

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0900100	(X3) Date Survey Completed 08/30/2023
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 recertification survey was completed on 8/30/2023. 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 42 CFR 493.1447 Technical Supervisor
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 staff interview, the laboratory failed to successfully participate in American Association of Bioanalysts (AAB), proficiency testing (PT) in the subspecialty of Syphilis Serology for events (2/2021, 3/2021, 3/2022 and 2/2023). (Refer to D2074).</p>

D2074

SYPHILIS SEROLOGY

CFR(s): 493.835(e)

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:

Repeat deficiency. Based on record review and interview, the laboratory failed to achieve an overall testing event score of 80% in American Association of Bioanalysts (AAB) Proficiency testing (PT) for two consecutive testing events in 2021 (event 2, 2021, and event 3, 2021) and two out of three consecutive testing events in 2022/2023 (event 3, 2022 and event 2, 2023) in the specialty of Diagnostic Immunology for subspecialty of Syphilis Serology. Findings include: 1) Review of Oscar Report 155D (Individual Laboratory Profile) indicated the following unsatisfactory scores of Syphilis Serology Event 2 (2021) = 0%, Event 3 (2021) = 0%, Event 3 (2022) = 60%, and 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. SP-11 confirmed proficiency testing for event 3, 2021 was submitted past the due date resulting in a 0% score. 3) Review of AAB results for Nonchemistry Q3 2022/ confirmed the 60% score for Syphilis Serology. 4) On 8/29 /23 at 2:03pm, an interview with SP-3 (Technical Supervisor) confirmed that the laboratory no longer wanted to use the AAB PT program, so the samples were not submitted for event #2 for 2023 for Syphilis (Serology) resulting in a score of 0%.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to verify the accuracy of 14 (metabolite of delta 9 tetrahydrocannabinol (THC), Buprenorphine, Hydrocodone, Hydromorphone, Norhydrocodone, Gabapentin, Tramadol, O-Desmethyltramadol, Methadone, Methadone Metabolite, Oxazepam, Codeine, Morphine, Pregabalin) out of 18 analytes in Drug Monitoring for Pain Management (DMPM) twice annually in 2022 for testing performed on one of one toxicology analyzer (Shimadzu LCMS-8030, 8040 (SN: L20705161633)). Finding(s): 1) Review of College of America Pathologists (CAP) proficiency test (PT) document "DMPM-B 2022 Drug Monitoring for Pain Management", original evaluation: 10/18/2022, showed a grade of "Unacceptable" in Drug Monitoring for Pain Management (DMPM) for event: DMPM-B/2022 for the following specimens and analytes. PT Specimen Not verified analytes for 2022 DMPM-05 Delta-9-THC Buprenorphine Hydrocodone Hydromorphone Norhydrocodone Gabapentin DMPM-06 Tramadol O-Desmethyltramadol Methadone Methadone Metabolite Oxazepam DMPM-07 Codeine Morphine Pregabalin 2) Review of the policy "Quality Assurance" created 2012, revised and signed by laboratory director on 3/29/2023, read "5. Assessment for Non-Regulated Analytes/Alternative Proficiency A. When testing is performed on analytes that are not regulated, an alternative proficiency may be performed twice a year to validate the accuracy of the testing procedure." 3) Review of patients' records

indicated one of three patients' samples (PT-5) ran on analyzer Shimadzu LCMS-8030, 8040 (SN: L20705161633) was tested during the submission of event DMPM-B/2022 and had results that were inconsistent with prescription. Patient (PT) Date Analyte(s) w/ Inconsistent Results PT-5 05/26/22 Buprenorphine (DMPM-05) Hydrocodone (DMPM-05) Norhydrocodone (DMPM-05) 4) On 8/29/23 at 1:15pm, Sp-3 (Technical Supervisor) acknowledged the above scores for DMPM-B/2022 and confirmed that a second verification of accuracy such as a split sample or blind sample had not been completed for 2022 after these failures. 5) Annual Test Volume for Toxicology is approximately 396,000.

