Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2075610	09/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
N T L Laboratory	8833 Gross Point Rd - Suite 308, Skokie, IL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: A) Based on review of laboratory policy and procedure manual, the Federal Casper Report 0096D, College of American Pathologist (CAP) proficiency testing (PT) records, laboratory test records, lack of documentation, and interview with the laboratory director (LD); the laboratory a) failed to enroll in appropriate PT testing challenges for 21 of 21 regulated analytes for the subspecialty of routine chemistry and two of two regulated analytes for the specialty of hematology, regarding coagulation, for the year 2024, affecting 22,344 patients. Findings include: 1. Review of the laboratory's policy and procedure manual revealed, under "Enrollment in Proficiency Testing", "Proficiency testing shall be enrolled in .... using whichever of the proficiency test providers is suitable and acceptable per CLIA regulations." 2. Review of the Federal Casper Report 0096D revealed no scores were reported to the Center for Medicare and Medicaid Services (CMS) for the following analytes in the year of 2024: a) Sodium b) Chloride c) Potassium d) Serum Creatinine e) Calcium f) Blood Urea Nitrogen (BUN) g) Glucose h) Alanine Aminotransferase (ALT) i) Aspartate Aminotransferase (AST) j) Total Bilirubin (T-Bili) k) Total Protein l) Alkaline Phosphatase (ALP) m) Albumin n) Cholesterol o) Triglycerides p) High Density Lipoprotein (HDL) q) Total Iron r) Uric Acid s) Magnesium t) Amylase u)

	Lactic Acid Dehydrogenase (LDH) 3. Review of CAP PT records revealed that the laboratory failed to enroll in testing for 21 of 21 above-mentioned regulated routine chemistry analytes in 2024. 4. Review of the laboratory's CAP PT records revealed the laboratory failed to enroll for the correct five challenges, three times per year for two of two regulated coagulation analytes for specialty of hematology for the year 2024. a) Protime b) Partial Thromboplastin Time (PTT) 5. Review of the laboratory's CAP PT records revealed the laboratory had enrolled in "Coagulation, Limited Quality Cross Check", which only provides three challenges, twice per year and states, under "Program Notes", "Quality Cross Check is not proficiency testing. These results will not be sent to any [United States] US [Clinical Laboratory Improvement Amendments] CLIA regulatory agency." 6. Review of patient test records found the laboratory reported out results for 21,525 chemistry patients and 819 coagulation patients from 01/01/2024 through the date of survey, 09/25/2024. 7. Interview with the LD at 4:05 pm, on 09/24/2024, confirmed that the laboratory failed to enroll in appropriate PT testing challenges for 21 of 21 regulated analytes of routine chemistry and two of two regulated coagulation analytes for specialty of hematology for the year 2024. B) Based on review of laboratory policies and procedure manual, proficiency testing (PT) records, laboratory test volume worksheet, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to maintain method accuracy testing procedures for 17 of 17 non-regulated analytes for the subspecialty of routine chemistry and nine of nine non-regulated analytes for the subspecialty of toxicology for the year of 2024, affecting 21,525 patients. (See D2003).
