

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0966583	(X3) Date Survey Completed 07/31/2025
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the new Laboratory Director, the laboratory failed to ensure the previous Laboratory Director signed the attestation statements for four of four events reviewed in 2023 through 2024. The findings include: 1. A review of the API PT records revealed the no signature by the previous Laboratory Director (or designee) on attestation statements for the following surveys: a) 2023 Hematology 1st Event. b) 2023 Hematology 2nd Event. c) 2023 Hematology 3rd Event. d) 2024 Hematology 1st Event. 2. During an interview on 7/31/2025, at 12:37 PM, the new Laboratory Director confirmed the above findings.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on a review of Hematology records and an interview with the Office Manager, the laboratory failed to retain documentation of daily CBC (Complete Blood Counts)</p>

	<p>calibrations performed on the Medonic Hematology analyzer in 2023 and 2024. This was noted for two possible calibrations, one for the second half of 2023 and one for the first half of 2024. The findings include: 1. A review of the Medonic Hematology analyzer revealed the laboratory discontinued CBC testing in May 2024. The last documented calibration provided was performed on 5/13/2023. There was no evidence of a documented calibration performed the second half of 2023 and the first half of 2024. 2. In an interview on 7/31/2025 at 12:37 PM, the Office Manager told the Surveyor she would email the calibration documentation. As of 8/15/2025, no calibration documentation has been received by the Surveyor.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the lack of bi-annual accuracy verification for Wet Prep documentation, and an interview with the new Laboratory Director, the laboratory failed to implement a mechanism for performing accuracy verification or perform proficiency testing on Saline Wet Prep testing. This was noted since the previous survey on 3/21/23 to the current survey on 7/31/25. The findings include: 1. A review of the bi-annual accuracy verification documentation for Saline Wet Prep revealed the laboratory discontinued proficiency testing through American Proficiency Institute (API) and failed to implement an alternative accuracy verification method twice yearly. 2. During an interview on 7/31/25 at 12:37 PM, the new Laboratory Director confirmed the above findings.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2023-2024 API (American Proficiency Institute) Proficiency Testing records and an interview with the Office Manager, it was determined the Laboratory Director failed to document review of returned results, and/or failed to perform and document corrective actions for scores less than 100 % (percent) for one of four Hematology surveys reviewed. The findings are: 1. A review of the API Hematology Proficiency Testing records revealed no documentation of review and/or no corrective action for scores of less than 100% for the following surveys: A.) 2023 Hematology Event #1: No documentation of review of the returned results. B.) 2023 Hematology Event #2: No documentation of review of the returned results. C.) 2023 Hematology Event #3: No documentation of review of the returned results. D.) 2024 Hematology Event #1: No documentation of review of the returned results and no corrective action for Wet Preps with a score of 0%. 2. During an interview on 7/31 /2025 at 12:37 PM, the Office Manager confirmed the above findings.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p>

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of Personnel files, and an interview with the Office Manager, the laboratory failed to ensure educational documentation was available for three of four new Testing Personnel (TP) performing moderate-complexity patient testing. The findings include: 1. A review of the personnel files revealed no educational documentation for Testing Personnel #2, #3, and #4. 2. During an interview on 7/31/2025 at 12:32 PM, the Office Manager said she was unaware that Wet Preps is a moderate complexity test and that testing personnel needed education on file.