Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0229379	01/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Waterside Health & Rehab Center, Llc	249 Newtown Road South, 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 initial survey was conducted at Waterside Health and Rehab Center, LLC on January 18, 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 facility's laboratory service 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: D6063 -42 CFR. 493.1487 Condition Testing Personnel.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a review of procedures, tour, and interview, the skilled nursing facility failed to label two (2) of 2 boxed chemistry quality control (QC) materials with appropriate expiration date, observed in use to monitor chemistry/blood gas panel test performance, on the date of the initial survey on January 18, 2023. Findings include: 1. Review of the facility's laboratory procedures revealed a protocol (Titled: Quality Control) that stated "Abbott iSTAT TriControls are to be stored refrigerated and are good until the expiration date on the box. Control vials stored at room temperature are viable up to 5 days. Once at room temperature the controls cannot go back into the refrigerator." 2. A tour of the facility's reagent storage area on 1/18/23 at approximately 1:00 PM revealed the following boxes of Abbott iSTAT QC (content 7 of 10 vials) stored at room temperature: TriControls Level 1 Lot Number 301154,

	manufacturer expiration date 10/31/23 if stored at 2-8 C; Tri Controls Level 3 Lot Number 321154, manufacturer expiration date 10/31/23 if stored at 2-8 C. The inspector observed the 2 boxes of QC outlined above did not have an open date or a revised expiration date denoted. The inspector inquired regarding the protocol for denoting expiration dates for room temperature storage of the iSTAT QC. The Respiratory Director (RD) stated on 1/18/23 at approximately 1:20 PM, "The iSTAT reagent cartridges and QC that have been opened and stored at room temperature should be marked with an opened expiration date." 3. The inspector inquired if the identified control materials, outlined above, were currently in use for the monitoring the iSTAT analyzer. The RD stated at approximately 1:30 PM, "Yes, they are being used to QC the iSTAT instrument." 4. An exit interview with RD on 1/18/23 at approximately 3:45 PM confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the initial survey Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files (review timeframe of September 2022 - January 18, 2023), procedures, lack of documentation, and an interview, the technical consultant (TC) failed to retain documentation of competency assessments for three (3) of twenty-two (22) testing personnel (TP) observed on the date of the survey, January 18, 2023 Findings include: 1. Review of the CMS 209 personnel form revealed that the facility's laboratory director (LD) identified 22 TP and a TC as responsible for performing hematology/chemistry iSTAT Chemistry Panel (Glucose, Sodium, Potassium, Chloride, Urea Nitrogen, Creatinine, Calcium, Hemoglobin, Hematocrit) and iSTAT Blood Gas (pH, PCO2, PO2, TCO2, HCO3, SO2) patient testing utilizing non-waived Abbott analyzer Chem8+ and CG8+ reagent test cartridges. 2. Review of personnel records revealed no Abbott iSTAT competency/training assessments for TP A, B, or C (See Personnel Code Sheet). The inspector requested to review iSTAT competency documentation for the TP outlined above. No records were available for review. 3. Review of the facility's iSTAT procedures revealed the following protocols: "CLIA Protocols-Records of qualifications, training will be maintained on all laboratory personnel. The laboratory personnel performance and knowledge will periodically be reviewed through direct observation as part of initial and ongoing training and competency. A review and re-evaluation of competency will be performed six months after hire and annually thereafter." 4. An interview with Respiratory Director on 1/18/23 at approximately 3:45 PM confirmed the above findings
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, lack of documentation, and interview, the skilled nursing facility's laboratory failed to retain documentation of education qualifications for three of twenty-two testing personnel responsible for reporting moderate complexity routine chemistry, hematology, and blood gas patient test results during a review timeframe of September 1, 2022 to the date of the inspection on January 18, 2023. See D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and 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), personnel records, lack of documentation, and an interview, the skilled care nursing facility laboratory failed to retain documentation of education qualifications for three (3) of twenty-two (22) hematology/chemistry/blood gas testing personnel (TP) for a review timeframe of September 1, 2022 to the date of the inspection on January 18, 2023. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) identified 23 TP as qualified to perform moderate complexity Chemistry 8 Panel (Glucose, Sodium, Potassium, Chloride, Urea Nitrogen, Creatinine, Calcium, Hemoglobin, Hematocrit) and Blood Gas (pH, PCO2, PO2, TCO2, HCO3, SO2) patient testing utilizing Abbott iSTAT analyzer Chem8 and CG8+ reagent test cartridges. 2. Review of the available laboratory personnel records for evaluation of education documentation revealed no records of education for TP D, E, and F (See Personnel Code Sheet). The inspector requested to review the education documentation for the 3 TP outlined above. The records were not available for review. 3. An interview with Respiratory Director on 1/18/23 at approximately 3:45 PM confirmed the above findings.