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedure manual, proficiency testing (PT) records, laboratory test volume worksheet, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to maintain method accuracy testing procedures for 17 of 17 non-regulated analytes for the subspecialty of routine chemistry and nine of nine non-regulated analytes for the subspecialty of toxicology for the year of 2024, affecting 21,525 patients. Findings include: 1. Review of the laboratory's policy and procedure manual revealed, under "Enrollment in Proficiency Testing", "Proficiency testing shall be enrolled in .... using whichever of the proficiency test providers is suitable and acceptable per CLIA regulations." 2. Review of CAP PT records revealed the laboratory failed to enroll in PT, and therefore failed to maintain method accuracy, for 17 of 17 non-regulated routine chemistry analytes in 2024: a) Carbon Dioxide b) Globulin c) Very Low Density Lipoprotein (VLDL) d) Urine Bilirubin e) Folic Acid (Folate) f) Urine Microalbumin g) Transferrin h) C-Reactive Protein, High Sensitivity (CRP-HS) i) Total Iron Binding Capacity (TIBC) j) Lipase k) Creatinine Urine l) Gamma-Glutamyl Transferase (GGT) m) Phosphorus n) Creatine Phosphokinase (CPK) Total o) Direct Bilirubin (D-Bili) p) C-Reactive Protein q) Urine Total Protein 3. Review of CAP PT records revealed the laboratory failed to enroll in PT, and therefore failed to maintain method accuracy, for nine of nine non-regulated toxicology analytes in 2024: a) Amphetamine b) Cocaine c) Opiate d) Barbiturates e) Benzodiazepines f) Methadone g) Phencyclidine (PCP) h) Buprenorphine i) Oxycodone 4. Review of patient test records found the laboratory

	reported out results for 21,525 chemistry patients, including toxicology patients, from 01/01/2024 through the date of survey, 09/25/2024. 5. Interview with the LD at 4:05 pm, on 09/24/2024, confirmed that the laboratory failed to maintain method accuracy testing procedures for the subspecialties of routine chemistry and toxicology for the year of 2024.
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 direct observations, review of laboratory records, policies and procedures, test volume worksheet, lack of documentation, and interviews with the laboratory director (LD) and testing personnel (TP); the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings include: 1. The laboratory failed to have a procedure manual in place for two of twelve molecular assays performed. See D5401. 2. The laboratory failed to outline all components of test procedures for ten of ten molecular assay procedures. See D5403. 3. The laboratory failed to ensure that the normal patient prothrombin mean study was performed after a new lot of Neoplastine reagent was implemented and prior to reporting patient results for the specialty of hematology, regarding to coagulation. See D5411. 4. The laboratory failed to ensure one of six agar media types, chocolate agar, used for bacteriology testing, had not exceeded its expiration date. See D5417. 5. The laboratory failed to establish the performance specifications for 12 of 12 molecular assays on three of four molecular platforms. See D5423. 6. The laboratory failed to include at least one control material that is capable of detecting errors through the extraction process for twelve of twelve molecular assays performed. See D5453. 7. The laboratory failed to check gram stains for positive and negative reactivity using control organisms at least each week of use. See D5503. 8. The laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between four of four thermal cycler platforms used for molecular testing. See D5775.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manuals, test volume worksheet, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to have a procedure manual in place for 2 of 12 molecular assays performed.

