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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 15D0900100 | (X3) Date Survey Completed 12/30/2021 |
| 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 |
|---------------------------|--|
| 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: Based on record review and interview, the laboratory failed to successfully participate in proficiency testing (PT) for two out of three consecutive events (2/2021 and 3 /2021) in the sub-specialties; Syphilis Serology, General Immunology, Routine Chemistry, Endocrinology, and Hematology. Refer to D-2074, D-2084, D-2096, D-2107, and D-2130.</p> |
| D2074 | <p>SYPHILIS SEROLOGY CFR(s): 493.835(e)</p> |

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to achieve an overall testing event score of satisfactory performance for two consecutive testing events (event 2, 2021 and event 3, 2021) for Syphilis Serology. Findings include: 1) Review of "Casper Report 0155D," indicated a score of 0% for event 2 and event 3 in Syphilis Serology. 2) In interview on 12/30/21 at 3:40 pm, SP-1 (laboratory manager) indicated they had no documentation of proficiency testing being performed or submitted for event 2, 2021. SP-1 confirmed proficiency testing for event 3, 2021 was submitted past the due date resulting in a 0% score.

D2084

GENERAL IMMUNOLOGY

CFR(s): 493.837(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:

Based on record review and interview, the laboratory failed to achieve a satisfactory performance (0%) for the same analyte or test for two consecutive testing events (event 2, 2021 and event 3, 2021) in General Immunology for the following analytes; Anti-Human Immunodeficiency Virus (HIV), Hepatitis B Surface Antigen (HBS-AG), Hepatitis B Core Antibodies (Anti-HBC), and Hepatitis B E Antigen (HBEAG). Findings include: 1) Review of "Casper Report 0155D," indicated a score of 0% for event 2 and event 3 in 2021 for Anti-HIV, HBS AG, Anti-HBC, and HBEAG. 2) In interview on 12/30/21 at 3:40 pm, SP-1 (laboratory manager) indicated the laboratory had no documentation of proficiency testing being performed or submitted for event 2, 2021. SP-1 confirmed proficiency testing for event 3, 2021 was submitted past the due date resulting in a 0% score for the above analytes.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(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:

Based on record review and interview, the laboratory failed to achieve a satisfactory performance (0%) for the same analyte or test for two consecutive testing events (event 2, 2021 and event 3, 2021) in Routine Chemistry for the following analytes; alanine transaminase (ALT), Albumin, Alkaline Phosphatase, aspartate aminotransferase (AST), Total Bilirubin, Total Calcium, Chloride, Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol, Total Creatinine Kinase, Creatine, Glucose, Total Iron, Magnesium, Potassium, Sodium, Total Protein, Triglycerides, Blood Urea Nitrogen (BUN), and Uric Acid. Findings include: 1) Review of "Casper

Report 0155D," indicated a score of 0% for event 2 and event 3 in 2021 for analytes; alanine transaminase (ALT), Albumin, Alkaline Phosphatase, aspartate aminotransferase (AST), Total Bilirubin, Total Calcium, Chloride, Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol, Total Creatinine Kinase, Creatine, Glucose, Total Iron, Magnesium, Potassium, Sodium, Total Protein, Triglycerides, Blood Urea Nitrogen (BUN), and Uric Acid. 2) In interview on 12/30/21 at 3:40 pm, SP-1 (laboratory manager) indicated the laboratory had no documentation of proficiency testing being performed or submitted for event 2, 2021. SP-1 confirmed proficiency testing for event 3, 2021 was submitted past the due date resulting in a 0% score for the above analytes.

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:
Based on record review and interview, the laboratory failed to achieve a satisfactory performance (0%) for the same analyte or test for two consecutive testing events (event 2, 2021 and event 3, 2021) in Endocrinology for the following analytes; Free Tyroxine, Tri-Iodothyronine, and Thyroid Stimulating Hormone. Findings include: 1) Review of "Casper Report 0155D," indicated a score of 0% for event 2 and event 3 in 2021 for Free Tyroxine, Tri-Iodothyronine, and Thyroid Stimulating Hormone. 2) In interview on 12/30/21 at 3:40 pm, SP-1 (laboratory manager) indicated the laboratory had no documentation of proficiency testing being performed or submitted for event 2, 2021. SP-1 confirmed proficiency testing for event 3, 2021 was submitted past the due date resulting in a 0% score for the above analytes.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

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

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to achieve a satisfactory performance (0%) for the same analyte or test for two consecutive testing events (event 2, 2021 and event 3, 2021) in Hematology for the following analytes; Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets. Findings include: 1) Review of "Casper Report 0155D," indicated a score of 0% for event 2 and event 3 in 2021 for Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets. 2) In interview on 12/30/21 at 3:40 pm, SP-1 (laboratory manager) indicated the laboratory had no documentation of proficiency testing being performed or submitted for event 2, 2021. SP-1 confirmed proficiency testing for event 3, 2021 was submitted past the due date resulting in a 0% score for the above analytes.