

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0705352	(X3) Date Survey Completed 07/16/2019
Name of Provider or Supplier Seasons Medical	Street Address, City, State 37 South 2nd East, Rexburg, ID	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on an observation and an interview with the technical consultant, the laboratory failed to observe safety procedures to ensure protection from chemical and biohazardous contamination. Findings: 1. An observation on July 16, 2019, at 3:00 PM, of the laboratory space in the Women's Clinic revealed two large plastic disposable drink containers with straws located on top of the refrigerator next to the counter space containing open urine cup specimens, as well as, yogurt, Coke, and bottled waters and juice in the refrigerator used to store testing reagents for hemoglobin and glucose. 2. An interview with the technical consultant on July 16, 2019, at 3:15 PM, confirmed the laboratory staff failed to observe safety procedures in the laboratory.</p>
D5217	<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 record review and an interview with the operations manager, the laboratory failed to verify the accuracy of microscopic fungal examinations using potassium hydroxide (KOH) at least twice a year since the last survey on October 24,</p>

2017. Findings: 1. A record review of laboratory documents revealed the laboratory failed to verify the accuracy of microscopic KOH examinations at least twice a year since the last survey. 2. The laboratory performed approximately 60 KOH examinations in 2018. 3. An interview with the operations manager on July 16, 2019, at 3:15 PM, confirmed the laboratory failed to document the accuracy of KOH examinations at least twice a year.

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:
The laboratory failed to monitor and evaluate the overall quality of testing for complete blood counts, pediatric bilirubin, and microscopic fungal examinations and failed to identify and correct problems in the test systems. Refer to D5403, D5413, D5415, D5439, D5481, D5775, D5781, and D5783.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the operations manager, the laboratory test system procedures for complete blood counts (CBCs), cardiac (creatinine kinase MB, myoglobin, and troponin I, D-dimer, brain natriuretic peptide (BNP), and pediatric bilirubin failed to include panic values, normal values, referral testing criteria, specimen rejection, or actions to take when the analyzers are inoperable since the last survey on October 24, 2017. Findings: 1. A record review of

the procedure manual review revealed the laboratory's procedures failed to include panic values for CBCs and cardiac analytes, as well as instructions to take when the test system analyzers become inoperable or referral criteria. 2. A record review of the bilirubin test procedure revealed the procedure failed to include normal reference values, panic values, and calibration verification procedures for the analyte. 3. An interview with the operations manager on July 16, 2019, at 3:45 PM, confirmed the laboratory's procedure manuals failed to include panic values, normal reference ranges, and referral criteria requirements.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on an observation, a record review, and an interview with the technical consultant, the laboratory failed to monitor and document the pediatric laboratory refrigerator temperature where the ABX Horiba Micros 60 hematology quality control and the Reichert Bilirubin quality control materials were stored since the last survey on October 24, 2017. Findings: 1. An observation on July 16, 2019, at 3:05 PM, of the pediatric laboratory refrigerator, revealed the refrigerator was used to store quality control reagents for the Horiba complete blood count analyzer and the Reichert Bilirubinometer. 2. A record review of temperature logs revealed the laboratory failed to document and monitor the pediatric laboratory refrigerator temperature where quality control material for each test system was stored since the last survey. 3. A review of the Horiba manufacturer's storage requirements revealed the instructions to store the quality control material between 2 and 8 C. 4. The pediatric laboratory performed approximately 1100 bilirubin and 1000 complete blood counts in 2018. 5. An interview with the technical consultant on July 16, 2019, at 3:25 PM, confirmed the laboratory failed to document the pediatric laboratory refrigerator temperature since the last survey.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on an observation and an interview with the technical consultant, the laboratory failed to label 9 out of 9 potassium hydroxide (KOH) bottles located in each exam room in the Women's Clinic with the name, concentration, preparation or expiration

