Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2143533	08/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advocate Children's Hospital Transport Team	395 W Lake St, Elmhurst, 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
D3017	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(a) Arrangement for services. The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. This STANDARD is not met as evidenced by: Based on review and interview, the facility failed to have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products. Findings include: 1. In a telephone interview at 1:30 PM on 09/10/18, the laboratory director indicated that, occasionally, the laboratory would transport patients while they were being transfused with blood products. 2. There were no written procedures that described the following information: a. Procedures to show which transfusion services were provided directly by this facility and which were provided through agreement. b. Policies for the proper storage and transportation of blood or blood products. c. Procedures to identify possible transfusion reactions. d. Procedures to notify the laboratory of a possible transfusion reactions. 3. In an interview at 1:30 PM on 09/10 /18, the laboratory director confirmed the surveyor's findings.
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 and interview, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299 as specified. 1. Competency assessments that were performed on personnel were not based on the responsibilities of the position the individual held in the laboratory. Testing personnel and technical consultants received the same competency assessments. See D5209 2. The laboratory failed to have a written or electronic test request when it tested patients' specimens and reported test results. See D5301
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 Laboratory Personnel Report (CLIA) (Form CMS 209), laboratory policies and procedures manuals, personnel records, and interview with the laboratory director; the laboratory failed to establish and follow written policies and procedure to assess employee and consultant competency. Findings: 1. Review of Form CMS 209 revealed that there were a total 3 Technical Consultants listed on Form CMS 209. 2. Review of laboratory policies and procedures revealed that there were no procedures that described the laboratory's process for assessing the competency of its technical consultants. 3. Review of personnel records revealed that competency assessments were performed on all testing personnel, which included the 3 technical consultants. However, there were no competency assessments, based on the duties and responsibilities of the position of technical consultant, performed on 3 of 3 technical consultants. 4. At 11:30 AM on 08/29/18, the laboratory director confirmed the surveyor's findings.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of laboratory's procedures manuals, laboratory records, and interview with the laboratory director, the laboratory failed to have a written or electronic request for patient testing from an authorized person. Findings include: 1. Review of laboratory procedures manuals revealed that there were no procedures that described the laboratory's process for how tests were ordered. 2. Review of laboratory records revealed that the patient transport team used a "patient transport" form as it requisition for documenting ordered tests. No test order was available for review. In a section titled, "Transport Medical Director Chart Triggers for review," under a section titled, "POINT OF CARE TESTING ON ADVOCATE TRANSPORT MACHINE," it instructs you to circle either "GLUCOMETER" or " ISTAT". These are not tests. There was no documentation to show that blood gas testing was ordered. 3. At 3:00 PM on 08/29/18, technical consultant # 2 (personnel # 3 on the personnel list) revealed that the laboratory had standing orders as well as verbal orders. Procedures manuals did not indicate which tests were included in the standing order. Also,

	technical consultant # 2 told the surveyor that verbal orders were not followed up with written orders within 30 days. 4. At 3:30 PM on 08/29/18, the laboratory director confirmed the surveyor's findings.
