confirm instrument calibration. Review your control results periodically. Keep a written record of this review. ... 2. Verify that there are no unexplained shifts or trends in the data. ..." [The laboratory failed to implement a procedure to monitor for shifts and trends in the QC, (refer to D5441), thus there was no documentation the laboratory was "confirming instrument calibration", as per manufacturer's instructions.] 3. During an interview on 12/8/2020 at 1:05 PM, the surveyor asked how often the Beckman Coulter AcT diff 2 should be calibrated. TP #1 stated she was not sure, and asked TP #2, who stated she thought it was twice a year. (The laboratory was unable to provide a policy stating this.) The surveyor reviewed and confirmed the above records with TP #1, including the use of the expired calibrator on 4/8/2020. The surveyor noted the instrument had not had a valid calibration in more than twenty months, and a lack of Levey-Jennings QC charts indicated the calibration status was not being monitored through review of the QC for trends and shifts. .
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

	laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a lack of quality control records and an interview with Testing Personnel #1, the laboratory failed to document reviews of Hematology quality control (QC) for shifts and trends over time for a two and a half year period since July 2018. The findings include: 1. A review of the QC records for the Beckman Coulter AcT diff 2 Hematology analyzer revealed only the instrument printouts of the daily QC. The laboratory had no records documenting the monitoring of QC shifts and trends over time since July 2018. (Examples include printing Levi-Jennings (L-J) charts or periodically submitting data to a QC company's Interlaboratory Quality Assurance Program [IQAP]). The surveyor reviewed the cumulative QC with L-J charts for April 2018 through 7/2/2018. A second surveyor-in-training reviewed cumulative QC data for 2/26 - 8/12/2019, however no L-J charts had been printed. 2. The surveyor also requested QC for 2020; during the survey TP #1 printed cumulative QC with L-J charts for 12/2/2019 through 5/19/2020. 3. During an interview on 12/8/2020 at 1:55 PM, the surveyor explained the requirement for implementing a method to monitor for shifts and trends in the QC. The surveyor showed TP #1 evidence of a downward trend in RBC (Red Blood Cells) in the 12/2/2019 through 5/19/2020 QC on the L-J chart, further noting the laboratory had not performed a valid calibration on Beckman Coulter AcT diff 2 Hematology analyzer to correct this trend since 3/27/2019. (Refer to D5437.) As the interview concluded at 2:20 PM, TP #1 confirmed the laboratory had printed only monthly cumulative reports for the patient data, and had failed to print the cumulative QC with the L-J charts. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter AcT diff 2 Hematology records, proficiency testing (PT) records, and personnel records, and interviews with Testing Personnel #1 and the Laboratory Director (who also serves as the Technical Consultant), the surveyor determined the Technical Consultant failed to adequately fulfill his responsibilities to provide effective technical and scientific oversight of the laboratory. The findings include: 1. A review of laboratory processes revealed the Technical Consultant had failed to provide effective technical and scientific oversight in the following areas: A) Failure to ensure PT attestation statements were signed (Refer to D2009), PT results were submitted within the time frame specified by CAP (College of American Pathologists) (Refer to D2123), and ensure reviews of performance evaluations (scores) were documented with corrective actions for any results less than 100% (Refer to D5221). B) Failure to have written policies and

	procedures for the testing personnel to reference (Refer to D5403.) C) Failure to ensure testing personnel utilized Hematology calibrators before expiry (Refer to D5417), and ensure the Hematology calibration timeframe frequency was specified and followed (Refer to D5437.) D) Failure to document reviews of Hematology quality control for shifts and trends over time (Refer to D5441.) E) Failure to perform and document annual competency evaluations for the two testing personnel (Refer to D6054.) 2. These concerns were discussed with Testing Personnel #1 and the Laboratory Director during the exit summation on 12/8/2020 from 3:20 to 3:45 PM. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a lack of documentation in the personnel files, and an interview with the Laboratory Director (who also serves as the Technical Consultant), the the Technical Consultant failed to ensure the 2018, 2019 and 2020 annual competency evaluations were performed and documented for two of two testing personnel. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed two testing personnel who had performed moderate-complexity Hematology testing since the previous survey on 4/19/2018. However, there were no annual competency evaluations available. 2. During an interview on 12/8/2020 at 3:20 PM, the Laboratory Director/ Technical Consultant stated he performed the annual competency evaluations for the two testing personnel, however he did not document them. 3. This is a repeat deficiency. [Note: The CMS Booklet "What do I Need to Do to Assess Personnel Competency?" was provided during the previous survey, however the laboratory failed to follow their Plan of Correction to utilize the guidelines in implementing an annual competency checklist.] SURVEYOR ID #32558 Licensure and Certification Surveyor