Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	19D0713341	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Richardson Medical Center	254 Hwy 3048, Rayville, LA	

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
D0000	A Certification Survey was performed at Richardson Medical Center-CLIA ID # 19D0713341 on January 31, 2018. Richardson Medical Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1210 CONDITION: Routine Chemistry 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey May 23, 2016*** Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director and Testing Personnel signed the attestation statement for one (1) of three (3) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Log" revealed Personnel 5, Personnel 7, and Personnel 13 performed proficiency testing for the 2017 Blood Gas 3rd Event. 2. Review of the laboratory's WSLH Proficiency records for 2017 revealed the laboratory did not have documentation of the following: a) 2017 Blood Gas 3rd Event: Laboratory Director signature on the attestation statement b) 2017 Blood Gas 3rd Event: signature of all testing personnel who performed testing on the attestation statement 2. Further review of the laboratory's 2017 Blood Gas 3rd Event PT records revealed only Personnel 5 signed as an "analyst" on the attestation statement and Personnel 10 signed as Laboratory Director/Designee. 3. In interview on January 31, 2018, Personnel 10 confirmed the 2017 Blood Gas 3rd Event's attestation statement was not signed by the identified personnel.

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 observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure the Laboratory Director and Testing Personnel signed the attestation statement for one (1) of three (3) proficiency testing (PT) events reviewed. Refer to D2009. 2. The laboratory failed to follow their established policy for competency assessment. Refer to D5401 I. 3. The laboratory failed to establish a policy for twice a year comparison testing for blood gas testing performed on the Opti CCA-TS. Refer to D5401 II. 4. The laboratory failed to label control material for the Cobas b 221 with expiration dates for proper use. Refer to D5415. 5. The laboratory failed to ensure reagents have not exceeded their expiration date. Refer to D5417. 6. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445 I. 7. The laboratory failed to perform external controls monthly per the laboratory's Individualized Quality Control Plan (IQCP). Refer to D5445 II. 8. The laboratory failed to have a system in place for twice a year comparison testing for blood gas testing performed on the Opti CCA-TS. Refer to D5775. 9. The laboratory's Quality Assurance monitors failed to identify and correct quality issues. Refer to D5793.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to follow their established policy for competency assessment. Findings: 1. Review of the laboratory's "Competency" policy revealed the following: "Laboratory testing employees will be assessed to be competent to fulfill their duties as laboratory personnel as required by federal regulation by the following methods: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of the test results c) Review of test results, quality control records, proficiency testing results, and preventive maintenance records d) Direct observation of performance of instrument maintenance and function checks e) Assessment of test performance through testing previously analyzed specimens, or external proficiency testing samples f) Assessment of problem solving skills" 2. Review of personnel records revealed the laboratory utilizes a checklist "ABG Skills Analysis" form and "Blood Gas Laboratory" form with "Patient Comparison Samples" and "Quality Controls: Manual" sections. 3. Review of the laboratory's forms for personnel competency revealed the forms did not include "Direct observation" of tasks as listed in policy. 4.