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 review and interview, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 as specified. Findings include: 1. Review of laboratory procedures manuals revealed that the laboratory failed to have a comprehensive procedures manual. See D5403 2. The laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer. See D5421 3. Review of laboratory records revealed that there was no documentation to show that the laboratory determined its calibration procedures and control procedures based on the performance specifications verified or established by the laboratory. See D5425 4. Review of the laboratory's Individual Quality Control Plan (IQCP) revealed that results of the data used to develop their IQCP was run by another laboratory, and not this lab. Also, the Risk Assessment lacked one of the 5 essential components (environment) when the labs IQCP was developed. See D5445 5. Review of the Application for CLIA Certification (Form CMS 116) revealed that this laboratory is a mobile laboratory that moves form site to site, performing blood gas testing. However, there were no records to show that at least 1 level of control material was tested to demonstrate that the transport of equipment did not affect patients' test results. See D5539 6. The laboratory did not retain instrument printouts and corrective action reports. See D5589
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 policies and procedures manuals and interview with the laboratory director, the laboratory failed to have a comprehensive procedure manual that included processes for testing and reporting results for blood gas testing in the laboratory. Findings include: 1. Procedures manuals did not include 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. Procedures manuals did not include step-by-step performance of the procedure, including test calculations and interpretation of results. 3. Procedures manuals did not include preparation of solutions, calibrators, controls, reagents, and other materials used in testing. 4. Procedures manuals did not include the reportable range for test results for the test system as established or verified in 493.1253. 5. Procedures manuals did not include control procedures. 6. Procedures manuals did not include corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. 7. Procedures manuals did not include limitations in the test methodology, including interfering substances. 8. Procedures manuals did not include reference intervals (normal values). 9. Procedures manuals did not include imminently life-threatening test results, or panic or alert values. 10. Procedures manuals did not include pertinent literature references. 11. Procedures manuals did not include 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. 12. Procedures manuals did not include the description of the course of action to take if a test system becomes inoperable.
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 procedures manuals and laboratory records and interview with the laboratory director, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer before it performed blood gas testing on patients' specimens for the following performance specifications: *Accuracy *Precision *Reportable range of test results for the test system. *Manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Findings include: 1. Review of laboratory procedures revealed that there were no written procedures that described the laboratory's procedure for how it verified the performance specifications for its Istat analyzer for all moderate complexity tests (i.e. blood gas analytes) it performed. 2. There was no documentation to show that the laboratory verified the accuracy of its

	Istat analyzer for blood gas analytes. 3. There was no documentation to show that the laboratory verified the precision of its Istat analyzer for blood gas analytes. 4. There was no documentation to show that the laboratory verified the reportable range of test results for the test system. 5. There was no documentation to show that the manufacturer's reference intervals were appropriate for the laboratory's patient population. 6. Review of laboratory records show that verification reports were from "Advocate LGH/Children's Park Ridge," and not Advocate Children's Hospital Transport Team /Elmhurst. 7. Review of 8 patients test records revealed that blood gas results were performed and reported on 7 of 8 patients' specimens before the laboratory verified the performance specifications of the Istat analyzer. 7. At 3:30 PM on 08/29/18, the laboratory director confirmed the surveyor's findings.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory procedures manuals and test records and interview, the laboratory failed to determine calibration procedures and control procedures based on performance specifications it verified for its Istat analyzer for blood gas tests. Findings include: 1. Review of procedures manuals revealed that there were no instructions that described the laboratory's calibration procedure. 2. Review of laboratory records revealed that there was no documentation to show that the laboratory verified performance specifications established by the manufacture of it Istat analyzer. 3. Review of procedures manuals revealed that there were no procedures that described how the laboratory determined the number, type, and frequency with which it performed quality control based on performance specifications verification. 4. Review of 8 patients' test records revealed that 7 of 8 patients' specimens were tested and blood gas results reported, before the laboratory verified the performance specifications and quality control procedures of the blood gas analyzer for 7 of 8 patients' test records reviewed. 5. At 03:30 PM on 08/29/18, the laboratory director confirmed the surveyor's 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 review and interview, the laboratory failed to perform at least 1 level of control material with each day of patients' specimens as specified at 493.1267(c) (d)

