# Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	15D0900100	10/11/2024
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	51197 A complaint survey was completed on 10/11/2024. The following condition level deficiencies existed: 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain one of one Individualized Quality Control Plan (IQCP), implemented in 2016, and currently in use, for 20 of 20 analytes run on the "BioFire Gastrointestinal Panel (GI) Kit", and 20 of 20 analytes run on the "FilmArray Respiratory Panel (RP) Kit" using the Biomerieux FilmArray, Microbiology/Virology analyzer, (Serial Number=FA3224) and two (Pt-1 and Pt-9) of eleven patients reviewed. Findings included: 1. In an interview on10/1/24 at 10:06 am, SP-1 (Technical Supervisor), confirmed that Biomerieux FilmArray testing is not being batched, and Quality Control (QC) is performed monthly, and with new reagent lots. At 2:09 pm, SP-1, affirmed, that an IQCP was implemented a year after they installed the Biofire, and was signed by SP-7 (Former Laboratory Director). 2. Review of the Procedure #: D6.1, signed by SP-2 (laboratory director) on 1/18/2024, identified the following viruses and bacteria were tested using the "FilmArray Respiratory Panel (RP) Kit": Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtypeH1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus,

	Bordetella pertussis, and Chlamydophila pneumonia. Page 4 of 16, 4. External controls C. required positive and negative controls to be run once a month when there is a test requisition and on new lots of reagent kits. The policy did not mention an Individualized Quality Control Plan or a risk assessment. 3. Review of the Procedure #: D6.2, signed by SP-2 on 1/18/2024, identified the following bacteria, parasites and viruses identified using the "BioFire Gastrointestinal (GI) Panel Kit": Campylobacter, Clostridium difficile toxin A/B, Plesiomonas shigelloides, Vibrio, including specific identification of Vibrio Cholerae, Yersinia enterocolitica ,Enteroaggregative Escherichia coli (EAEC), Enteropathogenic Escherichia coli (ETEC), Enteropathogenic Escherichia coli (ETEC) It/st, Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2(including specific identification of the E. coli 0157 serogroup withing STEC), Shigella/Enteroinvasive Escherichia coli (EIEC), Cryptoporidium, Cyclosporacayetanenis, Entamoebahistolytica, Giardia lamblia (also known as G. intestinalis and G. duodenalis) Adenovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (Genogroups I, II, IV, and V). Page 4 of 16, 4. External controls C. required positive and negative controls to be run once a month when there is a test requisition and on new lots of reagent kits. The policy did not mention an Individualized Quality Control Plan or a risk assessment. 4. Review of document, 'IQCP Annual Quality Effectiveness Summary Biofire', signed by, SP-06, (Former Laboratory Director), dated 6/9/2017, stated that the IQCP plan was implemented 2016 and was signed by Laboratory Director. The document did not include the orginal Quality Control Plan or Risk Assessment. 5. Review of medical records indicated testing was performed on the Biomerieux FilmArray using the following panels: Respiratory panel- Not Detected on Pt-1 on 9/11/24 11:06 am, and GI panel Not Detected on Pt-9 on 7/9/24 at 1:06 pm. 6. In an interview on 10/2/24 at 12:30 pm, SP-1, confirmed the "BioFire Daily Quality Assurance" log has a line (6) marked Quality Control (QC), which is checked each day of testing, but this is the internal QC. External QC is performed monthly. SP-1 also confirmed they were unable to find any record of the IQCP, or any other records pertaining to the IQCP including the completed risk assessment. 7. Annual volume for microbiology/bacteriology is 300; Annual volume for microbiology /virology is 14,000.
