Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2046702	11/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Danbury Hospital Pulmonary Function Laboratory	33 Germantown Rd, Danbury, CT	

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
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed retain previous laboratory procedures for the required 2 year period after being discontinued. Findings include: 1. Record review of the laboratory procedures on 11/1/18 for the prior 2 years revealed the previous RapidLab procedure was not available for surveyor review. 2. Staff interview with technical consultant (TC #1) on 11/1/18 at 10:15 AM confirmed the above finding. TC #1 stated: a. The laboratory discontinued use of the RapidLab instrument for blood gas analysis in August 2017 and began using the i-Stat analyzer, Serial Number 378882 in August 2017. b. TC#1 further revealed that the RapidLab procedures had been archived but he/she was unable to provide a copy of the procedure and the exact date patient testing was discontinued.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain analytic records for blood gas analysis testing for at least 2 years. Findings include: 1. Record

	review of the 'Monthly ABG Review and Unacceptable Specimen Log' on 11/1/18 revealed the following: a. June 2017: Patient #1, 6/9/17: critical low PO2 59.8. b. October 2017: Patient #2, 10/18/17: analysis error: "Reported visible CO2 result edited Cerner for CO2 result on screen." 2. Staff interview with technical consultant (TC) #1 on 11/1/18 at 2:00 PM confirmed the above findings. TC #1 stated the following: a. Patient #1 was performed on the RapidLab instrumentation and instrument records were not available and TC#1 was unaware where the RapidLab records were located. b. From August 2017 to March 3, 2018, i-Stat results went electronically into the patient record through a middle ware program called RALS. c. The 2 OF 2 TCs do not have the ability to access and monitor data captured in the RALS program. d. From March 5, 2018 to November 1, 2018, i-Stat results are manually entered into a comment field in the patient record. e. RapidLab instrument printouts, calibration verifications, and patient results were not available for review from when the instrument was placed into service in August 2017. f. Quality control of G3+ i-Stat cartridges is performed at an offsite location by non-laboratory personnel.
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 record review and staff interview, the laboratory failed to have policies and procedures in place to assess the competency of the technical consultant (TC) and clinical consultant (CC) based on their regulatory responsibilities. Findings include: 1. Record review of the laboratory competency assessment records on 11/1/18 revealed competency documentation for the TC and CC and written competency assessment policies and procedures were not available for review. 2. Staff interview with technical consultant #2 on 11/1/18 at 2:30 PM confirmed confirmed the above 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 record review and staff interview, the laboratory failed to provide evidence that it meets the requirements to perform testing for the blood gas analysis testing in the subspecialty of routine chemistry. Refer to citations D5403, D5407, D5409, D5421, D5425, D5427, D5439, D5537, D5539, D5789, D5791, D5801, D5803, D5805, D5807 and D5891.

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 record review and staff interview, the laboratory failed to include step by step procedures for preanalytical, analytical and postanalytical systems for blood gas analysis utilizing the i-Stat analyzer in the subspecialty of routine chemistry. Findings include: 1. Record review of the laboratory procedures on 11/1/18 revealed documentation of step by step procedures for the i-Stat analyzer including operation, maintenance, calibration, calibration verification, quality control, normal and critical values, reportable ranges, entering and reporting results and corrective action when test system failures occur was not available. 2. Staff interview with technical consultant #1 on 11/1/8 at 10:15 AM confirmed the above findings. TC #1 further stated the laboratory began using the i-Stat analyzer, Serial Number S/N 378882 in August 2017.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure approved written procedures were in place prior to blood gas patient testing utilizing the i-Stat analyzer in the subspecialty of routine chemistry. Findings include: 1. Record review of the laboratory 'Quality Management Program' procedure on 11/1/18 revealed documentation of laboratory director approval was not available. 2. Record review of the laboratory 'DH/NMH Handling Critical Values' procedure on 11/1/18 revealed documentation of laboratory director approval was not available. 3. Staff interview with technical consultant (TC #1) on 11/1/18at 10:15 AM confirmed the above

