

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0966583	(X3) Date Survey Completed 03/21/2023
Name of Provider or Supplier Sharp & Stone Ob/Gyn	Street Address, City, State 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	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(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.</p> <p>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 July 2021 to March 2023. This is a repeat deficiency. The findings include: 1. A review of the 2022 API (American Proficiency Institute) Proficiency Testing records revealed the laboratory failed two of three Vaginal Wet Prep - KOH [Potassium Hydroxide] PT challenges as follows: a) 2022 Hematology 2nd Event - Vaginal Wet Prep - KOH 0% b) 2022 Hematology 3rd Event - Vaginal Wet Prep - KOH 0% Corrective action for 2022 Hematology 2nd and 3rd event 0% Vaginal Wet Prep - KOH stated testing personnel had difficulty evaluating the slides. 2. A further review of the Proficiency Testing records also revealed no documentation of corrective actions for scores less than 100% on the following events: a) 2021 Hematology 2nd Event: Red Blood Cell (RBC) and Hematocrit, each with a score of 80%, and b) 2022 Hematology 1st Event: Lymphocytes and Neutrophils, each with a score of 80%, resulting in a score of 87% for the White Blood Cell Differential. 3. A review of the July 2021 - March 2023 monthly Quality Assurance records revealed Proficiency Testing was included on the monthly checklists. However, the reviewer always checked the "Y" (Yes) column to indicate no problems were identified. No</p>

corrective actions were documented on the QA Checklist forms. 4. During an interview on 03/21/2023 at 9:41 AM, Testing Personnel #1 said the KOH slides were too difficult for the Testing Personnel to evaluate.