	In interview on January 31, 2018 at 10:06 am, Personnel 10 stated the identified forms are what the laboratory utilizes to perform competency assessments. In further interview, Personnel 10 confirmed the competency assessment forms did not reflect the six (6) required procedures. II. Based on observation, record review and interview with personnel, the laboratory failed to establish a policy for twice a year comparison testing for blood gas testing performed on the Opti CCA-TS. Findings: 1. Observation by surveyor during laboratory tour on January 31, 2018 revealed the laboratory utilizes the Cobas b 221 and the Opti CCA-TS for blood gas analysis. 2. In interview on January 31, 2018 at 9:05 am, Personnel 10 stated the Opti CCA-TS is utilized as the back-up analyzer for blood gas testing. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for twice a year comparison testing for the Opti-CCA-TS. 4. In interview on January 31, 2018 at 11:38 am, Personnel 10 confirmed the laboratory did not have a written policy for comparison testing on the blood gas back-up analyzer .
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to label control material for the Cobas b 221 with expiration dates for proper use. Findings: 1. Observation by surveyor during the laboratory tour on January 31, 2018 revealed the laboratory stored the following controls at room temperature without documentation of expiration dates: a) Cobas AUTO-TROL PLUS B Level 1, Lot # 21460753, Quantity 1 box, Shipment received November 13, 2017 b) Cobas AUTO-TROL PLUS B Level 1, Lot # 21460757, Quantity 1 box, Shipment received June 28, 2017 c) Cobas AUTO-TROL PLUS B Level 3, Lot # 21460946, Quantity 1 box, Shipment receive date not documented d) Cobas AUTO-TROL PLUS B Level 2, Lot # 21460850, Quantity 1 box, Shipment received November 13, 2017 e) Cobas AUTO-TROL PLUS B Level 2, Lot # 21460850,Quantity 1 box, Shipment received June 23, 2017 2. Review of the Cobas AUTO-TROL PLUS B package insert under the storage and stability section revealed the following requirements: "Unopened in the closed box: -Up to the stated expiration date at 2-8 degrees Celsius -Up to 3 months at room temperature -Up to 60 days on the AutoQC module Do not freeze. Roche Diagnostics cannot guarantee the performance of the quality control when stored outside of recommended range." 3. In interview on January 31, 2018 at 2:30 pm, Personnel 10 stated the identified controls stored at room temperature were not labeled with expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure reagents have not exceeded their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on January 31, 2018 revealed the following expired items: a) pCO2 Electrode, Lot # 21561850, Expiration date: 2016-11-04, Quantity: 1 electrode b) pCO2 Electrode, Lot # 21570549, Expiration date: 2017-08-04, Quantity: 1 electrode 2. In interview on January 31, 2018 at 9:15 am, Personnel 10 stated the instrument will not allow you to install expired reagents. Personnel 10 confirmed the identified electrodes were expired.
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: I. Based on observation, record review, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Findings: 1. Observation by surveyor during the laboratory tour on January 31, 2018 revealed the laboratory utilizes the Cobas b 221 for blood gas testing. 2. Review of the laboratory's IQCP "Quality Control Plan" revealed the following sections: a) External QC Samples: "External QC samples (Levels 1, 2, 3) to be analyzed monthly." b) Internal Procedural control c) Proficiency Testing d) Maintenance/Function Checks e) Training f) Required Quality Assessment Plan Monitoring: "Quality Control Assessment Plan to be reviewed annually." 3. Further review of the laboratory's IQCP documents, effective January 1, 2016, revealed the following components were not included: a) In-house QC data to support the reduction of performing external controls as listed above b) Effective Quality Assessment Plan c) Signature/approval by Laboratory Director 4. In interview on January 31, 2018 at 12:45 pm, Personnel 10 stated he thought the laboratory had quality control data for thirty (30) days, but was unable to find it. 5. In further interview on January 31, 2018 at 2:10 pm, Personnel 10 confirmed the IQCP documents were signed by himself, not the Laboratory Director. 6. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 1,600 blood gas tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to perform external controls monthly per the laboratory's Individualized Quality Control Plan (IQCP). Findings: 1. Observation by surveyor during the laboratory tour on January 31, 2018 revealed the laboratory utilizes the Cobas b 221 for blood gas testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) documents revealed "External QC samples (Levels 1, 2, 3) to be analyzed monthly." 3. Review of the laboratory's QC records for September 2017 through December 2017 revealed the laboratory did not perform external QC monthly. 4. In interview on January 31, 2018 at 2:10 pm, Personnel 10 confirmed the laboratory did not perform external QC monthly. Personnel 10 stated he was unable to determine that the external QC was performed