	findings. TC #1 further stated the laboratory went live with patient testing on the i-Stat analyzer in August 2017. 4. The laboratory performs 120 blood gas analysis annually.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Refer to D3029.
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 record review and staff interview, the laboratory failed to establish performance verification specifications and provide documentation prior to patient testing for the i-Stat analyzer serial number (S/N) 378882 in the subspecialty of routine chemistry. Findings include: 1. Record review of the verification document labeled as 'Danbury Hospital i-Stat System Verification' on 11/1/18 revealed the following: a. Coverpage of the document indicated 'Danbury Hospital i-Stat System Verification' dated March 8 - May 5, 2016. b. The following was handwritten on the coverpage: i. The word 'original' was crossed off and 'study updated' was added. ii. 'Pulmonary Lab' was added next to the Danbury Hospital title. iii. Document was reviewed and accepted on 6/16/16 by a person not on the laboratory's CMS 209 Personnel Form. c. Linearity documentation for reportable ranges for pH, partial pressure of carbon dioxide (pCO2) and partial pressure of oxygen (pO2) analytes was not available. d. Acceptability criteria for the comparison study of the i-Stat versus RapidLab was not available. e. Precision data for pH, pCO2 and pO2 is for the i-Stat S /N 378882 was not available. 2. Staff interview with technical consultant #2 on 11/1 /18 at 10:30 AM confirmed the above 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 record review and staff interview, the laboratory failed to establish performance specifications for calibration and quality control (QC) procedures utilizing the i-Stat analyzer in the subspecialty of routine chemistry. Findings include: 1. Record review of the verification document labeled as 'Danbury Hospital i-Stat System Verification' on 11/1/18 revealed the type, number and frequency of calibrations and controls for i-Stat analyzer was not established. 2. Staff interview with technical consultant #2 on 11/1/18 at 10:30 AM confirmed the above findings. 3. The laboratory performs 120 blood gas analysis annually.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to retain original instrument data of the verification studies for the i-Stat analyzer serial number 37882 in the subspecialty of routine chemistry. Findings include: 1. Record review of the verification document labeled as 'Danbury Hospital i-Stat System Verification' on 11/1/18 revealed raw data/measurements for accuracy, precision and reportable ranges were not available. 2. Staff interview with technical consultant #2 (TC #2) on 11/1/18 at 10:30 AM stated that he/she performed the verification studies. TC #2 stated he/she did not know the location of the instrument printouts. 3. The laboratory performs 120 blood gas analysis annually.
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 record review and staff interview, the laboratory failed to perform the

	calibration verification every six months on the blood gas analyzer in the subspecialty of routine chemistry. Findings include: 1. Record review of the calibration verification data for the i-Stat analyzer Serial Number 378882 revealed the following: a. Calibration verification for the analytes pH, PCO2, PO2 was performed on March 9, 2016, July 1, 2016, December 1, 2016, September 5, 2017, December 12, 2017 and October 16, 2018.. b. Evaluation and acceptability documentation of the above verifications was not available. 2. Staff interview with technical consultant #2 on 11/1 /18 at 12:55 PM confirmed the six months calibrations were not performed every 6 months. 3. The laboratory performs 120 blood gas tests annually.
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 record review and staff interview, the laboratory failed to perform quality control and document results for blood gas analysis on the i-Stat test system in the subspecialty of routine chemistry. Findings include: 1. Record review of quality control records for the i-Stat analyzer serial number 378882 on 11/1/18 revealed no records were available. 2. Staff interview with technical consultant #2 on 11/1/18 at 10:15 AM confirmed the above. TC #2 further stated blood gas analysis testing for pH, pCO2 and pO2 utilizing the above i-Stat started in August 2017. 3. The laboratory performs 120 blood gas analysis tests annually.
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 record review and staff interview, the laboratory failed to perform quality control and document results for blood gas analysis on the i-Stat test system in the subspecialty of routine chemistry. Findings include: 1. Record review of quality control records for the i-Stat analyzer serial number 378882 on 11/1/18 revealed no records were available. 2. Staff interview with technical consultant #2 on 11/1/18 at 10:15 AM confirmed the above. TC #2 further stated blood gas analysis testing for pH, pCO2 and pO2 utilizing the above i-Stat started in August 2017. 3. The laboratory performs 120 blood gas analysis tests annually.
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 record review and staff interview, the laboratory failed to maintain instrument printouts as part of patient testing records for blood gas analysis in the subspecialty of routine chemistry. Findings include: 1. Record review of i-Stat testing records on 11/1/18 revealed documentation of the analytic test record was not available. 2. Staff interview with technical consultant #2 (TC#2) on 11/1/18 at 10:15 AM confirmed the above findings. TC #2 stated the i-Stat has been in use for blood gas testing since August 2017 and testing personnel do not print results from the analyzer. 3. The laboratory performs 120 blood gas analysis annually.
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 record review and staff interview, the laboratory failed to develop policies to prevent recurrence when analysis errors occurred with arterial blood gas testing in the subspecialty of routine chemistry. Findings include: 1. Record review of the October 2017 'Monthly ABG review unacceptable specimen log' on 11/1/18 revealed the following: a. On 10/18/17, Patient #2 had a problem code '4' meaning analysis error. b. Outcome on the above testing stated "reported visible CO2 result edited Cerner for CO2 result on screen". c. Documentation of an investigation and prevention of recurrence was not available. 2. Staff interview with technical consultant #1 on 11/1 /18 at 2:00 PM confirmed the above. 3. The laboratory performs 120 blood gas analysis annually.
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 record review and staff interview, the laboratory failed to establish a mechanism to monitor for accuracy the postanalytical transmittal of test results to the final report destination in the subspecialty of routine chemistry. Findings include: 1. Record review of the laboratory procedures on 11/1/18 revealed a procedure for monitoring electronic or manual test results into the patient record was not available. 2. Staff interview with technical consultant #1 (TC #1) on 11/1/8 at 10:15 AM

