

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 29D2093411	<b>(X3) Date Survey Completed</b> 11/22/2019
<b>Name of Provider or Supplier</b> Orthopedic Specialty Hospital Of Nevada	<b>Street Address, City, State</b> 8656 W Patrick Ln, Las Vegas, NV	
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>D0000</b>	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on November 21 and 22, 2019. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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</p> <p>This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) proficiency testing records from testing years 2018 and 2019 and an interview with the laboratory manager, the laboratory failed to rotate the proficiency testing samples to be analyzed to all of the personnel who routinely perform patient laboratory testing. Findings include: A review of the CAP proficiency testing records for 2019 revealed that the laboratory failed to rotate the proficiency testing samples to be analyzed to all of the patient testing personnel. For testing year 2019, the records indicate that the laboratory manager performed and recorded all CAP proficiency testing events. This was confirmed by the laboratory manager on November 21, 2019 at approximately 1: 30 PM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p>

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 College of American Pathologists (CAP) proficiency testing records from testing years 2018 and 2019 and an interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results obtained from the proficiency testing agency. Findings include: 1. The laboratory failed to review and evaluate the CAP proficiency testing results for testing year 2019. 2. The CAP proficiency testing records indicate that for testing year 2019, the laboratory failed to review, evaluate and document the findings for the results from the Plasma Cardiac Markers (PCARM), the WB Prothrombin Time/INR, I-Stat (WP3), Blood Gas (AQ) and Blood Oximetry (SO). This was confirmed by the laboratory manager on November 21, 2019 at approximately 1:30 PM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.

**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 director approved policy and procedure manual, a request to review the Individualized Quality Control Plan (IQCP) for the i-Stat testing system and an interview with the laboratory manager, the laboratory failed to follow the directions in the policy and procedure manual for the annual review of the IQCP. Findings include: 1. The laboratory failed to follow the director approved policy and procedure for the IQCP for the i-Stat testing system. 2. The policy states that the IQCP for the i-Stat test system will be reviewed annually. A request to review the IQCP for the i-Stat test system revealed that the IQCP could not be found for review on the day of the survey. This was confirmed by the laboratory manager on November 22, 2019 at approximately 1:00 PM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.

**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 a review of laboratory instrument maintenance records from October 2017 through November 2019 and an interview with the laboratory manager, the laboratory failed to perform and document maintenance according to the frequency defined by the manufacturer of the instruments. Findings include: 1. The laboratory failed to perform and document the maintenance according to the instructions defined by the

manufacturer of the ABL 90 and the i-Stat testing systems. 2. For patient testing month October 2017, there was no maintenance documented 7 of 31 times for the i-Stat and 9 of 31 times for the ABL 90. 3. For patient testing month November 2017, there was no maintenance documented 6 of 30 times for the i-Stat and 9 of 30 times for the ABL 90. 4. For patient testing month January 2018, there was no maintenance documented 8 of 31 times for the i-Stat and 7 of 31 times for the ABL 90. 5. For patient testing month March 2018, there was no maintenance documented 4 of 31 times for the i-Stat and 4 of 31 times for the ABL 90. 6. There was no maintenance log available for review for December 2018 and February 2019. This was confirmed by the laboratory manager on November 21, 2019 at approximately 3:00 PM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Based on a review of laboratory instrument records and an interview with the laboratory manager, the laboratory failed to perform, compare and evaluate, at least twice a year, the laboratory instruments that perform the same testing. Findings include: 1. The laboratory failed to perform, document and review the twice a year comparison of blood gas results from the ABL 90 and the i-Stat test systems. 2. A request for the twice a year correlation records comparing the blood gas results from the ABL 90 to the i-Stat instrument, was not performed for testing year 2019 and was unable to be found on the day of the survey for testing year 2018. This was confirmed by the laboratory manager on November 22, 2019 at approximately 1:00 PM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on a review of the CAP proficiency testing reports for testing year 2018 and 2019 and an interview with the laboratory manager, the laboratory director failed to ensure that all proficiency testing reports are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that may require

corrective action. Findings include: 1. The laboratory director failed to ensure that the CAP proficiency testing results for 2019 were reviewed and evaluated to determine if there were any problems that would require corrective action. 2. The results from the CAP proficiency testing in 2019 revealed no signatures or dates of review for the AQ, SO, PCARM and WP3 proficiency testing reports. This was confirmed by the laboratory manager on November 21, 2019 at approximately 1:00 PM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on a review of the director approved policy and procedure manual and an interview with the laboratory manager, the laboratory director failed to ensure that the laboratory had a quality assessment program established and maintained to assure the quality of the laboratory services provided. Findings include: The laboratory director failed to have an established quality assessment program that would review on a regular basis, the pre-analytic, the analytic and the post-analytic phases of laboratory testing to determine the quality of the laboratory services provided. This was confirmed by the laboratory manager on November 22, 2019 at approximately 11:00 AM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on a review of the personnel training and competency records and an interview with the laboratory manager, the laboratory technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually after the first year. Findings include: The laboratory technical consultant failed to perform and document the evaluation of competency for 1 of 22 moderate complexity testing personnel for testing year 2018. This was confirmed by the laboratory manager on November 21, 2019 at approximately 11:00 AM. The laboratory performs approximately 827 patient Chemistry and Hematology tests annually.