Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229350	06/22/2021
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 June 22, 2021 by the Virginia Department of Health's Office of Licensure and Certification. 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.
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, instrument calibration verification records, patient test logs, and interviews, the laboratory failed to: 1. follow their established policy for blood gas chemistry QC performance every eight hours on five days while reporting six patient results in a sampled fourteen month review; 2. perform calibration verification on the OPTI AVL and OPTI CCA-TS2 every six months during the twenty-four months reviewed. See D5401 (Part A is a 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:
A. Based on a review of policies, quality control (QC) documentation, patient test logs, and an interview, the laboratory failed to follow the established policy for blood gas chemistry QC performance every eight hours on five (5) days with six (6) patients tested in the fourteen month timeframe reviewed. **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 April 2020 to 06/22/21. The sampled records revealed missing QC for the following dates and number of patients analyzed: 04/08/20 - 1 patient (one of three QC missed, 0700); 05/28/20 - 2 patient (one of three QC missed, 1500); 11/02/20 - 1 patient (one of three QC missed, 1500); 11/07/20 - 1 patient (one of three QC missed, 0700); 11/20/20 - 1 patient (one of three QC missed, 1500); A total of 5 days with 6 patients tested while not following the laboratory's QC protocols as outlined above. 3. In an exit interview with the Director of Respiratory Services, two Program Managers, and Vice President on 6/22 /21 at approximately 4:00 PM, the above findings were confirmed. B. Based on a review of procedures, instrument calibration verification records, patient test logs, and interviews, the laboratory failed to perform calibration verification for Hydrogen Ion Concentration (pH), Carbon Dioxide Partial Pressure (PCO2), Bicarbonate (HCO3), and Oxygen Partial Pressure (PO2) on the OPTI AVL and OPTI CCA-TS2 analyzers every six months while reporting three hundred eighteen (318) patient arterial blood gas (ABG) panels according to procedure during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's OPTI AVL and OPTI CCA-TS2 procedures revealed calibration verification protocols as: OPTI AVL: "Calibration verification or the analytical measurement range will be performed twice per year." OPTI CCA-TS2: "Calibration verification allows for the validation of the blood gas analyzer's ability to recover known values at various points within the reportable range of all parameters. Refer to your regulatory agency". 2. Review of the laboratory's calibration verification records during the timeframe of June 2019 to the date of the survey on 06/22/21, revealed no calibration verification or linearity studies for: OPTI AVL, Serial Number (SN) 6666-6666, OPTI CCA - TS2, SN 003487. The inspector requested to review documentation of calibration verification for the analyzers outlined above. An installation validation study was available for review for the OPTI CCA - TS2 (dated 08/18/20). No other records were available. 3. The inspector inquired regarding the manufacturer's user guidance and director's approved policy for calibration verification instructions. The Director of Respiratory Services, stated at approximately 2:30 PM: "I have spoken with our field service at OPTI and they informed us that the calibration verification needs to be done every 6 months. There is a kit we will have to purchase to be able to do this so as soon as I am able to purchase the kit and get it here, our protocol will be to run the calibration verification and continue to do so every 6 months going forward as our procedure outlines." 4. Review of the laboratory's blood gas patient test logs revealed the following number of patient ABG samples were reported during lapses in 6 month calibration verification: OPTI AVL from June 2019 to 09/18/20: two hundred forty (240); OPTI CCA - TS2 from 03/18/21 to 06/22/21: seventy-eight (78); A total of 318 ABG panels were assayed during a lapse in calibration verification during the review timeframe

	outlined. 5. In an exit interview with the Director of Respiratory Services, two Program Managers, and Vice President on 6/22/21 at approximately 4:00 PM, the above findings were confirmed.