Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0966583	11/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sharp & Stone Ob/Gyn	2700 10th Avenue South Suite 306, Birmingham, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, training and competency evaluations for the testing personnel listed on CMS Form-209, and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure proficiency testing samples were rotated between all personnel who routinely performed Hematology testing on patients. This was noted on all 2016-2018 surveys. The findings include: 1. A review of API attestation statements revealed Testing Personnel TP #1 performed the Hematology testing (all samples) on all 2016-2018 surveys: Event #1-2016 thru Event #2-2018 (eight surveys). 2. A review of training and competency evaluations in the personnel records revealed the following: A) TP #2 and #3 were full time, and had been qualified as a testing personnel since the previous CLIA survey, and B) TP #4 had been performing patient testing since November 2017. 3. During an interview on 11/27/2018 at 11:50 AM, the surveyor reviewed the PT records and the testing personnel on the CMS Form-209 with TP #1. When asked if the PT had been rotated between all personnel who performed patient testing, TP #1 stated, "I am the only one who does PT". Thus the above noted findings were confirmed. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	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 Testing Personnel #1, the laboratory failed to document reviews of two out of three of the returned 2017 Hematology survey results evaluations (scores). The findings include: 1. A review of the API PT records revealed no documentation of review (as indicated by a signature and date) of returned evaluations for the Events #2 and #3 2017 Hematology surveys. 2. In an interview and review of the records on 11/27/2018 at 12:50 PM, Testing Personnel #1 confirmed the laboratory had failed to document a review of the above noted surveys. .
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 reviews of the Hematology quality control records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to implement a mechanism to monitor quality control (QC) shifts and trends over time from May 2017 till the date of the current survey (11/27/2018). The findings include: 1. A review of the 2016-2018 Medonic Hematology analyzer QC records revealed only the daily QC instrument printouts had been printed and retained after May 2017. 2. During an interview on 11/27/2018 at 12:55 PM, Testing Personnel #1 was asked if the laboratory had implemented a new mechanism to routinely monitor control shifts and trends, such as submission of the QC results to an Interlaboratory Quality Assurance Program (IQAP), or printing cumulative Levy-Jennings (L-J) charts (as they had until May 2017). Testing Personnel #1 explained in May 2017, the Medonic company had changed the QC reporting mechanism from paper to "a stick" [electronic data], and the laboratory never received any QC reports thereafter. The laboratory had been unsuccessful in their attempts to receive any assistance from the company to resolve the issue, and had not been able to print L-J charts since May 2017. Thus the above noted findings were confirmed. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the 2017 Hematology quality control (QC) records, the patient results log, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of quality control were run and acceptable, prior to analyzing patient specimens and reporting the results. The findings include: 1. A review of the QC records for Medonic Hematology analyzer revealed no record of QC for 10/13 /2017. 2. A review of the cumulative patient log printed from the instrument revealed one patient CBC (Complete Blood Count) was performed on 10/13/2017. 3. During an interview on 11/27/2018 at 3:50 PM, Testing Personnel #1 reviewed the Hematology records and was unable to find QC results for the above mentioned date, and found one patient CBC had been run and reported. Thus the above findings were confirmed. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a lack of documentation in the personnel file for Testing Personnel #4 and an interview with TP #1, the Laboratory Director failed to ensure training for TP #4 was performed and documented before patient CBC (Complete Blood Count) testing began. This was noted on the records for one of four testing personnel. The finding include: 1. A review of the documentation provided for TP #4 revealed no evidence of training on the Medonic Hematology analyzer procedures. 2. During an interview on 11/27/2018 at 11:50 AM, the surveyor asked TP #1 about the scope of responsibilities for TP #4. TP #1 stated TP #4 only performed CBC (Complete Blood Count) testing on the quality control and patients samples. When asked if TP #4 received training to perform this procedure, TP #1 stated she had trained TP #4 "in the Fall 2017" (November 2017 according to Quality Assurance records), however she had no documentation of the training. Thus the above noted findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor