Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0900100	08/29/2023
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 recertification/ proficiency testing review survey was completed on 8/29/2023. 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 staff interview, the laboratory failed to successfully participate in the AAB and College of American Pathologist (CAP) PT for analyte creatine kinase (CK) Total in the subspecialty of Routine Chemistry for events (2/2021, 3/2021, 1/2023, and 2/2023). (Refer to D2096).

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: Repeat deficiency. Based on document review and interview, the laboratory failed to achieve satisfactory performance of 80% of greater for two consecutive events in 2021 (event 2, 2021, event 3, 2021) and for two out of three consecutive events in 2023 (event 1. 2023 and event 2, 2023) for the analyte creatine kinase (CK) Total in the subspecialty of Routine Chemistry. Findings include: 1) Review of Oscar Report 155D (Individual Laboratory Profile) indicated the following unsatisfactory scores for CK Total: 0% for event 2, 2021, event 3, 2021, event 1, 2023, and event 2, 2023. 2) In interview on 12/30/21 at 3:40 pm, SP-11 (laboratory manager) indicated the laboratory had no documentation of proficiency testing being performed or submitted for event 2, 2021 for CK total. SP-11 confirmed proficiency testing for event 3, 2021 was submitted past the due date resulting in a 0% score for CK Total. 3) On 8/21/2023 at 2:45 pm, upon request for Proficiency Test Evaluation scores for 2023 for CK Total, none was provided by SP-3 (Technical Supervisor). SP-3 explained the laboratory had a Lot issue, and a Roche Cobas technician had to service the analyzer. 4) Review of "Cobas 6000 Quality Control Monthly Review" signed by SP-3 (Technical Supervisor) on 4/06/23 confirmed "issues w/ ranges" associated with reagents and QC, "Quality Control Corrective Action Log" for date(s) 3/02/23 to 3/03 /23.
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: Based on document review and interview, the laboratory director failed to ensure the laboratory successfully participated in the AAB and CAP proficiency testing (PT) programs for creatine kinase (CK) Total. The laboratory failed to achieve satisfactory performance of 80% of greater for two consecutive events in 2021 (event 2, 2021, event 3, 2021) and for two out of three consecutive events in 2023 (event 1. 2023 and event 2, 2023) for the analyte CK Total in the subspecialty of Routine Chemistry. (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:

	Based on document review and interview, the laboratory director failed to ensure the laboratory successfully participated in the AAB and CAP proficiency testing (PT) programs CK Total. The laboratory had unsatisfactory overall PT event testing scores (less than 80%) for two consecutive events in 2021 (event 2, 2021, event 3, 2021) and for two out of three consecutive events in 2023 (event 1. 2023 and event 2, 2023) for the analyte CK Total. Findings included: 1. Review of Oscar Report 155D (Individual Laboratory Profile) indicated the following unsatisfactory scores: a. CK Total submitted by AAB 1. Event 2 (2021) = 0% 2. Event 3 (2021) = 0% b. CK Total submitted by CAP 1. Event 1 (2023) = 0% 2. Event 2 (2023) = 0% 2. In interview on 12/30/21 at 3:40 pm, SP-11 (laboratory manager) indicated they had no documentation of proficiency testing being performed or submitted for event 2, 2021 CK total. SP-11 confirmed proficiency testing for event 3, 2021 were submitted past the due date resulting in a 0% score for the same tests. 3. On 8/21/2023 at 2:45 pm, upon request for Proficiency Test Evaluation scores for 2023 for CK Total, none was provided by SP-3 (Technical Supervisor). SP-3 explained the laboratory had a Lot issue, and a Roche Cobas technician had to service the analyzer. 4. Further review of "Cobas 6000 Quality Control Monthly Review" signed by SP-3 (Technical Supervisor) on 4/06/23 confirmed "issues w/ ranges "associated with reagents and QC, "Quality Control Corrective Action Log" for date(s) 3/02/23 to 3/03/23.