Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0956413	03/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Shirley Ryan Ability Lab	355 E Erie St, 14th Floor, Chicago, IL	

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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory procedures, testing records, quality control records and patients' reports; the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299 when it performed chemistry tests. Findings: 1. There was no written comprehensive procedures manual available to laboratory personnel. See D tag 5403 2. There were no criteria established for monitoring conditions for proper storage of reagents and specimens and test performance. See D tag 5413 3. The laboratory did not verify performance specifications established by the manufacturer for their test method. See D tag 5421 4. The laboratory failed to perform and document quality control procedures, before testing and reporting patients test results. See D tags 5447, 5537, and 5539 5. The laboratory did not include all pertinent information on the final report of patients' records. See D tag 5805.
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 review of the laboratory's procedure manual and interview; the procedure manual did not include the following: *Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, process, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. *Step-by-step performance of the procedure, including test calculations and interpretation of results. *Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. *Calibration and calibration verification procedures. *The reportable range for test results for the test system as established or verified in 493.1253. *Control procedures. *Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. *Limitations in the test methodology, including interfering substances. *Reference intervals (normal values). *Imminently life-threatening test results, or panic or alert values. *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. *Description of the course of action to take if a test system becomes inoperable. Findings: 1. There were no procedures that described the requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, process, and referral; and criteria for specimen acceptability and rejection in the laboratory's written procedure manual. 2. There were no procedures that described step-by-step performance of the procedure, including test calculations and interpretation of results in the laboratory's written procedure manual. 3. There were no procedures that described Preparation solutions, calibrators, controls, reagents, and other materials used in testing 4. There were no procedures that described calibration and calibration verification procedures in the laboratory's written procedures manual. 5. There was no description of the reportable range for test results for the test system as established or verified by the laboratory. 6. There were no instruction that described control procedures in the laboratory's written procedures manual. 7. There were no instruction that described corrective actions to take when calibration or control results fail to meet the laboratory's criteria for acceptability in the laboratory's written procedures manual. 8. There were no procedures that described limitations in the test methodology, including interfering substances in the laboratory's written procedures manual. 9. There were no procedures that described reference intervals (normal values). 10. There were no procedures that described imminently life-threatening test results, or panic or alert values in the laboratory's written procedures manual. 11. There were no procedures that described 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 in the laboratory's written procedures manual. 12. There were no written procedures that

	described the course of action to take if a test system becomes inoperable in the laboratory. 13. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
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 review of manufacturer's procedures and test records; direct observation; and interview, the laboratory failed to monitor and document conditions essential for proper storage of reagents and specimens; accurate and reliable test system operation and test result reporting. Findings include: 1. Review of manufacturer's instructions for the operation of the EPOC analyzer revealed that the analyzer can be operated under the following environmental conditions: a. Temperature - between 15 - 30 degrees C. An internal Ambient Temperature Monitor that will disable the Reader functions if room temperature falls outside of this range." b. Atmospheric Pressure - between 400 - 825 mmHg. An internal Barometric Pressure Sensor monitors pressure and disables the Reader function if outside this range. c. Relative Humidity - The Reader must be used where the relative humidity is less than 85% at 30 degrees C, non-condensing. d. The Reader must rest on a flat horizontal surface without being moved during the entire testing process. e. Reagent Cartridges and Liquid Quality Control (QC) Material stored between 2- 8 degrees C. f. Two different test cards (1 for Blood Gases and the other for Creatinine) stored between 15-30 degrees C. 2. There was no documentation to show that the laboratory documented the following: a. Ambient Room Temperature where tests were performed and test cards stored. b. Atmospheric Pressure. c. Relative Humidity. d. Refrigerator Temperature where Reagent Cartridges and QC materials are stored. 