

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0900100	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier North Clark Medical Group	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A proficiency testing desk review survey was completed on 9/4/2024. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulation (CFR) 493.803(a)(b)(c) Successful Participation 42 CFR 493.1411 Laboratory Director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Repeat Deficiency Based on record review and interview, the laboratory failed to successfully participate in a proficiency testing program for four events for blood urea nitrogen and three events for Triiodothyronine in 2023 and 2024. The laboratory failed to successfully participate in four consecutive testing events in 2023 (event 2,</p>

2023 and event 3) and 2024 (event 1 and event 2) resulting in a score of 0 in Routine Chemistry for the analyte blood urea nitrogen (BUN) as reported by the College of American Pathologist (CAP) (Refer to D2089). The laboratory failed to achieve satisfactory performance of 80% or greater for three consecutive testing events in 2023 (event 3, 2023) and in 2024 (event 1 and event 2). Results for those events were 0% in for the analyte Triiodothyronine (T3) and 53% for event 3, 2023, 60% for event 1, 2024, and 66% for event 2, 2024 for the subspecialty of Endocrinology as reported by the CAP (Refer to D2107).

D2089

ROUTINE CHEMISTRY
CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Repeat Deficiency Based on record review and interview, the laboratory failed to successfully participate in a proficiency testing program. The laboratory failed to successfully participate in four consecutive testing events in 2023 (event 2 and event 3) and 2024 (event 1 and event 2) resulting in a score of 0 for four testing events in Routine Chemistry for the analyte blood urea nitrogen (BUN) as reported by the College of American Pathologist (CAP). Finding included: 1. Review of the "Casper Report 0155D," run date 12/18/2023 indicated a score of 0% for event 2 2023 and event 3 2023 for blood urea nitrogen (BUN) as reported by the CAP. 2. An email dated December 29, 2023 at 11:09 am, requesting confirmation of the 0% scores from urea nitrogen, SP-01 (Technical Supervisor) stated, "We don't test for urea nitrogen only uric acid." 3. Review of the "Casper Report 0155D," run date 8/20/2024 indicated a score of 0% for event 2 2023 and event 3 2023, 0% for event 1 2024 and 0% for event 2 2024 for blood urea nitrogen (BUN) as reported by the CAP. 4. In an email dated August 23, 2024 at 1:58 pm, upon request for confirmation of the 0% scores from urea nitrogen, SP-01 (Technical Supervisor) stated, "We have never stopped testing for BUN..." SP-1 further indicated they were unaware that BUN is reported for Urea Nitrogen. 5. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-B 2023 General Chemistry/Therapeutic Drugs" original evaluation: 7/11/2023 on page 9 of 11 indicated Urea Nitrogen for Proficiency Event 2023 2 had a score of 0/5 for 0%. On page 4 of 11, the grade for C-B 2023 (Event 2023 2) had a notation "See Note [42]". Page 1 of 11 had a legend for exception reason codes appearing in this evaluation, "[42] = No credit assigned due to absence of response." 6. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-C2023 General Chemistry/Therapeutic Drugs" original evaluation: 10/31/2023 on page 9 of 11 indicated Urea Nitrogen for Proficiency Event 2023 2 and Event 2023 3 had a score of 0/5 for 0%. On page 5 of 11, the grade for C-C 2023 (Event 2023 3) had a notation "See Note [42]." Page 1 of 11 had a legend for exception reason codes

appearing in this evaluation, "[42] = No credit assigned due to absence of response."

7. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-A 2024 General Chemistry /Therapeutic Drugs" page 9 of 11 original evaluation date 4/10/2024 indicated Urea Nitrogen had scores of 0/5 for 0% for event 2, 2023, event 3, 2023 and event 1, 2024. On page 5 of 11 the grade for C-C 2023 (Event 2023 3) had a notation "See Note [42]." Page 1 of 11 had a legend for exception reason codes appearing in this evaluation, "[42] = No credit assigned due to absence of response."

8. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-A 2024 General Chemistry /Therapeutic Drugs" page 9 of 11 original evaluation date 7/2/2024 indicated Urea Nitrogen had scores of 0/5 0% for event 3, 2023, event 1, 2024 and event 2, 2024. On page 5 of 11 indicated Urea Nitrogen for Proficiency Event 2024 2 had a score of 0/5. The grade for Event 2024 2 had a notation "See Note [42]." Page 1 of 11 had a legend for exception reason codes appearing in this evaluation, "[42] = No credit assigned due to absence of response."

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Repeat Deficiency Based on record review and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for three consecutive testing events in 2023 (event 3, 2023) and in 2024 (event 1 and event 2). Results for those events were 0% in for the analyte Triiodothyronine (T3) and 53% for event 3, 2024, 60% for event 1, 2023, and 66% for event 2, 2024 for the subspecialty of Endocrinology as reported by the CAP. Findings included: 1. Review of "Casper Report 0155D," run date 8/20/2024 indicated a score of 0% for event 2 2023, event 1 2024 and event 2 2024, 0% for T3 as reported by the CAP. 2. In an email on 8/22/2024 at 12:17 pm, SP-01 (Technical Supervisor) provided the PT results for for event 2 2023, event 1 2024 and event 2 2024 and confirmed 0% scores for T3. 3. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-C2023 General Chemistry/Therapeutic Drugs" original evaluation: 10/31/2023 on page 11 of 11 indicated Triiodothyronine (T3) had a score of 0/5 for 0% for Proficiency Event 2023 3. On page 7 of 11 the "Evaluation and Comparative Method Statistics" for "C-C 2023 General Chemistry /Therapeutic Drugs" showed five of five results provided by the laboratory for T3 were unacceptable. 4. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-C2023 General Chemistry/Therapeutic Drugs" original evaluation: 4/10/2024 on page 11 of 11 indicated Triiodothyronine (T3) had a score of 0/5 for 0% for Proficiency Event 2023 3 and Event 2024 1. On page 7 of 11 the "Evaluation and Comparative Method Statistics" showed five of five results provided by the laboratory for T3 were unacceptable. 5. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-C2023 General Chemistry /Therapeutic Drugs" original evaluation: 7/2/2024 on page 11 of 11 indicated Triiodothyronine (T3) had a score of 0/5 for 0% for Proficiency Event 2023 3, Event