date. Findings: 1. An observation on July 16, 2019, at 3:05 PM, of 1 out of 9 exam rooms in the Women's Clinic, revealed an unlabeled dark glass bottle of unknown solution that was used to perform microscopic KOH examinations. 2. The laboratory performed approximately 60 KOH examinations in 2018. 3. An interview with the technical consultant on July 16, 2019, at 3:15 PM, confirmed 9 out of 9 exams room all had unlabeled bottles of solution for use on patient microscopic fungal examinations.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on a record review and an interview with the technical consultant, the laboratory failed to perform calibration verification activities that include at least a low value, a mid-point value, and a high value at least one every 6 months or when required by the manufacturer since the last survey on October 24, 2017. This is a repeat deficiency from the last survey on October 24, 2017. Findings: 1. A review of the calibration verification records for the Unistat Reichert Bilirubinometer revealed the laboratory failed to include at least a low value, a mid-point value, and a high value at least one every 6 months or when required by the manufacturer. 2. The laboratory performed approximately 1100 pediatric bilirubin tests in 2018. 3. An interview with the technical consultant on July 16, 2019, at 3:35 PM, confirmed the laboratory failed to perform and document at least 3 levels of calibration verification materials.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on a quality control record review and an interview with the technical consultant, the laboratory failed to ensure at least 2 out of 3 levels of quality control results met the manufacturer's acceptability criteria before reporting pediatric patient complete blood count (CBC) tests between June 4, 2019 and June 18, 2019. Findings: 1. A record review of quality control test results revealed the normal and high levels of CBC control results for red blood cells and hemoglobin failed to meet the manufacturer's acceptability criteria on June 4, 15, 17, 18, 2019, before reporting patient results. 2. The pediatric laboratory reported approximately 52 CBC tests between June 4, 2019 and June 18, 2019. 3. A record review of CBC quality control test results revealed the laboratory failed to perform quality control tests prior to reporting 1 out of 1 patient CBC test result on June 16, 2019. 4. An interview with the technical consultant on July 16, 2019, at 3:30 PM, confirmed the laboratory failed to ensure at least 2 out of 3 levels of quality control results met the manufacturer's acceptability criteria before reporting patient CBC test results.

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 an observation, a record review, and an interview with the operations manager, the laboratory failed to evaluate the relationship between the two ABX Horiba Micros 60 hematology analyzers since the last survey on October 24, 2017. This is a repeat deficiency from the last survey on October 24, 2017. Findings: 1. An observation on July 16, 2019, at 3:05 PM, revealed two Horiba complete blood counts analyzers, one located in the pediatric clinic and the other in the family practice clinic. 2. A record review of laboratory documents revealed the laboratory failed to perform and document the comparison acceptability criteria between the two Horiba analyzers. 3. The family practice laboratory performed approximately 500 CBCs, and the pediatric laboratory performed approximately 1100 since July 2018. 4. An interview with the operations manager on July 16, 2019, at 2:15 PM, confirmed the laboratory failed to evaluate the acceptability criteria between the two Horiba analyzers.

D5783

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on a quality control record review and an interview with the technical consultant, the laboratory failed to take corrective actions and evaluate patient complete blood count (CBC) test results performed between June 4, 2019 and June 18, 2019, when 2 out of 3 levels of quality control testing failed to meet the manufacturer's acceptability criteria. Findings: 1. A record review of quality control test results revealed the laboratory failed to evaluate and take corrective actions for 52 pediatric patient CBC test results that were reported between June 4, 2019 and June 18, 2019, when 2 out of 3 levels of quality control reagents failed to meet the manufacturer's acceptability reference range. 2. An interview with the technical consultant on July 16, 2019, at 3:30 PM, confirmed the laboratory failed to evaluate pediatric patient's CBC test results to ensure accurate results.

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:
The laboratory director failed to provide overall management and direction for the testing of complete blood counts, pediatric bilirubin, and microscopic fungal examinations since the last survey. This is a repeat deficiency from the surveys conducted on October 24, 2017 and November 18, 2015. Refer to D6004, D6021, D6025, D6029, D6030, and D6032.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on record reviews the laboratory director failed to provide oversight for the operation of the laboratory and the competency of the testing personnel since the last survey on October 24, 2017. Findings: 1. A record review revealed the laboratory director failed to establish and write a policy or procedure for a system to identify, monitor, and correct problems in the preanalytic, general laboratory system, analytic, and post-analytic processes in the laboratory. Refer to D6021. 2. A review of personnel records revealed the laboratory failed to demonstrate that the 10 out of 12 testing personnel were trained and competent to perform tests on the ABX Horiba analyzer, Riechert Unistat Bilirubinometer, KOH examinations, and the Alere Triage analyzer prior to reporting patient results. Refer to D6029 and D6030.

