Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2335435	06/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Stuart Community Hospital Inc	18688 Jeb Stuart Hwy, Stuart, 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 Stuart Community Hospital , INC June 2-5, 2026 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:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a tour, review of protocols, system maintenance logs, lack of documentation, and interviews, the laboratory failed to document maintenance checks of their Milli Q 7000 Water System during four of four months reviewed(February 2026 through the dates of the initial inspection, June 2-5, 2026). Findings include: 1. During a tour of the core laboratory on 6/3/26 at 10:00 AM, the inspector noted the laboratory utilizing Milli-Q CLX 7000 Series Water Purification System for operation of their Beckman Coulter AU700 and Access 2 analyzers. 2. The inspector inquired regarding the policy for performing required maintenance for the water quality system. The Laboratory Manager and chemistry testing personnel stated on 6/3/26 at 11 AM, "We follow the online maintenance alarms and the field service representative provided a maintenance check sheet to follow. We also send out samples for culture once a month to our reference laboratory." The inspector noted that the monthly

	maintenance checklist required the following daily input: Tap Water Feed Temperature, Make Up Quality, Distribution Quality, RO Feed Conductivity, RO Permeate Conductivity, RO %, Alert Check, and Regular Monthly Bacteria Check. 3. Review of the Milli-Q monthly logs revealed the following dates with no daily maintenance checks as outlined above: February 2026 - 2/6, 2/11, 2/12, 2/15, 2/17-2 /20, 2/25, 2/26; March 2026 - 3/12, 3/16-3/19, 3/25-3/31; April 2026 - 4/4/, 4/5, 4/10-4 /23, 4/27-4/30 (no monthly Bacteria Check performed); May 2026 - 5/1-5/31 (no monthly Bacteria Check performed); 73 of 120 days reviewed lacked daily maintenance documentation and two of four months lacked bacteria checks. 4. Interviews on 6/4/26 at 3 PM with testing personnel, QA Manager, General Supervisor, Chief Technical Officer, Chief Executive Officer, Chief Compliance Officer, and Regional Manager of Laboratory Services, and exit interview on 6/5/26 at 1 PM with the Laboratory Director and Laboratory Manager confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policies and procedures, equipment maintenance records, manufacturer's user guide, and interviews, the laboratory failed to document that their centrifuge revolutions per minute (RPM) calibration protocol ensured reliable microscopy results from the centrifuge located/utilized in the urinalysis specimen processing area for four of four months reviewed (February 2026 through the dates of initial inspection, June 2-5, 2026). Findings include: 1. During a tour on June 2, 2026 at 10:00 AM, the inspector noted one STAT Spin centrifuge in the urinalysis specimen processing area utilized for urine sediment microscopy preparation (Serial Number: SN 2505M90103750). 2. Review of the laboratory's PolicySTAT Urine Microscopic procedure (Policy ID 194750580) revealed the following instructions, "Centrifuge 1.5 ml of patient sample for 2 minutes at a speed of approximately 5,000 RPM in the urine centrifuge." The inspector noted that the procedure's reference was footnoted as Todd-Sanford Clinical Diagnosis by Laboratory Methods, 13th edition. Review of the reference procedure revealed (under Microscopic Examination, Urine) instructions, "To be most accurate, the microscopic sediment examination should be done by an experienced physician or technician. The sediment is prepared as follows, centrifuge a 10 ml specimen at 2,000 RPM for 5 minutes, decant supernatant, resuspend the sediment of the remaining 1 ml of urine by tapping the tube gently against countertop and place one drop on a microscope slide for examination." 3. Review of the laboratory's biomedical equipment maintenance records revealed one RPM calibration recorded for the STAT Spin centrifuge (SN 2505M90103750) dated 3/27/26 with speed verified at 9,800 RPM. The inspector requested to review a 5,000 RPM calibration verification per the procedure outlined above. The documentation was not available for review. 4. Review of the STAT Spin manufacturer's user guide revealed specifications that cycle speed was variable between 9,800 -15,800 RPM. The inspector inquired of the discrepancies between the Todd Sanford reference method (2,000 RPM), the laboratory's procedure (5,000 RPM), and the STAT Spin centrifuge's limited capability specifications of much

	higher speed (9,800-15,800 RPM). The Quality Assurance (QA) manager stated, on 6 /2/26 at 4 PM, "I have questioned that the procedure's stated speed is too high for urine sediment examination and that we need a different centrifuge" 5. Interviews on 6 /4/26 at 3 PM with testing personnel, QA Manager, General Supervisor, Chief Technical Officer, Chief Executive Officer, Chief Compliance Officer, and Regional Manager of Laboratory Services, and exit interview on 6/5/26 at 1 PM with the Laboratory Director and Laboratory Manager confirmed the above findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review of the laboratory's Clinical Laboratory Improvement Amendments Certification form (CMS 116), tour, daily quality control (QC), Individualized Quality Control Plan (IQCP) and Abbot iSTAT validation records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the laboratory performed external QC material every day of patient iSTAT testing utilizing CG4+, Chem8+, and hsTroponin cartridges for four of four months reviewed while reporting 576 patient test results prior to review/approval of validation studies and IQCP (February 2026 through the dates of initial inspection, June 2-5, 2026). Findings include: 1. Review of the laboratory's CMS 116 form revealed that the laboratory utilizes Abbott iSTAT System for patient quantitative measured results of pH, partial pressure of carbon dioxide (pCO2), partial pressure of oxygen (pO2), Sodium (Na), Potassium (K), Chloride (Cl), Ionized Calcium (iCa), Glucose, Blood Urea Nitrogen (BUN), Creatinine, Total Carbon Dioxide (CO2), Hematocrit (Hct), Hemoglobin (Hb) and high-sensitivity cardiac troponin I (cTnI). 2. During a tour of the core laboratory on 6 /3/26 at 10:30 AM, the inspector noted one Abbott iSTAT analyzer (Serial Number SN 448460), with Abbott Downloader/Printer (SN 142655, 2500878) utilized for the testing outlined above by nonwaived cartridges CG4+ (for blood gas ph, pCO2, pO2), Chem8+ (for Na, K, Cl, iCa, Glucose, BUN, Creatinine, CO2, Hct, HB), and hsTroponin (for cTnI). 3. Review of the laboratory's iSTAT patient test logs and QC records for the review timeframe of February 2026 to 6/5/26 revealed that external QC was not performed on each date of iSTAT patient testing during the months of February, March, April, and May 2026. The inspector requested to review additional documentation that external QC was performed. No additional QC was available for review. The inspector noted that the iSTAT go live date was recorded as 1/6/26 but that the validation studies were not signed/approved by the LD until 5/27/26. 4. The inspector inquired regarding an IQCP for the iSTAT test cartridges outlined above. The QA Manager stated at 3 PM on 6/3/26, "I just got the lab director to sign an IQCP today. I realized while preparing for this inspection that we needed to complete the risk assessments". 5. Review of Harvest laboratory information system's test logs revealed the following number of patient tests were reported via iSTAT downloader during the inspection review timeframe of 2/1/26 - 6/5/26: 351 results by CG4+; 200 results by Chem8+; 25 cTnI; a total of 576 patient tests were resulted prior to the LD's approval of validation verification studies and established/approved IQCP. 6. Interviews on 6/4/26 at 3 PM with testing personnel, QA Manager, General

	Supervisor, Chief Technical Officer, Chief Executive Officer, Chief Compliance Officer, and Regional Manager of Laboratory Services, and exit interview on 6/5/26 at 1 PM with the LD and Laboratory Manager confirmed the above findings.