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: Repeat Citation Based on record review and interview, the laboratory failed to perform twice annual accuracy verification on 16 of 64 (Amitriptyline, Desipramine, Imipramine, ortriptyline, Ritalinic Acid, Sertraline, Phenylcyclohexyl piperidine (PCP), Zaleplon, Pentazocine, Methlenedioxpyrovaleron, Delta-9- Carboxy Tetrahydrocannabinol (THC-COOH), Gabapentin, Buprenorphine, Morphine, Amphetamine, and Alpha-hyroxyalprazolam) unregulated analytes performed on the Shimaszu LCMS 8030 (Serial Number=L20235154318) in 2023 and three (Pt-5, Pt-6, and Pt-7) of eleven patients reviewed. Findings included: 1. In an interview on 09/30 /2024 at 10:35 am, SP-1 (Technical Supervisor), confirmed enrollment in College of American Pathologist (CAP) for Proficiency Testing (PT) for drug testing performed on Shimaszu LCMS 8030. 2. Review of the list of drugs tested in the PT-CAP enrollment for 2023 indicated the following tests were missing from the review, but were included on Enclosure 1 as tests performed by the laboratory: Amitriptyline,

	Desipramine, Imipramine, ortriptyline, Ritalinic Acid, Sertraline, PCP, Zaleplon, Pentazocine, Methlenedioxpyrovaleron. 3. Review of CAP Proficiency Testing for 2023, revealed the following tests failed one of the two PT events: a) DMPM-A 2023- mailed 2/7/2023, evaluated 4/6/2023: Delta-9-THC-COOH (unacceptable), Gabapentin (unacceptable), Buprenorphine (unacceptable). b) DMPM-B 2023- mailed 8/8/2023, evaluated 10/4/2023: Morphine (unacceptable), Amphetamine (unacceptable), Alpha-hyroxyalprazolam (unacceptable). 4. In an interview on 10/2/24 at 12:45 pm, SP-1, indicated they were unaware that they were not enrolled with all of toxicology testing in CAP. They just ordered what had been previously ordered. SP-1 further confirmed no other verification for testing on the Shimaszu LCMS 8030 was completed in 2023. SP-1 acknowledged they did not know they needed to replace a failed Calibration Verification or Proficiency Testing failure on unregulated testing in order to have two verifications per year. 5. Review of medical records indicated the following patient tests: Pt-5, Pt-6, and Pt-7, had toxicology reports showing testing for Amitriptyline, Desipramine, Imipramine, Nortriptyline, Ritalinic Acid, Sertraline, PCP, Zaleplon, Pentazocine, Methlenedioxpyrovaleron, Amphetamines, Morphine, THC COOH, Alpha-hydroxyalprazolam, Gabapentin. a) Pt-5-ran on 10/6/23 at 3:22 pm: Amphetamines-Not detected, Morphine-Not detected, THC COOH-Positive >2000 nanograms/milliliters (mg/ml). Under Confirmation Results Summary the result for Amphetamines- Not Detected is inconsistent. Pt-5 prescribed: Adderall (Amphetamine) b) Pt-6 ran on 10/6/23 at 3:12 pm: Alpha-hydroxyalprazolam-Not detected, Gabapentin-Positive >20000 nanograms/milliliters (ng/mL). Under Confirmation Results Summary, Pt-6 was prescribed Xanax (Alprazolm) not Gabapentin the results of Alprazolam "Not Detected" and Gabapentin "Positive" were "Inconsistent". c) Pt-7 ran on 7/13/23 at 10:56 am: Buprenorphine- Postive (Pos) 71 nanograms/milliliters (ng/mL) 6. Annual volume for toxicology performed on Shimaszu LCMS 8030 is 384,000.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to meet the analytic system requirements found in 493.1251 through 493.1283. The laboratory failed to pass six-month Calibration Verification for 2 of 5 (Vitamin D (Vit D) and Vitamin B12 (Vit B12) non-regulated immunoassay ran on the Roche Cobas 6000 e601 Seral Number = 1263-09 (refer to D5439). The laboratory failed to successfully run two levels of quality control for Vitamin B12 (Vit B12) ran on the Roche Cobas 6000 e601, Seral Number = 1263-09 prior to running patients for three (Pt-2, Pt-10, and Pt-11) of eleven patients reviewed (Refer to D5447). The laboratory failed to evaluate the effectiveness of the Individualized Quality Control Plan (IQCP) implemented in 2016, and currently in use on 10/3/2024, for 20 of 20 analytes run on the BioFire Gastrointestinal Panel (GI) kit and 20 of 20 analytes run on the FilmArray Respiratory

	Pannel (RP) Kit tested on the on the Biomerieux FilmArray, Microbiology/Virology analyzer, (Serial Number=FA3224), for 2 of 2 years (2023 and 2024) and two (Pt-1 and Pt-9) of eleven patients reviewed (refer to D5739).
