Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229350	03/21/2019
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 March 21, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 a review of patient test logs, proficiency testing (PT) records, and interviews, the laboratory failed to enroll for Hemoglobin (Hgb) in calendar year 2017 and 2018 while reporting five hundred thirty-four (534) patient results. Findings include: 1. A review of the 2017 and 2018 OPTI CCA blood gas analyzer patient test logs revealed that the laboratory reported and trended 534 patient hemoglobin results as a component of the Blood Gas Panel. 2. A review of the laboratory's 2017 (Event A, B, C) , 2018 (Event A, B, C), and 2019 (Event A) College of American Pathologists (CAP) PT records (a total of seven Critical Care/Aqueous Blood Gas events) revealed no Hgb scored results. The inspector requested to review the results. The Director of Respiratory Services stated: "I am not sure if we are enrolled for that portion of the testing events'. 3. A telephone interview with a CAP technical specialist at approximately 2:00 PM revealed that the laboratory was not enrolled for the

	available Hemoglobin on the Critical Care/Aqueous Blood Gas module. 4. In an exit interview with the Director of Respiratory Services and Lab Supervisor hospital at approximately 3:00 PM the above findings were confirmed.
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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), proficiency testing (PT) records and an interview, the laboratory failed to rotate PT among personnel performing blood gas chemistry patient testing during the twenty-four (24) months reviewed. Findings include: 1. Review of the CMS Form 209 revealed forty-three (43) testing personnel (TP). The laboratory supervisor confirmed in an entrance interview that the 43 TP performed patient blood gas testing on the OPTI CCA blood gas analyzer in calendar years 2017 and 2018. 2. Review of the laboratory's scored College of American Pathologists (CAP) PT documentation, a total of six (6) events, revealed TP A performed three (3) of the 6 events reviewed: TP A signed PT attestation for: AQ-B 2017, AQ-C 2017, AQ-C 2018 (See Personnel Code Sheet). 3. In an exit interview with the Director of Respiratory Services and Lab Supervisor hospital at approximately 3:00 PM, the above findings were confirmed
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, and interviews, the laboratory failed to document remedial action taken for one (1) unsatisfactory scored event out of three (3) blood gas chemistry PT events reviewed for calendar year 2018. Findings include: 1. Review of the 2018 College of American Pathologists (CAP) chemistry PT result documentation, a total of three (3) events, revealed no evidence of remedial action for the 2018 AQ-C Routine Chemistry event (scored as 47%) with the following analytes scored as unacceptable: AQ-11: Blood Gas PCO2 and TCO2, Sodium (Na), Potassium (K), Chloride (Cl); AQ-12: Na, K, Cl; AQ-13: Na, K, Cl; AQ-14: Na, K, Cl; AQ-15: Na, K, Cl. Review of the laboratory's PT results revealed no corrective or remedial action documentation for the unacceptable scores listed above. The inspector requested documentation of remedial action. The Director of

	Respiratory Services stated, "We did not notice the unacceptable results." 2. In an exit interview with the Director of Respiratory Services and Lab Supervisor hospital at approximately 3:00 PM, the above findings were confirmed
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 the laboratory's procedures and policies, quality control (QC) documentation, patient test logs, and an interview, the laboratory failed to monitor the quality of the OPTI CCA blood gas analyzer's testing with QC documented every eight hours on four days while reporting six patient panel results during the fourteen months reviewed. See D 5401 (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: Based on 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 four (4) days with six (6) patients tested during the fourteen (14) months reviewed. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's QC policy (title: Quality Control in the Blood Gas Laboratory) revealed instructions to perform at least two (2) levels of QC every 8 hours. The procedure stated: "Three times a day (at 0700, 1500, 2300) three standard QC reference cartridges are to assayed for the OPTI CCA blood gas analyzer." 2. Review of QC documentation and OPTI CCA blood gas patient logs, from January 2018 to 3/21/19, revealed no QC recorded for the following: 08/21/18 - 2 patients tested and reported; 11/08/18 - 2 patients tested and reported; 02/01/19 - 1 patients tested and reported; 02/21/19 - 1 patients tested and reported; a total of 4 days with 6 patients tested. 3. In an exit interview with the Director of Respiratory Services and Lab Supervisor hospital at approximately 3:00 PM the above findings were confirmed
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of patient test logs, proficiency testing (PT) records (a total of six events), and interviews, the laboratory director failed to ensure PT enrollment for Hemoglobin (Hgb) in calendar year 2017 and 2018 while reporting five hundred thirty-four (534) patient results. Findings include: 1. A review of the 2017 and 2018 OPTI CCA blood gas analyzer patient test logs revealed that the laboratory reported and trended 534 patient hemoglobin results as a component of the Blood Gas Panel. 2. A review of the laboratory's 2017, 2018, and 2019 College of American Pathologists (CAP) proficiency testing (PT) records (a total of seven events) revealed no Hgb scored results. The inspector requested to review the results. No records were available for review. 3. A telephone interview with a CAP representative at approximately 2:00 PM revealed that the laboratory was not enrolled for the available Hemoglobin on the Critical Care/Aqueous Blood Gas module. 4. In an exit interview with the Director of Respiratory Services and Lab Supervisor hospital at approximately 3:00 PM the above findings were confirmed.