	for the blood gas testing. Findings include: 1. Review of laboratory procedures revealed that the laboratory did not test at least 1 level of control material each day it tested patient's specimens. Instead, an Individual Quality Control Plan (IQCP) was developed. Review of IQCP records revealed that the laboratory used results of another laboratory location when it developed its IQCP. 2. At 10:30 AM on 08/29/18, in an interview, technical consultant # 2 told the surveyor that the laboratory's Istat analyzers were transported with the transport team and blood gases may be performed on site in the emergency room, on board the ambulance, or on board a helicopter. 3. IQCP records revealed that the Risk Assessment (RA) did not include documentation to show that there was an assessment of the different environments that may affect blood gas results. 4. IQCP records revealed that there was no documentation to show the Quality Assessments were performed when the laboratory developed its IQCP. 5. IQCP records revealed that the laboratory performed quality control 2 times per week. However, there was no documentation to show that the laboratory director developed his Quality Control Plan based on the RA. 6. At 3:30 PM on 08/29/18, 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 surveyor observations, review of laboratory procedures manuals, laboratory records, patient test records, and interview with the laboratory director, the laboratory failed to perform and document one sample of quality control (QC) material each time they tested patients' blood gases. Findings include: 1. Based on surveyor's observations, the laboratory had 3 Istat analyzers it used for performing blood gas analysis in its mobile laboratory, which they moved form site to site. 2. There were no procedures that described the laboratory's process for ensuring the quality of blood gas testing when in the following situations: a. Moving the test equipment form various sites, including emergency rooms; ambulances; and helicopter. b. How to trouble shoot the analyzer when there are changes in termperature or barometric pressure. c. How to proceed if personnel were to bump or drop the Istat analyzer. 3. There was no documentation to show that the laboratory's Istat blood gas analyzers verified calibration at least every 30 minutes. 4. Review of 8 patients' test records revealed that there was no documentation to show that the laboratory performed at least 1 level of QC material every time patients' specimens were tested for 8 of 8 patients records reviewed. 5. At 10:30 AM on 08/29/18 review of the laboratory's application for certification revealed that the laboratory operated 24 hours per day. There was no procedure that described how the laboratory ensured that the quality of the test over a 24 hour period. 6. At 3:30 PM on 08/29/18, the laboratory director confirmed the surveyor's findings.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures manauls and patients test records and interview with the laboratory director, printouts of patients testing was not retained for blood gas testing. Findings include 1. There were no procedures that instructed testing personnel on what records should be retained and for how long. 2. At 3:00 PM on 08 /29/18 review of patients' test records revealed that there was no printout result for blood gas testing for 1 of 8 patients' test records reviewed for blood gas testing performed on 05/01/18 at 15:40 on patient assigned the number 1 by the surveyor. Results had been hand written and scanned into the patient chart. 3. At 3:30 PM on 08 /29/18, 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 observation; review of procedures manuals and patients records; and interview with the laboratory staff, patients test reports did not indicate the name and address of the laboratory location where blood gas, hematocrit, and hemoglobin tests were performed. Findings include: 1. At 9:00 AM on 08/29/18, the surveyor did a walk-through of the laboratory. She observed that the laboratory had a total of 3 Istat analyzers that it used to perform blood gas, hematocrit, and hemoglobin testing, along with other waived chemistry tests. 2. Review of procedures manuals revealed that there were no written procedures that described the laboratory's process for reporting patient's test results. 3. Review of 8 patients' test reports revealed the name and address of the laboratory where the test was performed was not documented on 8 of 8 patients' test reports reviewed. Further review revealed that on 05/28/18 at 05:33 AM, patient 001632594 was tested and blood gas results were reported. However, testing personnel told the surveyor that this patients' specimen was not tested by their laboratory. The surveyor could not tell the difference. Therefore, the surveyor asked testing personnel how they were able to tell the difference. Laboratory staff showed the surveyor that the name of the analyzer on the printed results was from a "GEM Premier 5000." Staff reminded the surveyor that this laboratory uses and Istat analyzer. Neither this laboratory nor the laboratory that performed blood gases using a GEM Premier 5000 included the name and address location of where the test was performed on its final report. 4. At 3:30 PM on 08/29/18, the laboratory director 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 record review and interview, the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1407. Findings include: 1. Review of laboratory records revealed that verification procedures used were not adequate to determine the accuracy and precision of the test method it used for blood gas testing. See D6013 2. Review of laboratory records revealed that quality control and quality assessment programs were not established and maintained to identify failures in quality as they occur. See D6022 3. Review of personnel records revealed that the laboratory director did not ensure that all personnel had the appropriate education before patient's specimens were tested. See D6029 4. The laboratory lacked an approved comprehensive procedures manual. See D6031 5. The laboratory director did not specify in writing the responsibilities and duties of the technical consultants. See D6032