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to pass six-month Calibration Verification for two (Vitamin D (Vit D) and Vitamin B12 (Vit B12) of five non-regulated immunoassays run on the Roche Cobas 6000 e601 Seral Number=1263-09 and four (Pt-3, Pt-2, Pt-10, Pt-11) of eleven patients reviewed. Findings included: 1. The "LN5-A 2024 Ligand Calibration Verification/Linearity Vitamin B12 pg/mL Linearity Evaluation", mailed on 4/8/24 and evaluated on 5/8/24 indicated the following: a) on page 11 the Evaluation Result was "Imprecise (Poor repeatability and/or Fit)". b) on page 12 the documentation for investigation and corretive action, read, "entry error for sample." c) This is the only Calibration Verification/Linearity for Vit 12 available for 2024 review. 2. The "LN40-A 2024 Total 25-OH Vitamin D Calibration Verificaton/Linearity", mailed 4/29/2024 and evaluated on 5/24/24 indicated: the following: a) on page 3 the Evaluation Result was "Imprecise (Poor repeatability and/or Fit)". b) on page 4 the documentation for investigation and corretive action, read, "new lot installed with verified QC." c) This is the only Calibration Verification/Linearity for Vit D available for 2024 review. 3. In an interview on 10/1/2024 at 1:00 pm, SP-1 (Technical Supervisor), explained that the failed calibration verification was not repeated on VIT B12 and Vit D, and the Roch Cobas for Vit B12 and Vit D were not recalibrated. SP-1 indicted the only corrective action for the failed calibration verification included switching to a new lot of reagents and verifying with quality control (QC). 4. The document of Vit B12 reagent lot changes titled: "B12 II Module E-1" indicated to following lot changes: Date Time Lot 4-Apr 9:27 524612 9-Apr 8:56 624614 16-Apr 8:56 624614 25-Apr 10:03 624614 30-Apr 12:31 624614 This document did not indicate a reagent lot change occurred after CalibrationVerification failure. 5. In an Interview on 10/2/24 at 12:45

	pm, SP-1, verified they did not know they needed to replace a failed Calibration Verification. 6. The following patients reviewed were tested when the calibration verification for Vit B12 and Vit D had failed: a) Pt-3- Vit D- 19 nanograms/milliliters (ng/dl), tested on 5/14/2024 at 10:00 am b) Pt-2 - Vit B12- 1274 pcograms per milliliter (pg/ml), tested on 4/11/2024 at 1:31 pm c) Pt-10- Vit B12-512.7 pg/ml, tested on 4/11/2024 at 1:31 pm d) Pt-11- Vit B12-809.6 pg/ml, tested on 4/11/2024 at 1:39 pm 7. Review of COBAS procedure (D2), signed and dated by Laboratory Director on 1/18/2024, section IV. Calibration, states, "Calibrations will be performed as per manufacturer's instructions and as needed for troubleshooting. Linearity /Calibration check was performed during installation and setup. Linearity is also performed for any test that has less than three (3) calibrators every six months." The procedure does not define what the manufacturer's instructions are regarding calibration or which tests have less than three calibrators. 8. Annual test volume for Vitamin D=3,100 and Vitamin B12=3,100.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to successfully run two levels of quality control for Vitamin B12 (Vit B12) ran on the Roche Cobas 6000 e601, Seral Number=1263-09 prior to testing patients for three (Pt-2, Pt-10, and Pt-11) of eleven patients reviewed. Findings included: 1. Review of Vit B12 levy Jennings (LJ) for the month of April 2024 revealed the Quality Control (QC) Level 1 Lot 85341 failed on 4/11/24, with no rerun. Reagent lot number was missing. 2. Review of medical records indicated the following patients were tested on 4/11/2024 without two successful QC levels: a) Pt-2 - Vit B12- 1274 picorgrams per milliliter (pg /ml), tested on 4/11/2024 at 1:31 pm. b) Pt-10- Vit B12-512.7 pg/ml, tested on 4/11 /2024 at 1:31 pm. c) Pt-11- Vit B12-809.6 pg/ml, tested on 4/11/2024 at 1:39 pm. 3. Review of daily QC: IA Level 1 Lot 85341 ran on 4/11/24 at 8:15am indicated: a) Vit B12 value was 405.3 High (H). b) Expected Value was 225-330. c) QC- was check marked as complete. 4. In an interview on 10/2/2024 at 1030am, SP-1, indicated the technician did not notice the QC was out on Vit B12 when they reported patient testing, because the Laboratory Information System (LIS) had not been updated with the new QC lot ranges (BIORAD IMMUNOASSAY lot 85341), and did not flag run as "QC out". SP-1 confirmed the new lot of controls were put in use and new ranges put in analyzer (RocheCobas6000e601 SN=1263-09) on 3/11/24, and they updated lot ranges in LIS when they noticed this on 6/1/24. 5. The document "Lot Information for Control IA +1-IMMUNOASSAY PLUS Level 1 level 1" indicated the new lot of controls were put in use and new ranges put in LIS on 6/1/24 for the following analytes: Free Thyroxine (Free T4), Vit B12, Thyroid Stimulating Hormone (TSH), Triiodothyronine (T3), Folate, Vit D, Testosterone, and Prostatic Specific Antigen (PSA). 6. The policy Procedure#: D2, approved by laboratory director on 1/18/2024, for the COBAS 6000 series on page 4 of 15 under section V. Quality Control, requires, "Quality Control materials will be run daily on all analytes prior to patient testing with two levels of control material." On page 6 of 15 under section VI.