3. During survey date 03/16/18, the surveyor observed that the laboratory had 2 separate 2 EPOC analyzers in the laboratory. One labeled, "EPOC 1", and the other labeled, "EPOC 2." The surveyor observed testing personnel from the Radiology department performing a creatinine test. After the results were displayed, testing personnel removed the EPOC 1 analyzers from the laboratory. When the surveyor asked the testing personnel why he took the analyzer with him, she was told that he needed to print, verify, and enter creatinine results before scanning the results into the electronic medical record (EMR). 4. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's procedures manual and the laboratory's written procedures manual and record review; the laboratory failed to demonstrate that it can obtain performance specification comparable to those established by the manufacturer. : Findings: 1. There were no procedures that describe the laboratory's process for how it verified the ECOS system analyzer for pO2, pCO2, pH, and Creatinine. 2. There was no documentation to show that testing personnel performed the Verification study to demonstrate the manufacturer's performance specifications for the following performance characteristics: A. Accuracy B. Precision C. Reportable range of test results for the test system D. Verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population. 3. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual; quality control (QC) records; patients' test records; and interview, the laboratory failed to include two control materials of different concentrations when it tested patients' samples for Creatinine. Findings 1. Review of the laboratory's procedures manual revealed that there were no procedures that described the laboratory's process for performing and documenting the QC of its Creatinine testing. 2. Review of QC records revealed that there was no documentation to show that the laboratory performed and documented the results of QC material. 3. During survey date 03/16/18, the surveyor requested 3 patients test records along with their corresponding QC records. There were no corresponding QC records for the dates where patients' test results were recorded for 3 of 3 patients' test reports reviewed. 4. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review the Clinical Laboratory Improvement Amendments (CLIA)

	Application for Certification (CMS 116); quality control (QC) records; patients' test reports and interview, the laboratory failed to test and document one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values for pCO2, pO2, and pH (Blood Gas Tests) Findings: 1. Review of the CMS 116 revealed that the laboratory listed its hours of operation as "24 /7." 2. Review of QC records revealed that there was no documentation to show that the laboratory performed QC of its Blood Gas Testing every 8 hours. 3. Review of 3 patients test records revealed patients test results for blood gases were reported when there was no documentation of QC performance for 3 of 3 patients' test records reviewed. 4. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
D5539	ROUTINE CHEMISTRY CFR(s): 493.1267(c)(d) For blood gas analyses, the laboratory must perform the following: (c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review quality control (QC) records and patients' test reports and interview, the laboratory failed to test one sample of control material each time Blood Gas specimens were tested. Findings: 1. Review of 3 patients test records revealed patients test results for blood gases were reported when there was no documentation of QC performance for 3 of 3 patients' test records reviewed. 2. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and patients' test reports and interview, the test report did not indicate the following: *The name and address of the laboratory location where the test was performed. Findings: 1. Review of the laboratory procedures' manual revealed that the laboratory's testing menu consists of the following analytes: a. pO2 b. pCO2 c. pH d. Creatinine 3. Review of patients' test records revealed that there were CBC results documented for 2 of 3 patients' reports reviewed. There was no documentation to indicate where the CBC testing and/or blood gases were performed. The surveyor could not determine which tests were performed by this laboratory. 2. During survey date 03/16/18, the laboratory manager confirmed the surveyor's findings.

