Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2174408	07/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Virtua Samson Cancer Center Laboratory	350 Young Avenue, Moorestown, NJ	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories Individualized Quality Control Plan (IQCP) for Routine Chemistry performed on the iStat analyzer and interview with the Technical Supervisor (TS), the laboratory failed to monitor, assess, and when indicated, correct problems identified in the preanalytic system in the calendar year 2022 the finding includes. 1. There was no documented evidence that the IQCP log "Virtua - Moorestwon Cancer Center "Quality Assessment" i-stat (chem8+)" which included review of the preanalytic system was completed in the calendar year 2022 2. The TS confirmed on 7/18/23 at 12:00 PM that the laboratory failed to monitor, assess, and when indicated, correct problems identified in the preanalytic system .
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 surveyor review of the Procedure Manual (PM), Final Report (FR) and interview with the Techincal Supervisor (TS) the laboratory failed to have a procedure

	for calculating estimated Glomerular Filtration Rate (eGFR) testing on the date of survey. The TS confirmed on 7/19/23 at 10:30 am that the laboratory procedure for calculating eGFR. b) Based on surveyor review of the PM, lack of Quality Control Verification (QVC) records and interview with the Techincal Supervisor (TS) the laboratory failed to have a procedure for QVC for routine chemistry testing on the date of survey. The TS confirmed on 7/19/23 at 10:30 am that the laboratory procedure for calculating eGFR.
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 surveyor review of Quality Control (QC) records and interview with the Techincal Supervisor (TS), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Routine chemistry tests performed on iStat analyzer on the date of survey. The finding includes: 1. There was no documented evidence that QC was verified before being put into use. 2. The TS confirmed on 7/19/23 at 12:20 pm that the QC material was not verified before putting in use.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories Individualized Quality Control Plan (IQCP) for Routine Chemistry performed on the iStat analyzer and interview with the Technical Supervisor (TS), the laboratory failed to monitor, assess, and when indicated, correct problems identified in the analytic system in the calendar year 2022 the finding includes. 1. There was no documented evidence that the IQCP log "Virtua - Moorestwon Cancer Center "Quality Assessment" i-stat (chem8+)" which included

	review of the analytic system was completed in the calendar year 2022 2. The TS confirmed on 7/18/23 at 12:00 PM that the laboratory failed to monitor, assess, and when indicated, correct problems identified in the analytic system .
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR), Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Reference Interval (RI) was accurate for Sodium tests performed on the I-Stat analyzer on the date of the survey. The findings include; 1. The PM stated the RI for Sodium was 134-146 mmol/L. 2.. The RI for Sodium on 10 out of 10 TR was 138-146 mmol/L. 3. The TP confirmed on 7/18/23 at 11:30 am that the laboratory failed to ensure the RI was accurate for Sodium tests.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Final Report (FR) and interview with the Techincal Supervisor (TS), the laboratory failed to have an ongoing mechanism to monitor the accuracy of estimated Glomerular Filtration Rate (eGFR) calculations from the Laboratory Information System (LIS) to the Electronic Medial Records (EMR) on the date of survey. The TS confirmed on 7/18/23 at 12:00 pm that the laboratory failed to have an ongoing mechanism to monitor the accuracy eGFR calculations. .
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories Individualized Quality Control Plan (IQCP) for Routine Chemistry performed on the iStat analyzer and interview with the Technical Supervisor (TS), the laboratory failed o review of the effectiveness of corrective actions taken to resolve problems, prevent recurrence of problems of

	postanalytic system in the calendar year 2022 the finding includes. 1. There was no documented evidence that the IQCP log "Virtua - Moorestwon Cancer Center "Quality Assessment" i-stat (chem8+)" which included review of the postanalytic system was completed in the calendar year 2022 2. The TS confirmed on 7/18/23 at 12:00 PM that the laboratory failed to monitor, assess, and when indicated, correct problems identified in the preanalytic system .
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 surveyor review of Proficiency Testing (PT) and interview with the Techincal Supervisor (TS), the Laboratory Director (LD) failed to ensure the laboratory was enrolled in an approved PT program in three events for Blood Cell Identification in the calendar years 2021 and 2022. The findings include; 1) The laboratory participated in two testing events for Blood Cell Identification with the College of American Pathologists (CAP) in the calendar years 2022 and 2021. 2) Blood Cell Identification is a regulated analyte. 3) The TS confirmed on 7/18/23 at 1: 00 pm the laboratory was not enrolled in three PT events.