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 Syphilis Serology. The laboratory failed to achieve an overall testing event score of 80% in AAB PT for two consecutive testing events in 2021 (event 2, 2021, and event 3, 2021) and two out of three consecutive testing events in 2022/2023 (event 3, 2022 and event 2, 2023) for subspecialty of Syphilis Serology. (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 for Syphilis Serology. The laboratory also had unsatisfactory overall PT event testing scores (less than 80%) for two consecutive testing events in 2021 (event 2, 2021, and event 3, 2021) and two out of three consecutive testing events in 2022/2023 (event 3, 2022 and event 2, 2023) for subspecialty of Syphilis Serology. Findings included: 1) Review of Oscar Report 155D (Individual Laboratory Profile) indicated the following unsatisfactory scores: a. Syphilis Serology submitted by AAB 1. Event 2 (2021) = 0%, 2. Event 3 (2021) = 0%, 3. Event 3 (2022) = 60%, and 4. 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 for Syphilis Serology. 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) Review of AAB results for Nonchemistry Q3 2022/ confirmed the 60% score for Syphilis Serology. 4) On 8/29/23 at 2:03pm, an interview with SP-3 (Technical Supervisor) confirmed that the laboratory no longer wanted to use the AAB PT program, so the samples were not submitted for event #2 for 2023 for Syphilis (Serology) resulting in a score of 0%.

D6108

LABORATORY TECHNICAL SUPERVISOR

CFR(s): 493.1447

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.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure three (SP-3, SP-4, and SP-10) of nine personnel performing the duties of a technical supervisor (TS) meet qualification requirements, from January 2023 until August 2023. (Refer to D6111) The laboratory failed to ensure the technical supervisor evaluated competency for four (SP-3, SP-8, SP-9, SP-10) out of nine testing personnel. (Refer to D6120)

D6111

TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum

of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the

specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the

specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must-- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least

one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j) (3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j) (5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii) (B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l) (2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B) (3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l) (3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology

by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral

degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure four (SP-3, SP-4, and SP-10) of nine personnel performing the duties of a technical supervisor (TS) met qualification requirements, from November 2022 until August 2023. Findings: 1) Review of "Laboratory Personnel Report (CLIA)", signed by the laboratory director on 9/06/23 indicated the following: a) SP-3 is a technical supervisor b) SP-4 is a testing person. c) SP-11 is a testing person. d) SP-10 is a testing person 2) On 8/29/23 at 12:15pm, SP-3 (Technical Supervisor) confirmed their hire date was March 27, 2023. 3) Review of SP-3 (Technical Supervisor) personnel file indicated SP-3 has a Bachelor of Arts Degree with a resume (CV) listing prior work experience. 4) Review of personnel files for SP-4 indicated they had a hire date of 11/3/2015 and an associates degree in medical laboratory technology. 5) Review of personnel files for SP-10 indicated they had a hire date of 6/2021 and an associates degree in medical laboratory technology. 6) Review of document "Competency Assessment for Testing Personnel" and "LCMS Competency Assessment" for SP-3 revealed there was no signature or date for "Reviewer". The signature for the "Laboratory Director/Designee