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: Based on review of the laboratory's procedures manual; proficiency testing records; quality control records; and personnel records, the laboratory failed to have a director who provides overall management and direction in accordance with 493.1407 of this subpart. Findings: 1. The laboratory director did not ensure that verification procedures were adequate to demonstrate the performance specifications established by the manufacturer of their chemistry analyzer. See D tag 6013 2. The laboratory director did not review proficiency testing results to ensure corrective actions are taken when there are proficiency testing failures. See D tag 6109 3. The laboratory director did not ensure that a quality control program was established for its testing procedures. See D tag 6020 4. The laboratory director did not ensure that all testing personnel received training. See D tag 6029 5. The laboratory director did no ensure that all testing personnel were competent to perform testing procedures in the laboratory. See D tag 6030 6. The laboratory director did not ensure that there was an approved comprehensive procedures manual available to all laboratory staff. See D tag 6031 7. The laboratory director did not specify in writing which tests each person can perform and the duties and responsibilities of the Laboratory Director, Technical Consultant, and Clinical Consultant. See D tag 6032
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview, the laboratory director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of its ECOS chemistry analyzer. Findings: 1. There was no documentation to show that the laboratory verified the accuracy, precision, and reportable range of its ECOS for pCO2, pO2, pH, and Creatinine. 2. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory' procedures manual and proficiency testing (PT) records and interview, the laboratory director failed to ensure that an approved corrective action plan is followed when any PT results are found to be unacceptable or unsatisfactory. Findings: 1. There were no written procedures that described the laboratory's process for handling unacceptable or unsatisfactory PT analyte scores. 2. Review of PT records revealed that there was no documentation to show that that the laboratory evaluated their PT performance and initiated corrective actions for a grade of "Unacceptable" for the pCO2 anlayte for Sample BG-05 for the 1st PT Event in 2018. 3. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
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 review of the laboratory's procedures manual and quality control records and interview, the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. 1. There was no documentation to show that the laboratory established control procedures. 2. There was no documentation to show that the laboratory recorded the actual quality control results and / or observations of QC results... Records show, "Fluid Control Tests" were documented with an OK "Y" or "N" for pCO2, pO2, and pH. There was no documentation to show that QC of Creatinine tests were performed. 3. During survey date 03/16/18, the laboratory director confirmed the surveyor's 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 review of Laboratory Personnel Report (CMS 209) and personnel records and interview, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform testing operations reliably. Findings: 1. The laboratory listed a total of 29 testing personnel on CMS 209. 2. Review of personnel records revealed that there was no documentation to show that 1 of 29 personnel was trained to perform blood gas and creatinine testing on the ECOS analyzer. The manager of the laboratory told the surveyor that they had not trained this person because she is part-time personnel. The surveyor noted that this person was hired in September 2017. 3. During survey date 03 /16/18, the laboratory director confirmed the surveyor's findings.
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 review of Laboratory Personnel Report (CMS 209) and personnel records and interview, the laboratory director failed to ensure that policies and procedures are established to assure that personnel are competent and maintain their competency to process specimens, perform test procedures and report test results, and identify needs for remedial training or continuing education to improve skills. Findings: 1. Review of CMS 209 revealed that the laboratory director was listed as the person who fulfils the following positions: a. Laboratory Director (LD) b. Clinical Consultant c. Technical Consultant There are also a total of 29 testing personnel who are also listed on the CMS 209 2. Review of Personnel records revealed that there is no documentation to show that the LD observed testing personnel performing testing procedures and documented their competency for 29 of 29 personnel records reviewed. 3. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures manual and interview, the laboratory director did not ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings: 1. There was no documentation to show that there was an approved comprehensive laboratory procedure manual that covered all aspects of the testing process available to testing personnel. 2. During survey date 03/16/18 the surveyor asked 1 of the testing personnel where was the procedures manual that she followed for testing patients specimens and reporting test results is located. Testing personnel showed the surveyor the manufacturer's user's guide.
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 review of Laboratory Personnel Report (CMS 209); the laboratory's procedures manual; personnel records; and intervew, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each person engaged in the performance of each phases of testing, that identifies which examination and procedures each individual is authorized to perfrom, whether supervision is required, and whether consultant or director review is required prior to reporting patient test results. Findings: 1. Review of the CMS 209 revealed that the laboratory director was listed as the person fulfilling the positions of Laboratory Director (LD), Clinical Consultant (CC), and Technical Consultant/Supervisor (TC /TS). Also, there were 29 testing persons listed on the CMS 209 (24 persons from Respiratory and 5 from Radiology). 2. Review of the personnel records revealed that the laboratory did not assign in writing who fulfilled the duties and responsibilities of the following positions in the laboratory: a. Laboratory Director b. Clinical Consultant c. Technical Consultant e. Testing Personnel (Blood Gases or Creatinine or Both) 3. During survey date 03/16/18, the laboratory director confirmed the surveyor's findings.