Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0912125	11/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Respiratory And Nursing Care Of Dayton	3421 Pinnacle Road, Dayton, OH	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and an interview with the Manager of Clinical Services (MCS), the laboratory failed to enroll in a proficiency testing (PT) program for the specialty of chemistry. This deficient practice had the potential to affect 11 patients tested under the specialty of chemistry from 08/26/2022 through 11/01/2022. Findings Include: 1. The laboratory failed to enroll in PT program for the regulated chemistry analytes.
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:

	ITEM 1 Based on record review and an interview with the Manager of Clinical Services (MCS), the laboratory failed to follow their arterial blood gas Proficiency Testing (PT) policy and procedure. This deficient practice had the potential to affect 11 patients tested under the specialty of chemistry from 08/26/2022 through 11/01 /2022. Findings Include: 1. Review of the "ABG Proficiency Testing" policy and procedure provided on the date of the inspection, found the following statements: "To assure safety and accuracy of performing proficiency testing and recording results. Employees are required to participate in proficiency testing. Proficiency test samples will be tested the same number of times that routine patient samples are tested. An employee log will be monitored by the department head/Supervisor." 2. Record review did not find any documentation of PT participation for 2022. 3. The Inspector requested the laboratory's 2022 PT documentation. The MCS confirmed the laboratory did not enroll and conduct PT activities as required and was unable to provide the requested documentation. The interview occurred 11/01/2022 at 11:10 AM. ABG; Arterial Blood Gas ITEM 2 Based on record review and an interview with the Manager of Clinical Services (MCS), the laboratory failed to follow their Quality Control policy and procedure for new CG4+ cartridge lot verification for reliable iSTAT testing procedures. This deficient practice had the potential to affect 11 patients tested under the specialty of chemistry from 08/26/2022 through 11/01/2022. Findings Include: 1. Review of the "Quality Control" policy and procedure provided on the date of the inspection, found the following statements: "The three levels are also run with every new lot and/or shipment of cartridges, with every software update, and/or if any problems are experienced with the instrument or result." 2. Review of 13 out of 15 test records from 11 patients found an iSTAT CG4+ cartridge lot number of D22127. 3. Review of two out of 15 test records from 11 patients found an iSTAT CG4+ cartridge lot number of D22189. 4. The Inspector requested the laboratory's documentation for new CG4+ cartridge lot verification for reliable iSTAT testing procedures from the MCS. The MCS confirmed the laboratory did not document new iSTAT CG4+ cartridge lots and was unable to provide the requested documentation. The interview occurred 11/01/2022 at 12:45 PM.
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 an interview with Manager of Clinical Services (MCS), the laboratory failed to establish and verify performance specifications of the i-STAT for arterial blood gasses before reporting patient test results. This deficient practice had the potential to affect 11 patients tested under the specialty of chemistry from 08 /26/2022 through 11/01/2022. Findings Include: 1. A review of the laboratory's policy and procedure titled "Foundations Health Solutions Policy and Procedures" provided on the date of inspection found no mention of verification of performance specifications for i-STAT arterial blood gas tests prior to testing patient specimens, including accuracy, precision, reportable range and normal range. 2. A review of the i-

	STAT test logs provided on 10/20/2022 at 10:40 AM via electronic mail (email) found 11 patients tested using the i-STAT for arterial blood gasses. 3. An email from the MCS on 11/09/2022 at 1:30 PM confirmed 11 patients had been tested using the i-STAT for arterial blood gasses. 4. The inspector requested documentation of the performance specifications for the i-STAT arterial blood gas tests prior to testing patient specimens, including accuracy, precision, reportable range and normal range from the MCS. The MCS confirmed performance specifications were not completed and was unable to provide the requested document. The interview occurred 11/01 /2022 at 12:00 PM.
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 record review and an interview with the Manager of Clinical Services (MCS), the Laboratory Director (LD) failed to ensure four out of eight Testing Personnel (TP) were trained and demonstrated they could perform testing procedures reliably to provide and report accurate results prior to performing patient testing. This deficient practice had the potential to affect 11 patients tested under the specialty of chemistry from 08/26/2022 through 11/01/2022. Findings Include: 1. Review of the laboratory's policies and procedures, approved and signed by the LD on 11/18/2021, and provided on the date of the inspection, found the following statement: "1. New employees responsible for obtaining or reporting ABG measurements will be provided with the ABG Lab Competency during orientation, at 6 months and one year of employment. Ongoing, these employees will complete the ABG Lab Competency Assessment annually. 2. The Lab Director will evaluate through direct observation the six areas of minimum requirements defined by CLIA in this facility's ABO Competency Assessment. Initial Training." 2. The Inspector requested the laboratory's competency documentation for TP #1, TP #6, TP #7, and TP #8 from the MCS. The MCS confirmed the laboratory did not document competency in order to reliably provide and report accurate results prior to patient testing for TP #1, TP #6, TP #7, and TP #8, and was unable to provide the requested documentation on the date of the inspection. The interview occurred 11/01/2022 at 10:25 AM. ABG; Arterial Blood Gas
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 record reviews and an interview with the Manager of Clinical Services (MCS), the Laboratory Director (LD) failed to specify the duties and responsibilities of each person listed on the Form CMS-209. This deficient practice had the potential to affect 11 patients tested under the specialty of chemistry from 08/26/2022 through 11/01/2022. Findings include: 1. Review of the Form CMS-209 found two individuals listed as the Clinical Consultants, one individual listed as the Technical Consultant, and eight individuals listed as Testing Personnel. 2. Review of policies and procedures provided on the date of inspection failed to find evidence of the duties and responsibilities for the Clinical Consultants, Technical Consultant, and each Testing Personnel in writing by the LD. 3. The inspector requested the approved, signed and dated duties and responsibilities for the Clinical Consultants, Technical Consultant, and Testing Personnel from the MCS. The MCS confirmed the LD failed to specify in writing the duties of all personnel listed on the Form CMS-209 and was unable to provide the requested document. The interview occurred 11/01/2022 at 10:45 AM.