

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0688159	<b>(X3) Date Survey Completed</b>  04/28/2022
<b>Name of Provider or Supplier</b>  Boyette Orthopedics & Sports Medicine	<b>Street Address, City, State</b>  4205 Ben Franklin Boulevard, Durham, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2019, 2020, 2021, and 2022 hematology records and interview with TC (technical consultant) #1 on 4/28/22, the laboratory failed to retain all analytic systems records for at least two years. Review of 2019, 2020, 2021, and 2022 hematology records revealed there were no backgrounds available for the Sysmex XS 1000i hematology analyzer prior to 10/25/21. During interview at approximately 2:45 p.m., TC #1 stated that they make sure backgrounds are acceptable prior to patient testing each day, but they do not usually print them.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2020, 2021, and 2022 American Proficiency Institute (API) proficiency testing results, and technical consultant (TC) #1 interview 4/28/22, the laboratory failed to review and evaluate all results obtained on proficiency testing to ensure corrective action was taken and documented as required. Findings: Review of the laboratory procedure "Proficiency and Split Sample Testing" revealed..."13. Any result graded as</p>

unacceptable, No consensus, Not Graded, or labeled with any code will be investigated and documented, which includes a self-grade for any proficiency not submitted by the required due date... 15. All laboratory staff, including the Laboratory Director, will review the above investigation, signing the Performance Review Summary included with the results acknowledging the or she has reviewed the results and scoring of the proficiency as well as any corrective action required within 30 days of receipt. 16. The review and investigation information will be maintained in the proficiency notebook under the appropriate tab and maintained for a period of at least 2 years." Review of API PT results revealed there was no evidence of review of graded results for the API 2020 first hematology event. Review of 2020 API PT records also revealed that the lab received a score of 0% on the 2020 third chemistry event for failure to submit their results by the due date. Interview with TC #1 at approximately 3:00 p.m. confirmed there was no documentation of review and evaluation of the PT results for the API 2020 first hematology event or the 2020 third chemistry event. TC #1 stated there was no formal process for reviewing PT results as sometimes results are reviewed online and sometimes the hard copies of results are sent from the PT agency and they are reviewed by staff in a meeting after receipt.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on review of manufacturer's instructions, review of 2019, 2020, 2021, and 2022 hematology maintenance records, and interview with TC (technical consultant) #1 on 4/28/22, the laboratory failed to perform and document maintenance for the Sysmex XS 1000i hematology analyzer at the frequency specified by the manufacturer. Review of Sysmex XS 1000i manufacturer's instructions revealed the manufacturer requires performance of a rinse sequence monthly or every 1200 cycles. Review of 2019, 2020, 2021, and 2022 Sysmex XS 1000i maintenance logs revealed the laboratory failed to document the manufacturer's specified monthly maintenance for 5 of 20 months from September 2019 - April 2022. Monthly maintenance was not documented the following months: a. 2019 - September; b. 2021 - January, February, May, and June. During interview at approximately 4:30 p.m., TC #1 stated the maintenance was done but not documented.

**D6040**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:  
Based on review of 2019, 2020, 2021, and 2022 laboratory records, observation, and interview with TC (technical consultant) #1 on 4/28/22, the TC failed to ensure verification of performance specifications for the Clinitek 500 urine analyzer. Review of 2019, 2020, 2021, and 2022 laboratory records revealed the following handwritten

notation at the bottom of one of the urine quality control assay sheets: "Clinitek Advantus out of service on 11/19/21. Clinitek 500 back in service 11/19/21". A notation on the "URINE PROBLEM LOG" stated "11/10/21 Cleaning crew cleaned screen and is now dim and surging. Clinitek ref #1020240 'no option for repair' Trimedx Ref #C04107642". During a tour of the laboratory at approximately 3:20 p. m., the surveyor observed the Clinitek 500 in use in the laboratory. During interview at approximately 3:35 p.m., the TC confirmed the laboratory currently uses the Clinitek 500. He stated they have not been able to find a replacement analyzer for the Clinitek Advantus. He stated the Clinitek 500 was stored in a cabinet in the laboratory, so they were able to get it out and use it. He stated they ran quality control but did not perform any other validation activities to ensure the analyzer was functioning properly prior to testing patient specimens. He verified there was no other documentation available for review.