Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2176119	07/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Statcare Urgent And Walk-In Medical Care	80-10 Northern Blvd, Jackson Heights, NY	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the package inserts for the Seksui OSOM Rapid Strep A (RST); Bio-sign Influenza A & B; Henry Schein One Step for Infectious Mononucleosis & Urine Pregnancy; Uri Spec 11 Way analyzer & urine test strips; Chembio HIV ; and the Medline Urine test strips; lack of Quality Control (QC) records; direct observation of test kits in exam room #1; and an interview with the technical consultant (TC), the laboratory failed to follow the manufacturer's QC test kit requirements from June 7, 2021, though the survey date. FINDINGS: 1. The manufacturer's requirements for Seksui OSOM Rapid Strep A (RST); Bio-sign Influenza A & B; Henry Schein One Step for Infectious Mononucleosis; Uri Spec 11 Way analyzer & urine test strips; Chembio HIV ; and the Medline Urine test strips required that QC materials included with the test kits be utilized for each new lot and/or shipment. Also, the Uri Spec 11 Way analyzer & urine test strips and Medline Urine test strips required performance of an external commercial control for each new vial of test strips, prior to use for patient testing. It was noted that the Henry Schein One Step Urine Pregnancy manufacturer's requirements did not require performance of an external control prior to patient testing. a. The laboratory failed to document lot numbers and expiration dates for test kits received and utilized. It was therefore not possible to determine the number of test kits received and utilized from June 7, 2021, through the survey date. b. The surveyor was permitted less than five minutes in exam room one to observe and review test kit inventory due to high patient volume. Also due to high patient volume, the surveyor was unable to visit the three additional exam rooms to observe and review test kit inventory. c. The surveyor was unable to determine the patient

	volume and number of waived test kits utilized as the respective tests were performed and results documented by the Clinical Medical Assistant (CMA) personnel in the Electronic Medical Record (EMR) from June 7, 2021, through the survey date. 2. The TC confirmed on July 28, 2023, at approximately 9:30 A.M. that the providers ordered the tests in the EMR and the CMA personnel performed and documented the results. a. TC confirmed lack of documentation for kit lot numbers and expiration dates. No QC records were available at the time of the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of QC and validation records for the Beckman DHX 560 hematology analyzer as well as an interview with the TC, the laboratory failed to retain control material assay sheets for QC controls performed from June 7, 2021, to the prior lot in use. FINDINGS: 1. The laboratory performed three levels of Beckman DHX hematology analyzer controls each day of testing. However, the testing personnel did not retain control material assay sheets for QC controls performed from June 7, 2021, to the prior lot in use. a. It was noted that the laboratory did retain a copy of the control assay sheet for current QC lot in use, #3523150, expiration date 9 /2023. b. It was noted that the laboratory did retain a copy of the calibrator assay sheet for the validation study performed on June 7, 2021, lot # 4921138800. 2. The TC confirmed on July 28, 2023, at approximately 10:00 A.M. that the laboratory testing personnel were not aware that it was required for the control and calibration assay sheets to be retained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of training records and an interview with the TC, the laboratory director (LD) failed to follow the established competency evaluation policy regarding the training, six-month, and annual performance evaluations for CMA personnel. FINDINGS: 1. There was no documentation of training, six-month, and annual competency evaluations for the CMA personnel who performed QC and laboratory testing utilizing the Seksui OSOM Rapid Strep A (RST); Bio-sign Influenza A & B; Henry Schein One Step for Infectious Mononucleosis & Urine Pregnancy; Uri Spec 11 Way analyzer & urine test strips; Chembio HIV ; and Medline Urine test strips. 2. The TC confirmed on July 28, 2023, at approximately 9:30 A.M. that the LD failed to comply with the established competency evaluation policy regarding the training, six-month, and annual performance evaluations for CMA personnel. a. It was not possible to determine the identity of CMA personnel who performed QC and laboratory testing as CMA personnel frequently rotated among other office locations. Refer to D6029.

D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on reviews of the Quality Assessment (QA) policy, QA records for 2021, 2022, and 2023, TC's duties and responsibilities, the laboratory's standard operating procedure manual (SOP), and an interview with the TC, the laboratory failed to follow established QA policies, address errors, take remedial action, and resolve errors as they occurred from June 7, 2021, through the survey date: FINDINGS: 1. The laboratory QA policies included instructions for a quarterly review of the following General Laboratory Systems: Preanalytic, Analytic, and Preanalytic Systems. 2. Review of quarterly QA records and documents for 2021, 2022, and 2023 confirmed lack of corrective action to resolve the following errors: a. The laboratory failed to ensure that CMA personnel underwent training and competency evaluations based on their duties and responsibilities for waived testing performed. b. It was noted that the TC performed QA reviews as part of his duties and responsibilities. However, the TC stated in the QA report that he reviewed the calibrations for the Beckman DHX hematology analyzers, that laboratory failed to perform calibrations at six months from October 6, 2021, through survey date, and failed to retain the copies of the control assay sheets. c. The laboratory failed to record and document the room temperatures and humidity of the four exam rooms where waived test kits were stored and laboratory testing was performed. 3. The TC confirmed on July 28, 2023, at approximately 12:00 P.M. that quarterly QA reports were not in compliance with established QA policies from June 7, 2021, through the survey date. Refer to D6022 and D6024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 the lack of room temperature and humidity records of the four exam rooms; waived testing manufacturer's package insert instructions; and an interview with the TC, the laboratory failed to monitor and document room temperatures and humidity of the four exam rooms where waived laboratory test kits were stored and laboratory testing was performed from June 7, 2021, through the survey date. FINDINGS: 1. The manufacturer's package inserts for the Seksui OSOM Rapid Strep A (RST); Bio-sign Influenza A & B; Henry Schein One Step for Infectious Mononucleosis & Urine Pregnancy; Uri Spec 11 Way analyzer & urine test strips; Chembio HIV ; and

