Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229350	05/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lake Taylor Transitional Care Hospital	1309 Kempsville Road, Norfolk, VA	

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	An announced CLIA recertification survey was conducted at Lake Taylor Transitional Care Hospital on May 2, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the facility performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Condition: Analytic Systems.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), proficiency testing (PT) records, and interviews, the laboratory failed to rotate PT among personnel responsible for performing patient blood gas testing in 2022. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified twenty-one (21) testing personnel (TP) as responsible for performing patient non waived blood gas chemistry testing. 2. Review of the laboratory's 2022 College of American Pathologists (CAP) Critical Care Blood Gas with Chemistry module PT documentation (AQ Events A-C) revealed TP #1 performed/signed attestations for: CAP AQ- A, CAP AQ- B. (See Personnel Code Sheet.) 3. During an interview with the Respiratory Therapy Director on 05/02/23 at approximately 11:30 AM, the inspector inquired regarding how the laboratory's proficiency testing is assigned noting that TP #1 signed and performed two (2) of three (3) events in 2022. The Respiratory Therapy Director stated, "Our protocol is for

	the PT samples to be rotated and tested among all staff members who perform testing". 4. An exit interview with the Respiratory Therapy Director, Program Manager, and Vice President on 05/02/23 at approximately 1:30 PM confirmed the above findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation, lack of documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for two (2) of five (5) events reviewed. Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Critical Care Blood Gas with Chemistry module PT documentation (2021 Event C, 2022 Events A-C, 2023 Event A) revealed no signed attestation statements for the following two events: 2022 CAP AQ Event A - no attestation signatures for LD and TP; 2022 CAP AQ Event C - no attestation signatures for TP. The inspector requested to review the attestation signature documentation for the blood gas chemistry module events outlined above. No documentation was available for review. 2. An exit interview with the Respiratory Therapy Director, Program Manager, and Vice President on 05/02/23 at approximately 1:30 PM 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 review of laboratory policies, quality control (QC) documentation, patient test logs, and interviews, the laboratory failed to follow their established policy for QC performance every eight hours on eight days while reporting eleven patient blood gas panel results in a sampled nineteen month review. See D5401 (repeat deficiency).
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: Based on a review of policies, quality control (QC) documentation, patient test logs, and interviews, the laboratory failed to follow the established policy for QC performance every eight hours for eleven (11) patient blood gas panel tests assayed /reported on eight (8) days of the nineteen (19) months reviewed (October 2021 to the date of the inspection on May 2, 2023). *REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's procedure manual (title: Respiratory Care Department-Blood Gas Laboratory) revealed QC instructions "three times a day at 0700, 1500, 2300, the three standard QC reference cartridges are to assayed for the OPTI CCA - TS2 blood gas analyzer." 2. The inspector requested to review QC documentation and OPTI CCA blood gas patient logs from October 2021 to 05/02/23. The sampled records revealed missing QC for the following dates and number of patients analyzed: 10/10/21 -1 patient - Medical Record (MR) #15723 (one of three QC missed, 1500); 07/28/22- 1 patient - MR #30686 (one of three QC missed, 1500); 08/19/22- 1 patient - MR #30158 (one of three QC missed, 1500); 09/27/22- 2 patients- MR #26344, #30872 (one of three QC missed, 1500); 01/06/23- 1 patient - MR #31035 (one of three QC missed, 0700); 01/16/23- 1 patient - MR #31213 (one of three QC missed, 0700); 02/15/23- 1 patient - MR #30135 (one of three QC missed, 2300); 03/14/23- 3 patients- MR #31034, 31035, 31035 (one of three QC missed, 2300). A total of 8 days with 11 patient blood gas panel results reported while not following the laboratory's QC protocols as outlined above. 3. An exit interview with the Respiratory Therapy Director, Program Manager, and Vice President on 05/02/23 at approximately 1:30 PM confirmed the above findings.