	each month. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 1,600 blood gas tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey May 23, 2016*** Based on observation, record review, and interview with personnel, the laboratory failed to have a system in place for twice a year comparison testing for blood gas testing performed on the Opti CCA-TS. Findings: 1. Observation by surveyor during laboratory tour on January 31, 2018 revealed the laboratory utilizes the Cobas b 221 and the Opti CCA-TS for blood gas analysis. 2. In interview on January 31, 2018 at 9:05 am, Personnel 10 stated the Opti CCA-TS is utilized as the back-up analyzer for blood gas testing. 3. In further interview on January 31, 2018 at 11:38 am, Personnel 10 stated three samples are run annually on the Cobas and Opti analyzers for a comparison. 4. Review of the laboratory's 2017 records revealed the laboratory did not have documentation of an annual comparison of three (3) samples on the Cobas and Opti analyzers. 5. In further interview on January 31, 2018 at 11:38 am, Personnel 10 stated he did not see where the comparison between the two analyzers was performed in 2017. 6. In interview on January 31, 2018 at 12:50 pm, Personnel 10 stated it had been years since the laboratory used the Opti for patient testing.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey May 23, 2016*** Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. Review of the laboratory's "Blood Gas Laboratory Quality Assurance Plan" revealed the following monitors: a) Specimens b) ABG values reported c) Quality Control d) Proficiency Testing e) Calibration Verification Testing f) Personnel Assessments g) Complaints 2. Review of the laboratory's records revealed the laboratory did not identify the following issues: a) The laboratory failed to follow their established policy for competency assessment. Refer to D5401 I. b) The laboratory failed to establish a policy for twice a year comparison testing for blood gas testing performed on the Opti CCA-TS. Refer to 5401 II. c) The laboratory failed to label control material for the Cobas b 221 with expiration dates for proper use. Refer to D5415. d) The laboratory

	failed to ensure reagents have not exceeded their expiration date. Refer to D5417. e) The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445 I. f) The laboratory failed to perform external controls monthly per the laboratory's Individualized Quality Control Plan (IQCP). Refer to D5445 II. g) The laboratory failed to have a system in place for twice a year comparison testing for blood gas testing performed on the Opti CCA-TS. Refer to D5775. 3. In interview on January 31, 2018 at 2:15 pm, Personnel 10 stated as part of QA review the Laboratory Director performs a monthly QC assessment. Personnel 10 confirmed the laboratory did not identify the issues found.
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: ***REPEAT DEFICIENCY from survey May 23, 2016*** Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 2. The Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D6018. 3. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 5. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
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: Based on observation, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory

	failed to label control material for the Cobas b 221 with expiration dates for proper use. Refer to D5415. 2. The laboratory failed to ensure reagents have not exceeded their expiration date. Refer to D5417.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey May 23, 2016*** Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D2009.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445 I. 2. The laboratory failed to perform external controls monthly per the laboratory's Individualized Quality Control Plan (IQCP). Refer to D5445 II.
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: ***REPEAT DEFICIENCY from survey May 23, 2016*** Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D5793.
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: ***REPEAT DEFICIENCY from survey May 23, 2016*** Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of twelve (12) testing personnel reviewed. Refer to D6053. 2. The Technical Consultant failed to evaluate and document personnel competency annually for three (3) of twelve (12) testing personnel reviewed. Refer to D6054.
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 record review and interview with laboratory personnel, 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: 1. The laboratory failed to follow their established policy for competency assessment. Refer to D5401 I. 2. The laboratory failed to establish a policy for twice a year comparison testing for blood gas testing performed on the Opti CCA-TS. Refer to D5401 II.
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 interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of twelve (12) testing personnel reviewed. Findings: 1. Review of the laboratory's "Quality Control Plan" policy under the section titled "Training" section revealed "Staff training performed within six months of employment and annually thereafter." 2. Review of personnel records revealed the laboratory did not have documentation of performance of a semi-annual competency assessment for the following personnel: Personnel 11 (due July 2017) 3. In interview on January 31, 2018 at 10:13 am. Personnel 10 stated he could not find the semi-annual evaluation for Personnel 11.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document personnel competency annually for three (3) of twelve (12) testing personnel reviewed. Findings: 1. Review of the laboratory's "Quality Control Plan" policy under "Training" section revealed "Staff training performed within six months of employment and annually thereafter." 2. Review of personnel records revealed the Technical Consultant did not perform an annual competency assessment in 2017 for the following personnel performing moderate complexity testing: Personnel 2 Personnel 10 Personnel 13 3. In interview on January 31, 2018 at 9:55 am, Personnel 10 stated Personnel 13 mainly performs sleep testing. Personnel 10 further stated the laboratory lists Personnel 13 as Testing Personnel on the CMS-209 (Laboratory Personnel Report) since he is a licensed Respiratory Therapist. 4. In interview on January 31, 2018 at 10:06 am, Personnel 10 further stated Personnel 2 is a part-time employee who has not worked in the laboratory much. Personnel 10 confirmed the laboratory did not have documentation of annual competency assessments for the identified personnel.