

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0900100	<b>(X3) Date Survey Completed</b>  12/10/2024
<b>Name of Provider or Supplier</b>  North Clark Medical Group	<b>Street Address, City, State</b>  1804 East 10th Street, Jeffersonville, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6108</b>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review, interview, and observation the laboratory failed to fulfill the Technical Supervisor responsibilities requirements found in 493.1451. The technical supervisor failed to validate one of one Laboratory Information System (LIS), for Free Thyroxine (FT4), implemented 8/14/24, and ran on the Roche Cobas 6000 e601 (Serial Number=1263-09) and three (Pt-12, Pt-13, Pt-14) of three patients reviewed on 12/09/24 and three (Pt-15, Pt-16, Pt-17) of eight patients reviewed on 12/10/24. (Refer to D6115) The technical supervisor failed resolve technical problems and ensure remedial actions were taken whenever test systems deviate from the laboratory's established performance specification by failing to ensure the laboratory successfully completed six-month Calibration Verification for two of two Calibration Verification for Testosterone non-regulated immunoassays ran on the Roche Cobas 6000 e601 (Serial Number=1263-09) and three (Pt-15, Pt-16, Pt-17) of eight patients reviewed on 12/10/24. (Refer to D6119)</p>
<b>D6115</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p>

This STANDARD is not met as evidenced by:  
 Based on observation, record review and interview, the technical supervisor failed to validate one of one Laboratory Information System (LIS), for Free Thyroxine (FT4), implemented 8/14/24, and ran on the Roche Cobas 6000 e601 (Serial Number=1263-09) and three (Pt-12, Pt-13, Pt-14) of three patients reviewed on 12/09/24 and three (Pt-15, Pt-16, Pt-17) of seven patients reviewed on 12/10/24. Findings included: 1. On 12/10/2024 at 11:16 am. review of FT4 results submitted for the College of American Pathologist (CAP) proficiency testing evaluation 11/1/2024, indicated results from the LIS results did not match the results observed coming from The Roche Cobas 6000 e601 for the same event: 9/24/24-CAP C-C 2024 LIS Cobas CAP, CHM11C FT4 IV=HIGH FT4 4=2.51 CAP, CHM12C FT4 IV=HIGH FT4 4=1.92 CAP, CHM13C FT4 IV=NORMAL FT4 4=0.91 CAP, CHM14C FT4 IV=HIGH FT4 4=1.67 CAP, CHM15C FT4 IV=HIGH FT4 4=2.2 2. On 12/09/2024 at 2:19 pm, SP-1 (Technical Supervisor) indicated that Roche had made changes in the FT4 reagent and validated the new FT4 4 on the Cobas 6000 e601 on 2/28/24, but the laboratory did not start using the new FT4 4 reagents until 8/14/24. 3. Review of medical records on 12/09/24 indicated: a) Pt-12- FT4 IV= NORMAL, tested on 9/26/2024 at 5:34 pm, Normal Range=0.9-1.7 ng/dL b) Pt-13 - FT4 IV =NORMAL, tested on 9/30/2024 at 4:07 pm, Normal Range= 0.9-1.7 ng/dL c) Pt-14- FT4 IV=NORMAL, tested on 09/24/2024 at 3:29 pm, Normal Range= 0.9-1.7 ng/dL 4. Review of medical records on 12/10/24 indicated: a) Pt-15- FT4 IV=1.6 ng/dL, tested on 10/02/2024 at 1:05 pm, No Normal Range b) Pt-16 - FT4 IV =1.33 ng/dL, tested on 10/04/2024 at 12:35 pm, No Normal Range c) Pt-17- FT4 IV=1.08 ng/dL, tested on 10/01/2024 at 3:39 pm, No Normal Range 5. In an interview on 12/10/24 at 1:00 pm, SP-1 (Technical Supervisor), confirmed that no LIS validation had been completed after the implementation of the new FT4 4 reagents on 8/14/24 before resuming patient testing. 6. Annual volume for Free Thyroxine (FT4) =3,100

**D6119**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(6)

The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.

This STANDARD is not met as evidenced by:  
 Based on record review and interview, the technical supervisor failed resolve technical problems and ensure remedial actions were taken whenever test systems deviate from the laboratory's established performance specification by failing to ensure the laboratory successfully completed six-month Calibration Verification for two of two Calibration Verification for Testosterone ran on the Roche Cobas 6000 e601 (Serial Number=1263-09) and three (Pt-14, Pt-15, Pt-16) of seven patients reviewed on 12/10/2024. Findings included: 1. Review of the Calibration Verification /Linearity for 2024: a) "LN8-A 2024"- Reproductive Endocrinology Calibration Verification/Linearity Testosterone ng/dL Calibration Verification Evaluation mailed 4/2/24 and evaluated 4/30/24 indicated: Evaluation Result: Different (Allowable Error: 12.5% or ng/dL, whichever is greater) b) "LN8-B 2024"- Reproductive Endocrinology Calibration Verification/Linearity Testosterone ng/dL Calibration Verification Evaluation mailed 9/23/24 and evaluated 10/23/24 indicated: Evaluation Result: Different (Allowable Error: 12.5% or ng/dL, whichever is greater) 2. Review of form, "CVL Survey Investigation Checklist for Problematic Results" indicated: a) "LN8-A 2024" Survey Name: LN8-A Evaluation Date: 4/30/24 Analyte: Testosterone

Corrective Action: Self-grade performed with converted results which put the results in normal range. Investigated By: SP-1 10/24/24 Reviewed By: Blank with no signature or review date. b) "LN8-B 2024" Survey Name: LN8-B Evaluation Date: 10/23/24 Analyte: Testosterone Corrective Action: Self-grade performed with converted results which put the results in normal range. Units did not match between reported results and CAP survey results. Investigated By: SP-1 10/24/24 Reviewed By: Blank with no signature or review date. 3. In an interview on 12/10/2024 at 12:03 pm, SP-1 (Technical Supervisor), explained that the failed Testosterone calibration verification for both CAP events was due to the units not being converted before they were entered into the CAP survey. SP-1 (Technical Supervisor) confirmed that no other calibration verification was performed on Testosterone in 2024. 4. The following patients reviewed were tested when the calibration verification for Testosterone had failed: a) Pt-14- Testosterone- 8.9 ng/mL, tested on 10/02/2024 at 1:05 pm b) Pt-15 - Testosterone- 1.6 ng/mL, tested on 10/04/2024 at 2:35 pm c) Pt-16- Testosterone-2.8 ng/mL, tested on 10/01/2024 at 3:39 pm 5. Review of COBAS Procedure (D2), signed and dated by Laboratory Director on 10/24/2024, required the following: a. Section IV. Calibration, "3. Linearity/Calibration verification is also performed for any test that has less than three (3) calibrators every six months ..." The policy includes Testosterone in this requirement. b. Section IV. Calibration, "4. If linearity or calibrator verification fails and (sic) investigation will be performed. A retest will be performed with those calibrators to ensure the Calibrators are linear and verified before patient testing resumes." c. Section VII. Reporting, "2. Reporting Units e601", states, Testosterone is reported: "ng/dL". 6. Annual test volume Testosterone=2,000