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:

D6021 Based on a record review and an interview with the technical consultant, the laboratory director failed to ensure a quality assessment program was established for the ABX Horiba complete blood count (CBC) hematology analyzer, microscopic fungal examinations using potassium hydroxide (KOH), and the Reichert Bilirubinometer to ensure corrective actions and problems in the pre-analytic, analytic, and post-analytic phases were identified since the last survey on October 24, 2017. This is a repeat deficiency from the last survey on October 24, 2017. Findings: 1. A record review revealed the laboratory director failed to establish and write a policy or procedure for a system to identify, monitor, and correct problems in the preanalytic, general laboratory system, analytic, and post-analytic processes in the laboratory. 2. An interview with the technical consultant on July 16, 2019, at 3:55 PM, confirmed the laboratory director failed to establish a policy or procedure for a system to monitor all quality assessments activities for the laboratory's test performance in CBC, bilirubin, and fungal examinations.

D6025

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(7)

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)(7) Ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the technical consultant, the laboratory director failed to ensure that patient complete blood counts (CBCs) and pediatric bilirubin tests were reported only when the test systems are functioning properly. Findings: 1. A record review of quality control test results revealed the laboratory failed to ensure at least 2 out of 3 levels of quality control results met the manufacturer's acceptability criteria before reporting 52 patient CBC test results between June 4, 2019 and June 18, 2019. 2. A record review of the calibration verification activities for the Unistat Reichert Bilirubinometer revealed the laboratory failed to include at least a low value, a mid-point value, and a high value at least once every 6 months or when required by the manufacturer. 3. An interview with the technical consultant on July 16, 2019, at 4:15 PM, confirmed the laboratory failed to ensure patient test results were reported only when the test systems function properly.

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 a review of personnel records and an interview with the operations manager, the laboratory director failed to ensure 10 out of 12 testing personnel have the appropriate training and experience and can perform tests and report accurate results for complete blood counts (CBC), chemistry tests, and microscopic fungal examinations using potassium hydroxide (KOH) since the last survey on October 24, 2017. This is a repeat deficiency from the last surveys conducted on November 11, 2015 and October 24, 2017. Findings: 1. A review of personnel records revealed the laboratory failed to perform and document 10 out of 12 testing personnel listed on the CMS-209 form were trained to perform tests on the ABX Horiba analyzer, Riechert Unistat Bilirubinometer, microscopic KOH examinations, and the Alere Triage analyzer prior to reporting patient results. 2. The laboratory performed approximately 60 KOH exams, 1100 chemistry tests, and 2000 CBC tests in since July 2018. 3. An interview with the operations manager on July 16, 2019 at 1:00 PM, confirmed the laboratory director failed to ensure testing personnel were trained prior to reporting patient specimens.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on a review of the procedure manual and an interview with the operations manager, the laboratory director failed to ensure that policies and procedures were established for monitoring the competency of 12 out of 12 testing personnel performing complete blood counts (CBCs), chemistry tests, and microscopic fungal examinations using potassium hydroxide (KOH) since the last survey on October 24, 2017. Findings: 1. A review of the laboratory's procedures revealed the laboratory failed to establish a procedure for monitoring the competency of 12 out of 12 testing personnel listed on the CMS-209 Personnel Report form performing CBCs, chemistry

tests, and KOH exams. 2. A review of personnel competency documents revealed competency assessments for the 9 out of 12 testing personnel was not evaluated by a qualified technical consultant for 2018 and 2019. 3. An interview with the operations manager on July 16, 2019, at 2:15 PM, confirmed the laboratory director failed to establish a procedure or policy to ensure competency assessments for testing personnel met the CLIA regulations.

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 a record review and an interview with the laboratory manager, the laboratory director failed to specify in writing, the responsibilities and duties of the technical consultant and each person engaged in the preanalytic, analytic, and post-analytic phases of testing since the last survey on October 24, 2017. Findings: 1. A record review of laboratory documents revealed the laboratory failed to specify in writing the responsibilities and duties of the technical consultant and each person engaged in the pre-analytic, analytic, and post-analytic phases of testing. 2. An interview with the operations manager on July 16, 2019, at 3:15 PM, confirmed the laboratory director failed to specify in writing the responsibilities for the technical consultant and each person engaged in patient testing.