Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0966583	06/08/2021
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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on reviews of proficiency testing (PT) records, quality assurance (QA) records, and an interview, the laboratory failed to ensure the corrective actions taken effectively remediated problems identified in the general laboratory systems. This was noted from August 2018 to January 2021. The findings include: 1. A review of the 2018 - 2021 API (American Proficiency Institute) Proficiency Testing records revealed the laboratory failed three out of eight of Vaginal Wet Prep PT challenges, and one out of eight Vaginal Wet Prep - KOH PT challenges as follows: a) 2019 Hematology 1st Event - 0% Vaginal Wet Prep b) 2019 Hematology 1st Event - Not Graded Vaginal Wet Prep - KOH b) 2020 Hematology 2nd Event - 0% Vaginal Wet Prep - KOH c) 2020 Hematology 3rd Event - 0% Vaginal Wet Prep d) 2021 Hematology 1st Event - 0% Vaginal Wet Prep No corrective action was documented for three of the four failures listed above and a self grade was not performed for the event that was not graded. For 2020 Hematology 2nd Event - 0% Vaginal Wet Prep - KOH corrective action stated trouble with picture. 2. A review of the Proficiency Testing records also revealed the attestation was not signed by the testing personnel (Doctors) who performed the Vaginal Wet Prep, Vaginal Wet Prep - KOH, Fern Test, and Sperm for eight of eight Proficiency Testing Events reviewed. 3. A review of January 2019 - April 2021 monthly Quality Assurance Checklists covered Proficiency Testing. The reviewer always answered "Y" (Yes) and no problems or corrective action documented on the QA Checklist forms. 4. During an interview on 06/08/2021

	at 12:00 PM, Testing Personnel #1 was unaware a self grade was needed if not graded by API, unaware pictures needed corrective action for failures, and unaware Doctors performing the Vaginal Wet Prep, Vaginal Wet Prep - KOH, Fern Test, and Sperm needed to sign the attestation statement.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual and an interview with Testing Personnel #1, the laboratory failed to have a written procedure for Potassium hydroxide (KOH) preparations, Fern Tests, and Post-coital direct - qualitative examinations of vaginal or cervical mucous. The findings include: 1. A review of the Procedure Manual revealed a lack of written procedures for Potassium hydroxide (KOH) preparations, Fern Tests, and Post-coital direct - qualitative examinations of vaginal or cervical mucous. 2. During an interview on 06/08/2021 at 11:10 AM, Testing Personnel #1 confirmed the laboratory did not have a procedure for the tests above.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the 2020 Hematology quality control (QC) records for the Medonic, 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. This was noted one day out of 12 months reviewed from April 2019 to March 2021 by the surveyor. The findings include: 1. A review of the QC records for the Medonic Hematology analyzer revealed on 05/07/2020 a) Low control run at 9:40 AM the following analytes were out of acceptable range Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelet. b) Normal control was not run on 05/07 /2020. c) High control run at 9:42 AM the following analytes were out of acceptable range Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, Absolute Lymphocytes, and Platelet. 2. A review of the cumulative patient log printed from the instrument revealed two patient CBCs (Complete Blood Count) were performed on 05 /07/2020 at 7:52 AM and 12:26 PM. 3. During an interview on 06/08/2021 at 1:20 PM, Testing Personnel #1 confirmed QC was out for both Low and High control on 05 /07/2020. It was also confirmed the first patient was run before controls were attempted to be run on 05/07/2020.