	Findings include: 1. Review of the laboratory's test volume worksheet revealed the following twelve molecular assays performed: a) Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas vaginalis Assay Set b) Claro Series Bacterial Vaginosis c) Claro Series Candida Vaginitis d) Claro Series Covid Direct Method e) Claro Series Respiratory Multiplex f) Sigmoida Gastroenteritis Panel g) Sigmoida Respiratory Pathogen Panel (RPP) h) Sigmoida Sexually Transmitted Infection (STI) Panel i) Sigmoida Antibiotic Resistance (ABR) Panel j) Sigmoida Urinary Tract Infections (UTI) Panel k) Sigmoida Series Wound Infection Panel l) Sigmoida Series Nail Panel 2. Review of the laboratory's policy and procedure manual found the laboratory lacked procedures for 2 of 12 molecular assays performed. i) Sigmoida Respiratory Pathogen Panel (RPP) ii) Sigmoida Series Nail Panel 3. Interview with the LD on 09 /25/2024, at 12:29 pm, revealed the laboratory failed to have procedures for 2 of 12 molecular assays performed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manuals, test volume worksheet, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to outline all components of test procedures for ten of ten molecular assay procedures. Findings include: 1. Review of the molecular assay procedures revealed the following ten of twelve molecular procedures failed to outline all components of a test procedure: 1) Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas vaginalis Assay Set 2) Claro Series Bacterial Vaginosis 3) Claro Series Candida Vaginitis 4) Claro Series Covid Direct Method 5) Claro Series Respiratory Multiplex 6) Sigmoida Gastroenteritis Panel 7) Sigmoida Sexually Transmitted Infection (STI) Panel 8) Sigmoida Antibiotic Resistance (ABR) Panel 9) Sigmoida Urinary Tract Infections (UTI) Panel 10) Sigmoida Series Wound Infection Panel 2. Review of the molecular assay procedures revealed the lack of the following required components of a test procedure: i) Step-by-step performance of the procedure. ii) Control procedures (See also D5453). iii) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. iv) The laboratory's system for entering results in the patient record and reporting results. 3. Interview with the LD on

	09/25/2024, at 12:29 pm, confirmed the laboratory failed to include all the required components of a test procedure for ten of ten molecular assays performed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on laboratory records, lack of documentation, and interviews with testing personnel (TP) #10 and the laboratory director (LD); the laboratory failed to ensure that the normal patient Prothrombin mean study was performed after a new lot of Neoplastine was implemented and prior to reporting patient results for the specialty of hematology, regarding to coagulation, affecting 45 patients. Findings include: 1. Review of laboratory policies and procedures revealed a lack of a coagulation procedure to ensure prothrombin reagent lot switchovers were conducted in a manner that provides test results within the laboratory's stated performance specifications. 2. Review of laboratory records revealed the laboratory lacked documentation for the establishment of a new normal patient Prothrombin mean study for a new lot of Neoplastine CI Plus Prothrombin reagent (Lot Number: 270756). 3. Interview with TP #10 on 09/25/2024, at 12:23 pm, revealed the Neoplastine CI Plus Prothrombin reagent was placed into use on 09/13/2024. 4. Review of patient test records found the laboratory reported out results for 45 patients from 09/13/2024 through the date of survey, 09/25/2024, for Prothrombin time. 5. Interview with the LD on 09/25/2024, at 11:52 am, confirmed the laboratory failed to verify that the normal patient Prothrombin mean study was performed prior to reporting patient results, affecting 45 patients.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and interviews with testing personnel (TP) #7 and the laboratory director (LD); the laboratory failed to ensure one of six agar media types, chocolate agar, used for bacteriology testing, had not exceeded its expiration date for patient testing for 16 days, from 09/09/2024 through 09/25/2024. Findings include: 1. Upon a tour of the laboratory on 09/24/2024, at 4:45 pm, surveyors observed expired chocolate agar media in the microbiology departments media refrigerator. a) Hardy Diagnostics Chocolate Agar, Reference Number E14, Expiration: 09-08-2024. 2. Interview with TP #7 and the LD on 09/25/2024, at 1:17 pm, confirmed the presence of expired chocolate agar media in the microbiology departments media refrigerator.