	Medline Urine test strips included storage temperature ranges of 15 - 30 C or 68 - 86 F and humidity range of 10 - 80%. a. No documentation of storage temperatures and humidity were available for review. 2. The TC confirmed on July 28, 2023, at approximately 11:30 A.M. that the laboratory failed to install a thermometer, monitor, and document the storage temperature and humidity of the four exams rooms where waived test kits were stored and laboratory testing was performed. Refer to D6022 and D6024.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of Beckman DHX560 hematology analyzer SOP, review of the QC records, and an interview with the TC, the laboratory failed to perform the required six-month calibration of the DHX560 analyzer due on October 6, 2021, through the survey date. FINDINGS: 1. The laboratory and Beckman DHX560 hematology analyzer manufacturer's policies included instructions for calibration to be performed every six months and/or as needed as preventative maintenance. a. The most recent calibration record available for review was dated April 6, 2021; also when the most recent validation study was performed. 2. The TC confirmed on July 28, 2023, at approximately 12:00 P.M. that the laboratory did not perform calibration as required. a. It was noted that the laboratory performed Beckman DHX560 hematology analyzer patient testing and reporting of results as well as API PT from June 7, 2021, through the survey date. Refer to D6022 and D6024.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or

	replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of Beckman AU480 chemistry analyzer SOP, the QC and calibration records, and an interview with the TC, the laboratory failed to perform the required six-month AU480 analyzer calibration verification from October 6, 2021, through the survey date. FINDINGS: 1. The laboratory's calibration verification policy included instructions for calibration verification to be performed every six months on test analytes with less than three-point calibrators. a. The most recent calibration record available for review was dated April 6, 2021; also when the most recent validation study was performed. 2. The TC confirmed on July 28, 2023, at approximately 12:00 P.M. that the laboratory did not perform calibration verification as required. a. It was noted that the laboratory performed Beckman AU480 hematology analyzer patient testing and reporting of results as well as API PT from June 7, 2021, through the survey date.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on QC record review of the Siemens Adiva Centur CP endocrinology analyzer, Beckman AU480 chemistry analyzer, DHX560 hematology analyzer, and an interview with the TC, the laboratory failed to perform verification of current lot numbers to new lot numbers for the endocrinology, chemistry, and hematology analyzer controls. FINDINGS: 1. There was no documentation of lot to lot QC validation for the three analyzers from June 7, 2021, through the survey date. 2. The TC confirmed on July 28, 2023, at 10:45 A.M. that lot to lot QC material validations for the endocrinology, chemistry and hematology analyzers were not performed. Refer to D6022 and D6024.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403

	The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's SOP manual, and review of QC, QA, calibration, validation, and personnel records, as well as confirmed by interview with TC, the LD failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The LD failed to ensure that: 1. CMA personnel who perform the waived testing were reporting accurate results. Refer to D6042. 2. QC and QA policies were maintained for all phases testing. Refer to D6022. 3. Remedial action was performed and documented when problems were identified. Refer to D6024. 4. Appropriate training was performed and documented for CMA personnel who performed waived testing QC and testing. Refer to D6029.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the laboratory's SOP manual, personnel records, and an interview with the TC, the LD failed to ensure that the CMA personnel who performed waived testing were reporting accurate results. Refer to D1001, D5209, and D6029.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of QA procedures, QA quarterly reports, QC records, and confirmed by interview with the TC, the LD failed to ensure compliance with the laboratory's QA and QC procedures for waived, endocrinology, chemistry, and hematology laboratory testing. Refer to D1001, D3031, D5291, D5413, D5437, D5439, and D5469.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)

	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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on the review of QC records, lack of temperature and humidity records, and confirmed by interview with the TC, the LD failed to ensure that remedial action was performed and documented when problems were identified. Refer to D1001, D3031, D5413, D5437, D5439, and D5469.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records, lack of training documentation, and interview with the TC, the LD failed to ensure that appropriate training was performed and documented for CMA personnel who performed QC and waived testing. Refer to D5209.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on QC, calibration, validation, and quarterly QA records, review of the TC's duties and responsibilities, as well as an interview with the TC, the TC failed to ensure that corrective action was performed and documented when test systems deviated from the laboratory's approved test procedures. Refer to D1001, D3031, D5291, D5413, D5437, D5439, and D5469.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and

	assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on the lack of the CMA personnel training and competency records and an interview with the TC, the TC failed to ensure that the CMA personnel were properly trained prior to patient waived laboratory testing. Refer to D5209.