Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0876565	02/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Care Station Medical Group	328 West St Georges Ave, Linden, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 the surveyor review of the Procedure Manual (PM) and interview with the Technical Consultants (TC) the PM lacked a correlation procedure for Virology tests performed from 9/1/24 to 2/5/25. The findings include: 1. The PM lacked a procedure for instrument correlation between the Solana and Cepheid GeneXpert analyzers which both perform FLU A/B, Respiratory Syncytial Virus and SARS-COV2 testing. 2. The TC confirmed on 2/5/25 at 12:20 pm, the above mentioned procedure was not available for review.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, review of the Liquichek Immunoassay Plus Control Kit Manufactuers Package Insert (MPI) and

	interview with the Techincal Consultant (TC), the laboratory failed to put correct expiration dates on QC material for the routine chemistry tests on 2/5/25. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory had an open date of 2/3/25 and expiration date of 2/10/25 (seven days of stability) on QC material in use. 3. The MPI states Folate had 3 days stability. 4. The TC confirmed on 2/5/25 at 11:45 am the laboratory failed to put correct expiration dates on the control material.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of Beckman coulter Cleaning Solution,and interview with the Techincal Consultant (TC), the laboratory failed to discard expired reagent from 1/5/25 to 2/5/2025. The findings include: 1. Beckman Coulter Cleaning Solution Lot# 2772 expired 1/5/25. 2. The TC confirmed on 10/3/24 at 10:30 am that the laboratory failed to discard expired reagent.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on the lack of Quality Control Verification (QCV) records and interview with the Technical Consultants (TC), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment used on the Cepheid GeneXpert analyzer for Bacteriology and Virology testing from 2/1/23 to 2/5/25. The finding includes: 1. There were no QCV records available for review for the Cepheid GeneXpert analyzer. 2. The TC confirmed on 2/5/25 at 12:20 pm, the assayed values of QC material were not verified before patient testing.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

	This STANDARD is not met as evidenced by: Based on surveyors observation of Quality Control (QC) material in use, review of Zeptometrix Manufacturers package inserts (MPI) and interview with the Technical Consultants (TC), the laboratory failed to follow Manufacturers Specifications (MS) for Zeptometrix QC material used for Bacteriology and Virology tests performed on the Cepheid GeneXpert analyzer from 2/1/23 to 2/5/25. The finding includes: 1. Zeptometrix QC material used in Virology tests was observed to be aliquotted and stored in a freezer at a temperature of-23 to -25C. 2. The MPI states "positive control should be stored at 2-8C upon arrival" 3. Zeptometrix QC material used in Bacteriology tests was observed to stored in a freezer at a temperature of -23 to -25C. 4. The MPI states "controls should be stored at 2-8C", "Each vial is intended for single use." 5. The TC confirmed on 2/5/25 at 1:20 pm that MS were not followed.
D5807	TEST REPORT CFR(s): 493.1291(d) (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 Finial Report (FR), Procedure Manual (PM), and interview with the Techincal Consultant (TC), the laboratory failed to ensure that the Reference Interval (RI) was accurate for Cholesterol run on the AU480 analyzer form May 2024 to 2/5/25. The finding includes: 1. There was no RI on the FR for Cholesterol. 2. The TC confirmed on 2/5/25 at 11:30 am that the laboratory failed to ensure the RI was accurate.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) (b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: Based surveyor review of the Quality Control Records (QCR) and interview with the Technical Consultants (TC), TP failed to document all Quality Control (QC) information on the QCR for Bacteriology and Virology tests performed on the Cepheid GeneXpert analyzer from 2/1/23 to 2/5/25. The findings include: 1. TP did not document the lot number and expiration dates of QC material used on the QCR performed on 1/27/25 for Virology tests. 2. TP did not document the lot number and expiration dates of QC material used on the QCR performed on 1/16/25 for Bacteriology tests. 3. The TC confirmed on 2/5/25 at 11:50 am, the laboratory did not document all QC information on the QCR for the Cepheid GeneXpert analyzer.