

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D1025475	<b>(X3) Date Survey Completed</b>  09/30/2022
<b>Name of Provider or Supplier</b>  Az Orthopedic Specialty Hospital	<b>Street Address, City, State</b>  2905 W Warner Road Ste 101, Chandler, AZ	
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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Proficiency Testing (PT) records for review from 2021 and 2022 and interview with the testing personnel, the laboratory failed to maintain a copy of all PT records for a minimum of 2 years from the date of the proficiency testing event. Findings include: 1. The laboratory performs patient testing in the specialties of chemistry and hematology, with an approximate annual test volume of 5,004. The laboratory performs the Chem8+ test on the i-Stat analyzer and participates in 3 Proficiency Testing events annually. 2. During the survey conducted on September 30, 2022, the laboratory failed to produce evidence of the following PT documentation from each testing event of 2021 and the first and second testing events of 2022: - Attestation statements signed by the Laboratory Director and testing personnel - Copies of the instrument printouts - Copies of the PT program report forms used by the laboratory to record PT results 3. The testing personnel interviewed on 09/30/22 at 10:45am confirmed that the PT records indicated above could not be located during the survey.</p>

**D3027**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(1)

Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

This STANDARD is not met as evidenced by:

Based on lack of test requisitions for review and interview with the testing personnel, the laboratory failed to retain test requisitions and test authorizations for at least two years. Findings include: 1. The laboratory began patient testing on 04/09/2020 in the specialties of Chemistry and Hematology, with an approximate annual test volume of 5,004. The laboratory performs the Chem8+ test on the i-Stat analyzer. It is the practice of the laboratory to maintain test requisitions in the patient's Electronic Health Record (EHR). 2. The laboratory failed to provide evidence of the test requisition for patient ID#00909718 from testing performed on 11/23/2021. 3. The testing personnel interviewed on 9/30/22 at 11:24am acknowledged that the test requisition indicated above was no longer accessible in the EHR.

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on lack of Proficiency Testing (PT) records for review from 2021 and 2022 and interview with the testing personnel, the laboratory failed to retain PT records for at least 2 years. Findings include: 1. The laboratory performs patient testing in the specialties of chemistry and hematology, with an approximate annual test volume of 5,004. The laboratory performs the Chem8+ test on the i-Stat analyzer and participates in 3 Proficiency Testing events annually. 2. The laboratory failed to produce evidence of PT records from each testing event of 2021 and the first and second testing event of 2022. See D2015 for specific findings. 3. The testing personnel interviewed on 09/30/22 at 10:45am confirmed that the PT records referenced above could not be located during the survey.

**D5209**

**PERSONNEL COMPETENCY ASSESSMENT POLICIES**

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Assurance policy and interview with the facility personnel, the laboratory failed to follow established policies and procedures to assess employee competency. Findings include: 1. The laboratory began patient testing on 04/09/2020 in the specialties of Chemistry and Hematology, with an approximate annual test volume of 5,004. 2. The laboratory policy reviewed during the survey titled, "Quality Assurance Plan" states, "Initial training - When a new

employee is trained in the Arizona Orthopedic Surgical Hospital Lab, they complete a standard skills checklist to ensure that each employee is trained in a consistent manner and that they can demonstrate competency before they can verify patient test results. 6 Month Competency - After 6 months of testing each trained employee is given the skills checklist to ensure they understand all aspects of the laboratory testing. Annual Skills Checklists - As a part of every employee's annual evaluation, they are once again given the skills checklists, this time as a self-assessment to ensure that they understand all aspects of the laboratory testing. Competency Assessment - Throughout the year, all testing personnel are given the opportunity to demonstrate competency through a series of assessments, which may include written tests, running QC specimens, direct observation, etc". 3. The laboratory failed to follow the established policy indicated above to assess employee competency. See D6053 and D6054 for specific findings. 4. The facility personnel interviewed during the survey at 10:30am on 09/30/2022 confirmed the laboratory failed to follow established personnel competency policies to assess employee competency.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
 CFR(s): 493.1236(a)

