Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0900100	01/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
North Clark Medical Group	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 1/4/2024. 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Repeat Deficiency Based on record review and interview, the laboratory failed to sucessfully participate in a proficiency testing program. The laboratory failed to participate in two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023) resulting in a score of 0 for both testing events in Hematology and for the following

	analytes; Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets as reported by the American Association of Bioanalysts (AAB). (Refer to D2123) The laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive testing events in 2021 (event 2, 2021 and event 3, 2021) and two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023). Results for those events were 0% in Hematology and for the following analytes; Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets. (Refer to D2130)
D2123	HEMATOLOGY CFR(s): 493.851(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: Based on record review and interview, the laboratory failed to participate in two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023) resulting in a score of 0 for both testing events in Hematology and for the following analytes; Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets as reported by the American Association of Bioanalysts (AAB). Findings include: 1) Review of "Casper Report 0155D," indicated a score of 0% for event 2 2023 and event 3 2023 for Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets as reported by the American Association of Bioanalysts (AAB). 2) In email on 12/29/2023 at 10:13 am, SP-3 (Technical Supervisor) confirmed the laboratory is still performing hematology testing. 3) In email on 12/29/2023 at 11:09 am, SP-3 (Technical Supervisor) indicated the laboratory did not submit any results to AAB for event 2 and event 3 of 2023. SP-3 further confirmed the laboratory did not perform proficiency testing for any proficiency testing program for event 2 or event 3 2023 for hematology and the analytes Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets.
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: Repeat Deficiency Based on record review and interview, the laboratory failed to achieve satisfactory performance of 80% or greater for two consecutive testing events in 2021 (event 2, 2021 and event 3, 2021) and two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023). Results for those events were 0% in Hematology

	and for the following analytes; Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets as reported by the American Association of Bioanalysts (AAB). Findings include: 1) Review of "Casper Report 0155D," indicated a score of 0% for event 2 2021 and event 3 2021 and 0% for event 2 2023 and event 3 2023 for Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets as reported by the American Association of Bioanalysts (AAB). 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. 3) In email on 12/29/2023 at 10:13 am, SP-3 (Technical Supervisor) confirmed the laboratory is still performing hematology testing. 4) In email on 12/29/2023 at 11:09 am, SP-3 (Technical Supervisor) indicated the laboratory did not submit any results to AAB for event 2 and event 3 of 2023. SP-3 further confirmed the laboratory did not perform proficiency testing for any proficiency testing program for event 2 or event 3 2023 for hematology and the analytes Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets.
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 document review and interview, the laboratory director failed to ensure the laboratory achieved satisfactory performance of 80% or greater for two consecutive testing events in 2021 (event 2, 2021 and event 3, 2021) and two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023). Results for those events were 0% in Hematology and for the following analytes; Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets. (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 achieved satisfactory performance of 80% or greater for two consecutive testing events in 2021 (event 2, 2021 and event 3, 2021) and two consecutive testing events in 2023 (event 2, 2023 and event 3, 2023). Results for those events were 0% in Hematology and for the following analytes; Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets as reported by the American Association of Bioanalysts (AAB). Findings include: 1) Review of "Casper Report 0155D," indicated a score of 0% for event 2 2021 and event 3 2021 and 0% for event 2 2023 and event 3 2023 for Cell Identification, Red Blood Cell,

	Hematocrit, Hemoglobin, White Blood Cell, and Platelets as reported by the American Association of Bioanalysts (AAB). 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. 3) In email on 12/29/2023 at 10:13 am, SP-3 (Technical Supervisor) confirmed the laboratory is still performing hematology testing. 4) In email on 12/29/2023 at 11:09 am, SP-3 (Technical Supervisor) indicated the laboratory did not submit any results to AAB for event 2 and event 3 of 2023. SP-3 further confirmed the laboratory did not perform proficiency testing for any proficiency testing program for event 2 or event 3 2023 for hematology and the analytes Cell Identification, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cell, and Platelets.