2024 1, and Event 2024 2. On page 7 of 11 the "Evaluation and Comparative Method Statistics" showed five of five results provided by the laboratory for T3 were unacceptable.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Repeat Deficiency Based on record review and interview, the laboratory director failed to provide overall management and direction needed to ensure the laboratory successfully participated in a proficiency testing program for four of four testing event in 2023 (event 2 and event 3) and 2024 (event 1 and event 2) for blood urea nitrogen (BUN) and achieve a satisfactory performance for three of three consecutive testing events in 2023 (event 3, 2023) and in 2024 (event 1 and event 2) for Triiodothyronine (T3) and Endocrinology (Refer to D6089).

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Repeat Deficiency Based on record review and interview, the laboratory director failed to ensure the laboratory successfully participated in a proficiency testing program for four of four testing event in 2023 (event 2 and event 3) and 2024 (event 1 and event 2) for blood urea nitrogen (BUN); and failed to ensure the laboratory achieved a satisfactory performance for three of three consecutive testing events in 2023 (event 3, 2023) and in 2024 (event 1 and event 2) for Triiodothyronine (T3) and the subspecialty of Endocrinology. Findings included: 1. Review of "Casper Report 0155D," run date 12/18/2023 indicated a score of 0% for event 2 2023 and event 3 2023 for blood urea nitrogen (BUN) as reported by the CAP. 2. In email dated December 29, 2023 at 11:09 am, upon request for confirmation of the 0% scores from urea nitrogen, SP-01 (Technical Supervisor) stated, "We don't test for urea nitrogen only uric acid." 3. Review of "Casper Report 0155D," run date 8/20/2024 indicated a score of 0% for event 2 2023 and event 3 2023, 0% for event 1 2024 and 0% for event 2 2024 for blood urea nitrogen (BUN); and a score of 0% for event 2 2023, event 1 2024 and event 2 2024, 0% for T3 as reported by the CAP. 4. In an email dated August 23, 2024 at 1:58 pm, SP-01 (Technical Supervisor) confirmed the scores for BUN and T3 and further stated, "We have never stopped testing for BUN." SP-01 further indicated they were unaware that BUN should be reported for Urea Nitrogen. 5. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-B 2023 General Chemistry/Therapeutic Drugs" original evaluation: 7/11/2023 on page 9 of 11 indicated Urea Nitrogen for Proficiency Event 2023 2 had a score of 0/5 for 0%. On page 4 of 11, the grade for C-B 2023 (Event 2023 2) had a notation "See Note [42]". Page 1 of 11 had a legend for exception reason codes appearing in this

evaluation, "[42] = No credit assigned due to absence of response." 6. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-C2023 General Chemistry/Therapeutic Drugs" original evaluation: 10/31/2023 on page 9 of 11 indicated Urea Nitrogen for Proficiency Event 2023 2 and Event 2023 3 had a score of 0/5 for 0%; page 11 of 11 showed T3 had a score of 0/5 for 0% for Proficiency Event 2023 3. On page 5 of 11, the grade for C-C 2023 (Event 2023 3) had a notation "See Note [42]." Page 1 of 11 had a legend for exception reason codes appearing in this evaluation, "[42] = No credit assigned due to absence of response." On page 7 of 11 the "Evaluation and Comparative Method Statistics" for "C-C 2023 General Chemistry /Therapeutic Drugs" showed five of five results provided by the laboratory for T3 were unacceptable. 7. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-A 2024 General Chemistry /Therapeutic Drugs" page 9 of 11 original evaluation date 4/10/2024 indicated Urea Nitrogen had scores of 0/5 for 0% for event 2, 2023, event 3, 2023 and event 1, 2024; page 11 of 11 showed T3 had a score of 0/5 for 0% for Proficiency Event 2023 3 and Event 2024 1. On page 5 of 11 the grade for C-C 2023 (Event 2023 3) had a notation "See Note [42]." Page 1 of 11 had a legend for exception reason codes appearing in this evaluation, "[42] = No credit assigned due to absence of response." On page 7 of 11 the "Evaluation and Comparative Method Statistics" for "C-C 2023 General Chemistry /Therapeutic Drugs" showed five of five results provided by the laboratory for T3 were unacceptable. 8. Review of the CAP evaluation "CMS Performance Summary for Analytes Regulated under the Clinical Laboratory Improvement Amendment of 1988" for "C-A 2024 General Chemistry /Therapeutic Drugs" page 9 of 11 original evaluation date 7/2/2024 indicated Urea Nitrogen had scores of 0/5 0% for event 3, 2023, event 1, 2024 and event 2, 2024; page 11 of 11 showed T3 had a score of 0/5 for 0% for Proficiency Event 2023 3, Event 2024 1 and Event 2024 2. On page 5 of 11 indicated Urea Nitrogen for Proficiency Event 2024 2 had a score of 0/5. The grade for Event 2024 2 had a notation "See Note [42]." Page 1 of 11 had a legend for exception reason codes appearing in this evaluation, "[42] = No credit assigned due to absence of response." On page 7 of 11 the "Evaluation and Comparative Method Statistics" showed five of five results provided by the laboratory for T3 were unacceptable