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 procedure used were adequate to determine the accuracy, precision, and pertinent performance characteristics of its Istat analyzer when it performed blood gas testing. Findings include: 1. Review of laboratory records revealed that there was no documentation to show that the laboratory verified the accuracy, precision, and normal ranges for its blood gas analyzer. 2. Review of documentation revealed that the documentation used to verify the performance of the laboratory's Istat analyzer came from a different address location, and not from the address location of the laboratory. 3. At 3:30 PM on 08/29/18, the laboratory director confirmed the surveyor's findings.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of laboratory procedures manuals and records and interview, the laboratory director failed to ensure that quality control (QC) program and quality assessment (QA) programs were established and maintained to identify failures in quality as they occur. Findings include: 1. There was no approved, comprehensive procedures manual that covered the laboratory's preanalytic, analytic, and post analytic processes. 2. Review of quality control records revealed that the laboratory established an Individual Quality Control Plan (IQCP) based on records that came from a different hospital site. The surveyor could not tell if Istat results were actually reported by this laboratory. Also, there were no written procedures that show that the laboratory established a QC program that included the following: a. Type of control (e. g., manufacturer or in-house, electronic); b. Identity (e.g., normal, abnormal, level I, II, patient or a control); c. Number and frequency of testing controls; d. Control limits established in accordance with 493.1253 and 493.1256; and e. Criteria to determine acceptable control results. f. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. 4. Review of quality control (QC) records revealed that testing personnel were only performing and documenting quality control results twice a week. This was confirmed by technical consultant #2. 5. Testing personnel were not competent in maintaining the accuracy of the Istat analyzer. At 11:00 AM on 08/29/18, the surveyor asked one of the technical consultants who performed testing, what she would do if the analyzer were dropped. The technical consultant told the surveyor that she would insert the chip for a control result. The surveyor noted that the chip only checked the electronics of the device. The surveyor asked the technical consultant why wouldn't she run at least 1 level of liquid control. The technical consultant told the surveyor that she was not aware that she need to run a liquid control. 6. There was no documentation to show that the laboratory performed QA(s). At 3:00 PM on 08/29/18 review of patients' test records revealed that there was no printout result for blood gas testing for 1 of 8 patients' test records reviewed. For patient #1 on 05/01/18 at 15:40, blood gas results had been hand written and scanned into the patient's chart. The laboratory director was not even aware of this problem, and was not notified of the meeting that took place about the problem. 7. At 3:30 PM on 08/29/18, 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 and interview, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel had the appropriate education and experience. Findings include: 1. Review of 34 personnel records revealed that there

	was no documentation that shows the highest level of education of 9 of 34 testing personnel. See D6065. 2. At 1:30 PM on 09/10/18, 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 and interview, the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings include: 1. Review of laboratory procedures manuals revealed that there was no documentation to show that the laboratory had a comprehensive procedures manual that included preanlytic, analytic, and post analytic processes, that was approved, signed, and dated by the current laboratory director. 2. At 03:30 PM on 08/29/18, the laboratory director confirmed the surveyor's findings.
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 and interview, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant. Findings include: 1. Review of Laboratory Personnel Report- CLIA (Form CMS 209) collected during the survey, revealed that the persons were listed as follows: a. Laboratory Director/Clinical Consultant b. Total of 3 Technical Consultants/Testing Personnel c. Total of 31 Test Personnel 2. Review of laboratory procedures manuals revealed that the laboratory director did not assign or specify, in writing, the responsibilities and duties of Technical Consultant for 3 of 3 Technical Consultants listed on Form CMS 209. The surveyor noted that personnel records only reflected documentation of training and competency for performance of blood gas testing. 3. At 3:30 PM on 08/29/18, the laboratory director confirmed the surveyor's findings.