

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0876565	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Care Station Medical Group	Street Address, City, State 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Manufactures Package Insert, observation of the Quality Control (QC) material, and interview with the General Supervisor (GS), the laboratory failed to put new expiration dates on endocrinology Controls from (other survey) to the date of survey. The findings include. 1. The MPI for Lyphochek Immunoassay Plus Controls stated that QC material for Prostate-Specific Antigen expired 3 days after opening if stored at 2 to 8 degrees Celsius. 2. The GS was not aware that QC material expired 14 days after opening. 3. The GS on CMS form 209 confirmed on 3 /28/19 /19 at 3:00 pm the laboratory failed to put new expiration dates on the control material.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the laboratory failed to verify the Manufacturer's Reference Interval (MRI) for routine chemistry, and Hematology tests performed on Tosho AIA-2000 and Sysmex XSi1000 analyzer respectively from April 2018 to the date of survey. The TS confirmed on 3/28/19 at 12:30 pm that MRI was not verified for routine chemistry, and hematology testing.

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:
a) Based on surveyor review of the Final Report (FR), Manufacturer Package Insert (MPI) and interview with the General Supervisor (GS), the laboratory failed to identify the source of the Reference Intervals (RI) used for Folate, Vitamin B12 (vitB12), and Prostate-Specific Antigen (PSA) from April 2018 to the date of survey. The findings include: 1. The GS stated the laboratory used the RI listed in the MPI. 2. The RI in the PM differed from the FR as follows: a. Folate: FR: 3-17 ng/dL - MPI: 3-16 ng/dL b. vitB12: FR 230-1050 pg/mL - MPI 173-700 pg/mL c. PSA: FR 0-4.3 ng/mL - >4.0 ng/mL 3. The GS confirmed on 3/28/19 at 1:00 pm that the RI on the FR was not that of the RI in the MPI. b) Based on the surveyor review of the Final Reports (FR) and interview with the GS, the laboratory failed to have a Reference Range (RR) for rapid plasma reagin test on the FR from (other survey) to the date of the survey. The GS confirmed on 3/28/19 at 2:20 pm that the above test did not have a RR on the FR.