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 review of Proficiency Testing (PT) records from 2021 and 2022 and interview with the testing personnel, the laboratory failed to provide a documented review of the PT results for testing events in the specialty of Chemistry and Hematology. Findings include: 1. The laboratory performs patient testing in the specialties of chemistry and hematology, with an approximate annual test volume of 5,004. The laboratory performs the Chem8+ test on the i-Stat analyzer and participates in 3 Proficiency Testing events annually. 2. No evidence, either by written comment or signature, was presented during the survey conducted on 9/30/22 to indicate the laboratory director or other facility personnel reviewed the PT results for each testing event of 2021 and the first and second testing events of 2022. 3. The facility personnel interviewed on 9/30/22 at 10:45am confirmed that the PT results indicated above were not reviewed by laboratory personnel.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
 Based on review of Proficiency Testing (PT) records, lack of established policies and procedures and interview with the testing personnel, (A) the laboratory failed to establish policies and procedures related to the retention of PT records; and (B) the laboratory failed to follow established Quality Assessment (QA) policies and procedures to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

Findings include: A1. 1. The laboratory performs patient testing in the specialties of chemistry and hematology, with an approximate annual test volume of 5,004. The laboratory performs the Chem8+ test on the i-Stat analyzer and participates in 3 Proficiency Testing events annually. A2. No documentation was presented for review during the survey conducted on 9/30/22 to indicate the laboratory established written policies and procedures related to the retention of PT records for a minimum of 2 years from the testing date. See D2015 for specific findings. A3. The testing personnel interviewed on 9/30/22 at 10:50am confirmed the laboratory failed to establish a policy and procedure for the retention of PT records for a minimum of 2 years from the testing date. B1. The laboratory's established QA policy titled, "Quality Assurance Plan (reference# 3103)" reviewed during the survey failed to include information on how the laboratory will monitor, assess, and when indicated, correct problems identified with Proficiency Testing and Personnel competency, including but not limited to, the frequency of QA review, how the laboratory will document the QA review, and the corrective actions to take if an error is identified. B2. The testing personnel interviewed at 11:50am on 9/30/22 acknowledged that the laboratory's established QA policy failed to include information related to the documentation of QA activities to monitor PT and personnel competency.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on the severity and number of deficiencies cited for quality practices identified during the survey conducted on September 30, 2022, it was determined that the laboratory failed to monitor the overall quality of the analytic systems and correct problems as specified in 493.1289 for patient testing performed by the laboratory in the specialties of Chemistry and Hematology. See D5445, D5775 and D5791 for findings.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Control (QC) documentation and interview with the testing

personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialties of Hematology and Chemistry. Findings include: 1. The laboratory began Chem8+ testing on the i-Stat analyzer on 4/09/2020 under the specialties of Chemistry and Hematology, with an annual approximate test volume of 5,004. 2. On the date of the survey, September 30, 2022, review of the laboratory's quality control policy titled, "i-STAT Chem 8+ System (reference# 3245)" stated, "Three levels of liquid control are run monthly." 3. No daily QC documentation was provided for review during the survey for the Chem8+ test, to indicate the laboratory performed two levels of control material of different concentrations each day of patient testing as required. The laboratory had not established an Individualized Quality Control Plan (IQCP) for this test at the time of the survey. 4. The number of patients tested from 4/09/2020 through 9/30/2022 could not be determined at the time of the survey. 5. The testing personnel interviewed on 9/30/22 at 11:00am confirmed that the laboratory did not perform and document external controls each day of patient testing as required.

**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 lack of test comparison results from 2020, 2021 and 2022 and interview with the testing personnel, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results using two separate i-Stat instruments. Findings include: 1. The laboratory began patient testing on 04/09 /2020 in the specialties of Chemistry and Hematology, with an approximate annual test volume of 5,004. 2. The laboratory utilizes two separate i-Stat instruments to perform Chem8+ testing on patient specimens. The serial numbers are 370473 and 376108. 3. No documentation was presented for review to indicate that twice a year the laboratory evaluated and defined the relationship between test results generated from each i-Stat analyzer from 4/09/2020 though the date of the survey, 9/30/22. 4. The testing personnel interviewed on 9/30/22 at 11:48am confirmed that the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results generated from the i-Stat analyzers during the timeframe indicated above.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of quality assessment (QA) policies and procedures and interview

with the testing personnel, the laboratory failed to follow QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems, including problems identified with the frequency of Quality Control (QC) performance. Findings include: 1. No documentation was provided for review during the survey conducted on 9/30/2022 to indicate the laboratory's established analytic QA processes identified and corrected problems related to the frequency of Quality Control (QC) performance. See D5445 for specific findings. 2. The laboratory's established QA Policy titled, "Quality Assurance Plan (reference# 3103)" states, "Daily quality control will be reviewed monthly. The threshold of compliance for daily QC is 100%." 3. The testing personnel interviewed on 9/30/22 at 11:50pm confirmed the laboratory's established QA processes failed to monitor, assess and correct problems identified with the analytic systems.