	Procedure requires under 2.O."Review and verify QC results. i. Troubleshoot and repeat as necessary, documenting corrective action on Policy C1 Form 2 Quality Control Corrective Action Log." 7. Annual test volume Vitamin B12=3,100
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to evaluate the effectiveness of the Individualized Quality Control Plan (IQCP) implemented in 2016, and currently in use on 10/4/2024, for 20 of 20 analytes run on the BioFire Gastrointestinal Panel (GI) kit and 20 of 20 analytes run on the Film Array Respiratory Pannel (RP) Kit tested on the on the Biomerieux FilmArray, Microbiology /Virology analyzer, (Serial Number=FA3224), for 2 of 2 years (2023 and 2024) and two (Pt-1 and Pt-9) of eleven patients reviewed. Findings included: 1. In an interview on 10/1/24 at 10:06 am, SP-1 (Technical Supervisor), confirmed that Biomerieux FilmArray testing is not being batched, and Quality Control (QC) is performed monthly, and with new reagent lots. At 2:09 pm, SP-1, affirmed, that a IQCP was implemented a year after they installed the Biofire, and was signed by SP-6 (Former Laboratory Director). 2. Review of document, 'IQCP Annual Quality Effectiveness Summary Biofire', signed, SP-06, (Former Laboratory Director), dated 6/9/2017, states that IQCP plan was implemented 2016 and was signed by Laboratory Director. This was the only IQCP Review document found. 3. Review of the Procedure #: D6.1, approved by the SP-2 (Laboratory Director) on 1/18/2024, identified the following viruses and bacteria tested using the FilmArray Respiratory Panel (RP): Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtypeH1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus /Enterovirus, Bordetella pertussis, and Chlamydophila pneumonia. Page 4 of 16, 4. External controls C. required positive and negative controls to be run once a month a test requisition and on new lots of Reagent Kits. The policy did not mention an Individualized Quality Control Plan or a risk assessment. 4. Review of the Procedure #: D6.2, signed by SP-2 on 1/18/2024, identified the following bacteria, parasites and viruses identified using the BioFire GI Panel: Campylobacter, Clostridium difficile toxin A/B, Plesiomonas shigelloides, Vibrio, including specific identification of Vibrio Cholerae, Yersinia enterocolitica ,Enteroaggregative Escherichia coli (EAEC), Enteropathogenic Escherichia coli (ETEC), Enteropathogenic Escherichia coli (ETEC) It/st, Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2(including specific identification of the E. coli 0157 serogroup withing STEC), Shigella /Enteroinvasive Escherichia coli (EIEC), Cryptoporidium, Cyclosporacayetanenis, Entamoebahistolytica, Giardia lamblia (also known as G. intestinalis and G. duodenalis) Adenovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (Genogroups I, II, IV, and V). Page 4 of 16, 4. External controls C. required positive and negative controls to be run once a month when there is a test requisition and on new lots of reagent kits. The policy did not mention an Individualized Quality Control Plan or a

	risk assessment. 5. Review of Policy #: A Quality Assurance, approved by SP-2 on 1/18/2024, did not include a review of the Quality Control plan for the BioFire Gastrointestinal Panel (GI) or the Film Array Respiratory Pannel (RP) or review of the risk assessment. 6. Review of Policy #: A4: Quality Control, approved by SP-2 on 1/18/2024, did not include a review of the Quality Control plan for the BioFire Gastrointestinal Panel (GI) or the Film Array Respiratory Pannel (RP) or review of the risk assessment. 7. Review of medical records indicated testing was performed on the Biomerieux FilmArray using the following panels: Respiratory panel- Not Detected on Pt-1 on 9/11/24 11:06 am, and GI panel Not Detected on Pt-9 on 7/9/24 at 1:06 pm. 8. In an Interview on 10/2/24 at 12:30pm, SP-1, confirmed the BioFire Daily Quality Assurance log has a line (6) marked Quality Control, which is checked each day of testing, but this is the internal QC. External QC is performed monthly. SP-1 also confirmed they were unable to find any record of the IQCP, or any other records pertaining to the IQCP including review of the IQCP in the monthly or annual Quality Assessment program for 2023 or 2024. 9. Annual volume for microbiology /bacteriology is 300; Annual volume for microbiology/ virology is 14,000.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (SP-2) (SP=staff person) failed to specify in writing, by way of signature and date, the responsibilities and duties for four of four moderate complexity testing personnel (SP3-SP6) and one high complexity testing person (SP-1). Findings include: 1) Job descriptions titled, "High-Complexity Laboratory Testing Personnel Job Description," had no signature /date by SP-2 indicating their approval for SP3-SP5 to perform high complexity testing. 2) The Laboratory Personnel Report (CLIA) (CMS Form-209), signed by SP-2 on 10-9-24, listed SP3-SP5 as moderate complexity testing personnel. 