Signature under "This individual demonstrates appropriate technique to run this test(s) /instrument(s) and report test results" was SP-3 and there was no date listed. The document was marked as the initial competency for SP-3 on analyzer Roche Cobas 8000/c502, e602 (SN: 18M3-03) and LCMS Shimadzu 8030 (SN: L20705161633). 7) Review of document "Competency Assessment for Testing Personnel" for SP-6 signed by SP-3 on 8/16/23 as the "Reviewer" on analyzers Roche Cobas 8000/c502, e602 (SN: 18M3-03), Roche Cobas 6000/c501, e601 (SN: 1263-09), and Sysmex XS 1000i (SN: C5158). Another document titled, "Filmarray Respiratory Panel Training" for SP-6 on 7/27/23 was signed by SP-4 (testing personnel) as the "trainer" on analyzer: Biomerieux Film Array (SN: 2FA00388). 8) Review of document "Cobas Laboratory Competency" for SP-8 (testing personnel), not signed by SP -8 or SP-1 (laboratory director) revealed SP-11 (testing personnel) initialed under "Trainer initials" for competency on analyzers Roche Cobas 8000/c502, e602, SN: 18M3-03, Roche Cobas 6000/c501, e601 (SN: 1263-09) on "11/2022" with no specific date specified. 9) Review of document "Cobas Laboratory Competency" and "Laboratory Competency (Hematology)" for SP-11 (testing personnel) performed on 6/6/22 revealed SP-10 (testing personnel) initialed under "Trainer initials" for competency on analyzers Roche Cobas 8000/c502, e602, SN: 18M3-03, Roche Cobas 6000/c501, and Sysmex XS 1000i (SN: C5158). 10) Review of "Personnel Competency Assessment" Policy# A3, Subject: Quality Assurance, revised on 03/29/2023, under I. Summary and Explanation/ Intended Use, states, "technical supervisor is responsible for performing and documenting competency assessments". The requirements for assessment of competency for all personnel performing laboratory testing is1) Direct observations of routine patient test performance, specimen handling, processing, and testing, and 4) Direct observations of performance of instrument maintenance and function checks. 11) On 8/31/2023 at 12:14 pm, an email was sent to SP-3 (Technical Supervisor) requesting documentation for prior work experience to qualify SP-3 as a Technical Supervisor. 12) On 8/31/2023 at 12:40pm, SP-3 provided two documents, a job description for Technical Supervisor signed by SP-3 on December 20, 2021, and document, "Technical Supervisor Competency" form signed by SP-3 on December 20, 2022, from a previous employer (Laboratory B). The dates (12/20/21, 12/20/2022) from prior employment and start date (3/27/23) at current laboratory indicates 1 year and 3 months' work experience in the specialty of Chemistry and subspecialty of Toxicology. SP-3 did not provide additional documents of work experience to support 4 years of work experience needed to qualify as a Technical Supervisor for a High Complexity Laboratory. 13) Annual Test Volume for Routine Chemistry is approximately 782,000. 14) Annual Test Volume for Hematology is approximately 32,280. 15) Annual Test Volume for Microbiology is approximately 12,230.

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TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the technical supervisor failed to evaluate

competency for four (SP-3, SP-8, SP-9, SP-10) out of nine testing personnel for performance on analyzer(s): Roche Cobas 8000/c502, e602 (SN: 18M3-03), Roche Cobas 6000/c501, e601 (SN: 1263-09), LCMS Shimadzu 8030 (SN: L20705161633), and Biomerieux Film Array (SN: 2FA00388). Findings: 1) Review of document "Competency Assessment for Testing Personnel" and "LCMS Competency Assessment" for SP-3 revealed there was no signature or date for "Reviewer". The signature for the "Laboratory Director/Designee Signature under "This individual demonstrates appropriate technique to run this test(s)/instrument(s) and report test results" was SP-3 and there was no date listed. The document was marked as the initial competency for SP-3 on analyzer Roche Cobas 8000/c502, e602 (SN: 18M3-03) and LCMS Shimadzu 8030 (SN: L20705161633). 2) Review of the document titled, "LCMS Competency Assessment" for SP-8 had no signature or date for "Reviewer" of competency on the LCMS Shimadzu 8030 (SN: L20705161633). 3) Review of personnel file for SP-9 (testing personnel) indicated there was no annual competency on the "Film array Respiratory Panel Training" on analyzer: Biomerieux Film Array (SN: 2FA00388). 4) Review of personnel file for SP-10 (testing personnel) indicated there was no annual competency for 2022 for the "Film array Respiratory Panel Training" on the analyzer: Biomerieux Film Array (SN: 2FA00388). 5) During personnel file review on 8/29/2023 at 12:15 pm, SP-3 confirmed there was no annual competency in 2022 for SP-8, SP-9 and SP-10. SP-3 confirmed that these testing personnel were still testing using the Biomerieux Film Array until the following dates: SP-8 - 4/2023, SP-9 -6/2023, and SP-10 - 5/2023. 6) Annual Test Volume for Routine Chemistry is approximately 782,000. 7) Annual Test Volume for Microbiology is approximately 12,230. 8) Annual Test volume for Toxicology is 396,000