	confirmed the above finding. TC #1 stated: a. The laboratory began using the i-Stat analyzer, Serial Number S/N 378882 in August 2017 with results electronically transmitted to the patient electronic record. b. On March 3, 2018 due to an upgrade to the laboratory information system, Cerner, a computer mapping issue exists and patient test results stopped electronically transmitting to the electronic medical record. c. Since March 5, 2018 until November 1, 2018, testing personnel manually entered blood gas results into the electronic patient record, Powerchart, as a blood gas sample comment. d. Documentation of quality assessment for accuracy of reporting electronically or manually was not available.
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 record review and staff interview, the laboratory failed to produce a final patient test report encompassing the required elements for blood gas analysis in the subspecialty of routine chemistry. 1. Record review on 11/1/18 of Patient #3 blood gas test results for 10/18/18 revealed the following: a. Test results were entered directly into a comment field in the patient's electronic chart. b. The name and address of the laboratory location is not on the electronic chart report. b. Units of measure, normal ranges for pH, pCO2 and pO2 are not available on the report. 2. Staff interview with technical consultant #1 on 11/1/18 at 2:00 PM confirmed Patient #3 blood gas results are entered into the comment field in the patient record and the name and address of the laboratory, units of measure and normal ranges are not available on the report. 3. The laboratory performs 120 blood gas analysis annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Refer to D5805.
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 record review and staff interview, the laboratory failed to establish policies and procedures to verify the accuracy of results sent to an interfaced system or when inoperable, establish a mechanism to verify manually entered results in the subspecialty of routine chemistry. Findings include: 1. Record review of the laboratory procedures on 11/1/18 revealed the following: a. Policies and procedures for monitoring test reporting of patient test results was not available. b. Monitoring for accuracy of electronic communication of patient test results was not available. c. Monitoring for accuracy of manual entry of results was not available. 3. Staff interview with technical consultant #1 on 11/1/18 at 10:15 AM confirmed the above findings. 4. The laboratory performs 120 blood gas analysis annually.
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 staff interview, the laboratory director failed to provide overall management and direction in accordance with 493.1407. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the subspecialty of routine chemistry. Findings include: 1. The laboratory director failed to ensure testing systems developed and used by the laboratory provide quality services for all aspects of test performance. Refer to D6007. 2. The laboratory director failed to ensure verification procedures were complete and approved prior to patient testing. Refer to D6013. 3. The laboratory director failed to ensure testing personnel have up to date procedure manual for accurate and reliable results. Refer to D6014. 4. The laboratory director failed to ensure quality control procedures were established and maintained to assure quality of laboratory services provided. Refer to D6020. 5. The laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6021. 6. The laboratory director failed to ensure test reports include pertinent information required for interpretation. Refer to D6026. 7. The laboratory director failed to ensure an approved procedure manual was available to testing personnel for all phases of testing. Refer to D6031.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

	This STANDARD is not met as evidenced by: Refer to D5403, D5407, D5421, D5425, D5427, D5439, D5537, and D5539.
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: Refer to D5421, D5425, D5427, D5439.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Refer to D5403, D5407, D5409, D5421, D5425, D5427, D5439, D5537, and D5539.
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: Refer to D5425, D5439, D5537 and D5539.
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: Refer to D5801, D5803, D5805, D5807 and D5891.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Refer to D5805, and D5807.
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: Refer to D5407.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical consultant failed to verify the performance characteristics for the i-Stat test system in the subspecialty of routine chemistry prior to patient testing. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based of record review and staff interview, the technical consultant failed to establish an appropriate quality control program and analytical performance through out all phases of blood gas testing in the subspecialty of routine chemistry. Refer to D5425.
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 record review and staff interview, the laboratory technical consultant failed to evaluate and document competency assessment for testing personnel twice during the first year of blood gas testing utilizing the i-Stat analyzer in the subspecialty of routine chemistry. Findings include: 1. Record review of testing personnel competency assessment records on 11/1/18 revealed 6 of 6 testing personnel were assessed once during the first year of patient testing utilizing the i-Stat test system. 2. Staff interview with technical consultant #2 (TC # 2) on 11/1/8 at 10:15 AM confirmed the above. TC #2 stated the laboratory began using the i-Stat analyzer, Serial Number 378882 in August 2017. 3. Staff interview with technical consultant #2 on 11/1/18 at 2:00 PM confirmed the competency assessments were not performed twice in the first year and the assessments are overdue.