Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0713341	04/29/2022
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 Recertification Survey was performed at Richardson Medical Center Respiratory-CLIA # 19D0713341 on April 29, 2022. Richardson Medical Center Respiratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on observation during the laboratory tour, review of laboratory's policies and procedures and proficiency testing results as well as interview with personnel, the

	laboratory failed to successfully participate in proficiency testing for two (2) of six (6) events reviewed. Findings: 1. The laboratory failed to achieve a score of at least 80% for pO2 in two (2) of six (6) consecutive events reviewed, resulting in an initial unsuccessful performance for 2020 and 2021: a) CAP AQ-B 2020 Crit Care/Aqueous Blood Gas: score received 60% b) CAP AQ-C 2020 Crit Care/Aqueous Blood Gas: score received 0%
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the proficiency testing results from the CASPER 155D report, laboratory's proficiency test records and interview with personnel, the laboratory failed to achieve a score of at least 80% for pO2 in two (2) of six (6) consecutive events reviewed, resulting in an initial unsuccessful performance for 2020 and 2021. Findings: 1. Review of the CASPER 155D report and the laboratory's College of American Pathologists (CAP) proficiency test records from 2020 and 2021 for pO2 revealed the laboratory received the following scores in two (2) of six (6) events reviewed: a) CAP AQ-B 2020 Crit Care/Aqueous Blood Gas: score received 60% b) CAP AQ-C 2020 Crit Care/Aqueous Blood Gas: score received 0% 2. Further review of the laboratory's proficiency test records revealed the laboratory did have remedial action documentation for each of the identified events. 3. In interview on April 29, 2022 at 2:34 pm, Personnel 10 stated the 2nd event failure in 2020 was due to personnel error in running the sample and the 3rd event failure in 2020 was due to clerical errors in the submitting of results. Personnel 10 confirmed the above identified events did not receive score of 80% or greater.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's instrument manual and temperature logs as well as interview with personnel, the laboratory failed to monitor the room humidity where the Roche Cobas b 221 Blood Gas analyzer is utilized for twenty-seven (27) of twenty seven (27) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on April 29, 2022 at 2:00 pm revealed the laboratory utilizes the Roche Cobas b 221 Chemistry analyzer for Arterial Blood Gas (ABG) testing. 2. Review of the manufacturer's instrument manual under "Environmental parameters" revealed "Operating Conditions for Relative Humidity 20

	- 85%. 3. Review of the laboratory's Daily Temperature Log from January 2020 through March 2022 revealed the laboratory did not document humidity readings for each day of operation. 4. In interview on April 29, 2020 at 3:24 pm, Personnel 10 confirmed the laboratory did not document the humidity each day of patient testing.
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 observation by surveyor, review of laboratory records, 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 the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D6019.
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 direct observation by surveyor, review of laboratory policy and records, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5413.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing records and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D2096.