**D5801**

**TEST REPORT**  
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:  
Based on review of patient test reports and interview with the testing personnel, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the Laboratory Information System (LIS). Findings include: 1. The laboratory performs approximately 5,004 patient tests annually under the specialties of Chemistry and Hematology. 2. The test results generated from the i-Stat analyzers are manually entered by testing personnel into the laboratory's LIS (Pathnet). 3. No documentation was presented for review during the survey to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered from the analyzers to the LIS. 4. The testing personnel interviewed on 9/30/22 at 11:06am confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are manually entered from the analyzers to the LIS.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Assessment (QA) documentation and interview with the testing personnel, the laboratory failed to follow established policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems . Findings include: 1. The laboratory's

established QA policy titled, "Quality Assurance Plan (reference# 3103)" states, "At least monthly a review of laboratory records will be done. For tests performed at Arizona Orthopedic Surgical Hospital, all patient results are verified by comparing the results on either the printout of the testing log to the patient's chart to verify accuracy". 2. No QA documentation from 4/09/2020 (the date patient testing began) through 9/30/2022 (the survey date) was presented for review to indicate the laboratory followed the established QA policy indicated above to verify the accuracy of test results. Results of QA activities must be documented. 3. The testing personnel interviewed on 9/30/22 at 11:50pm confirmed the laboratory failed to provide documentation of QA activities to monitor, assess and correct problems identified with the postanalytic systems.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Due to the number and severity of deficient practices identified during the survey conducted on September 30, 2022, the Condition of Laboratory Director was found to be not met as evidenced by: D6020 - failure to ensure the quality control program is established with the required frequency and maintained to assure the quality of laboratory services provided; D6021 - failure to ensure the quality assessment program is maintained to assure the quality of laboratory services provided; D6029 - failure to ensure that prior to testing patients' specimens, all personnel have the appropriate education and training for the type and complexity of services offered; and D6032 - failure to specify, in writing, the responsibilities and duties of all laboratory personnel.

**D6020**

**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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Control documentation from each day of patient testing performed on the i-Stat analyzer, the laboratory director failed to ensure that the quality control program is established with the required frequency and maintained to assure the quality of laboratory services provided. See D5445 for findings.

**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 review of quality assessment policies and lack of quality assessment documentation, the laboratory director failed to ensure that the quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5791 and D5891 for findings.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on lack of education credentials and training documentation for testing personnel and interview with the facility personnel, (A) the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience for the type and complexity of services offered and (B) the laboratory director failed to ensure that all testing personnel receive the appropriate training for the testing performed, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: A1. No evidence of education credentials was presented for review for one out of one testing personnel who was hired as testing personnel in April 2020. A2. At 10:20am on 9/30/22, the facility personnel confirmed that the laboratory failed to provide a copy of the education credentials for the testing personnel indicated above. B1. No documentation was presented for review to indicate two out of two testing personnel received the appropriate training for testing performed on the i-Stat analyzer prior to testing patient specimens. B2. At 10:21am on 9/30/22, the facility personnel confirmed that there was no documentation of initial training for two out of two testing personnel who perform Chem 8+ testing on the i-Stat analyzer.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic,

and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on lack of written documentation and interview with the testing personnel, the laboratory director failed to specify, in writing, the responsibilities and duties of all laboratory personnel, including the Technical Consultant, engaged in the performance of the preanalytic, analytic and postanalytic phases of testing. Findings include: 1. No written documentation was presented for review to indicate the laboratory director specified, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results 2. The testing personnel interviewed on 9/30/22 at 11:55pm confirmed that the laboratory did not have written documentation as indicated above.

**D6053**

**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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on lack of performance evaluation documentation and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of two testing personnel, at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for two out of two testing personnel who began patient testing on the i-Stat analyzer in April 2020. 2. At 10:25am on 9/30/22, the facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the two testing personnel indicated above.

**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 lack of competency evaluation documentation for review from 2021 and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. During the survey conducted on September 30,

2022, no annual competency evaluation documentation from 2021 was presented for review for two out of two testing personnel who perform Chem 8+ testing on the i-Stat analyzer. 2. At 10:25am on 9/30/22, the facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2021 for the testing personnel indicated above.