2) Job description titled, "Moderate Complexity," had no signature/date by SP-2 indicating their approval for SP-6 to perform moderate complexity testing. SP6 was marked on the CMS Form-209), signed by SP-2 on 10-9-2024, as moderate complexity testing personnel. 3) The document "Signature sheet for JD" listed the initials for each staff person but had no signature/date by SP-2 indicating the personnel listed above were approved to perform moderate or high complexity laboratory testing. 4) Review of medical records, patients (Pt) # 1 thru #6, indicated SP1, SP3, SP4, SP5, and SP6 reported out the following results: a) Pt#12 was tested by SP-6 on 9-01-24 for Specific Gravity, the result was 1.015. b) Pt#13 was tested by SP-1 on 8-26-24 for Hydromorphone, the result was positive (POS). c) Pt#14 was tested by SP-4 on 8-27-24 for high density lipoprotein (HDL), the result was 29 mg/dL (milligrams per deciliter). d) Pt#15 was tested by SP-3 on 9-01-24 for Buprenorphine, the result was

	52 ng/mL (nanograms/milliliters). e) Pt#16 was tested by SP-5 on 8-22-24 for SARs-CoV-2 the result was Detected (SARS-CoV2 = severe acute respiratory syndrome coronavirus 2). 5) In an interview on 9/30/24 at 2:10 pm, SP-1 (technical supervisor) confirmed the job descriptions for high and moderate complexity along with, the signature sheet, had no approval signature/date by SP-2 (LD). SP-1 confirmed SP3-SP5 performed moderate complexity testing, not high complexity. 6) Annual moderate complexity testing=186,000 (Hematology and Microbiology).
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, one of two staff personnel (SP-1) performing duties of the technical consultant failed to meet the qualification requirements for moderate complexity testing for two of three specialties (Microbiology and Hematology) from March 2023 to the date of the survey. Refer to D-6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(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 (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, 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 (b)(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 (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant 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, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing

	tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review and interview, one of two staff personnel (SP-1) performing duties of the technical consultant failed to meet the qualification requirements for moderate complexity testing for two of three specialties (Microbiology and Hematology) from March 27, 2023, to the date of the survey. Findings include: 1) The CMS form 209, signed by the laboratory director (SP-2) on 10/7/2024, listed SP-1 as a Technical Supervisor and General Supervisor for the specialty of Chemistry. 2) Review of competency assessment forms for SP3-SP5 (moderate complexity testing personnel) indicated their competency was performed by SP-1: a. SP3-"Competency Assessment for Testing Personnel" signed by SP-1 on 7/4/23 and 2/10/24, lists moderate complexity testing evaluations including Microbiology and Hematology. b. SP4-"Competency Assessment for Testing Personnel" signed by SP-1 on 2/8/24, lists moderate complexity testing evaluations including Microbiology and Hematology. c. SP5-"Competency Assessment for Testing Personnel" signed by SP-1 on 9/11/23 and 7/11/24, lists moderate complexity testing evaluations including Microbiology and Hematology. 3) Personnel file for SP-1 indicated they had a bachelor's degree in chemistry. SP-1 start date was March 27, 2023. SP-1 did not have work experience in the specialties; Microbiology and Hematology prior to March 27, 2023. 5) In an interview on 10/01/24 at 10:16 am, SP-1 confirmed their start date was March 27, 2023, and they did not have two years' experience in the moderate complexity specialties of Microbiology and Hematology. 6) Annual test volume for Microbiology and Hematology=186,000.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (SP-2) failed to specify in writing, by way of signature and date, the responsibilities and duties for one of one high complexity testing person (SP-1). Findings include: 1) The Job description titled, "High-Complexity Laboratory Testing Personnel Job Description," had no signature /date by SP-2 indicating their approval for SP-1 to perform high complexity testing. 2) The document "Signature sheet for JD," had no signature/date by SP-2 indicating the personnel listed were approved to perform high or moderate complexity laboratory testing. 3) The medical records for patient Pt #13 indicated SP-1 reported the result of Positive for Hydromorphone on 8-26-24. 4) In an interview on 9/30/24 at 2:10 pm, SP-1 confirmed the high complexity job description and signature sheet had no approval signature/date by SP-2 (LD). 5) Annual high complexity testing=8,750,000 (Chemistry /Toxicology).