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory records, test volume worksheet, and interview with testing personnel (TP) #1; the laboratory failed to establish the performance specifications for 12 of 12 laboratory developed test (LDT) molecular assays, including 172 organisms/analytes, on three of four molecular platforms. Findings include: 1. During a tour of laboratory on 09/24/2024, at 4:45 pm, four molecular thermal cycler platforms used for molecular LDT assays were observed. Instrument: Serial Number: 1) Bio-Rad CFX96 785BR30385 2) Bio-Rad CFX96 785BR27254 3) Bio-Rad CFX96 785BR28729 4) Applied Biosystems 2750110055 2. Review of the laboratory's test volume worksheet revealed the following twelve molecular assays performed: a) Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas vaginalis Assay Set 1. Chlamydia trachomatis 2. Neisseria gonorrhea 3. Trichomonas vaginalis b) Claro Series Bacterial Vaginosis 1. BVAB-2 / Megasphaera 1 / Megasphaera 2 2. Atopobium vaginae 3. Gardnerella vaginalis c) Claro Series Candida Vaginitis 1. Candida albicans 2. Candida dubliniensis 3. Candida glabrata 4. Candida parapsilosis 5. Candida tropicalis d) Claro Series Covid Direct Method 1. Covid-19 ORF1ab & E gene 2. Covid-19 N-gene e) Claro Series Respiratory Multiplex 1. SARS-CoV-2 2. Influenza A/B 3. Respiratory Syncytial Virus A/B f) Sigmoida Gastroenteritis Panel 1. Clostridium difficile Binary Toxin A/B 2. Clostridium difficile Toxin A 3. Clostridium difficile Toxin B 4. Enterotoxigenic E. coli (ETEC) 5. Enteropathogenic E. coli (EPEC) 6. Shiga Toxin Producing E. coli (STEC) 7. Enteroaggregative E. coli (EAEC) 8. Shigella / Enteroinvasive E. coli (EIEC) 9. Plesiomonas shigelloides 10. Yersinia enterocolitica 11. Vibrio cholerae 12. Vibrio parahaemolyticus 13. Vibrio vulnificus 14. Campylobacter spp 15. Salmonella spp 16. Adenovirus 17. Cryptosporidium spp 18. Cyclospora cayetanensis 19. Entamoeba histolytica 20. Giardia lamblia 21. Rotavirus (A) 22. Norovirus (GI/GII) 23. Astrovirus 24. Sapovirus (GI, GII, GIV, GV) g) Sigmoida Respiratory Pathogen Panel (RPP) 1. Influenza A 2. Influenza B 3. Staphylococcus aureus 4. Human Enterovirus/Human Rhinovirus 5. Human Metapneumoviruses 6. Haemophilus influenzae 7. Streptococcus pneumoniae 8. Parainfluenza 1 9. Parainfluenza 2 10. Parainfluenza 3 11. Parainfluenza 4 12. Respiratory Syncytial Virus A/B 13. Bordetella pertussis 14. Mycoplasma pneumoniae 15. Chlamydophila pneumoniae 16. Adenovirus 17. Human Corona OC43 18. Human Corona HKU1 19. Human Corona NL63 20. Human Corona 229E 21. Legionella pneumophila 22. Human Bocavirus 23. Human Parechovirus 24. Moraxella catarrhalis h) Sigmoida Sexually Transmitted Infection (STI) Panel 1. Trichomonas vaginalis 2. Treponema pallidum 3. Ureaplasma urealyticum/parvum 4. Herpes Simplex Virus 1 5. Herpes Simplex Virus 2 6. Mycoplasma genitalium 7. Mycoplasma hominis 8. Chlamydia trachomatis 9. Neisseria gonorrhoeae 10. Gardnerella vaginalis i) Sigmoida Antibiotic Resistance (ABR) Panel 1. CTX-M ESBL - Beta Lactamase 2. Van A - Vancomycin 3. Van B -

	Vancomycin 4. OXA - 48 - Carbapenem 5. IMP - Carbapenem 6. VIM - Carbapenem 7. NDM - Carbapenem 8. KPC - Carbapenem 9. Sulfonamide (Sul) 10. Trimethoprim 11. Fluoroquinolone (Qnr) 12. Methicillin (mecA+mecC) j) Sigmoida Urinary Tract Infections (UTI) Panel 1. Candida albicans 2. Candida glabrata 3. Streptococcus agalactiae 4. Klebsiella oxytoxa 5. Klebsiella aerogenes 6. Escherichia coli 7. Enterobacter cloacae complex 8. Pseudomonas aeruginosa 9. Klebsiella pneumoniae 10. Citrobacter freundii 11. Acinetobacter baumannii 12. Morganella morganii 13. Aerococcus urinae 14. Serratia marcescens 15. Staphylococcus saprophyticus 16. Providencia stuartii 17. Enterococcus faecalis 18. Enterococcus faecium 19. Candida auris 20. Candida parapsilosis 21. Candida krusei 22. Proteus mirabilis 23. Proteus vulgaris 24. Candida tropicalis 25. Corynebacterium urealyticum 26. Staphylococcus aureus 27. Treponema pallidum 28. Ureaplasma urealyticum 29. Ureaplasma parvum k) Sigmoida Series Wound Infection Panel 1. Varicella zoster virus 2. Herpes Simplex Virus 1 3. Herpes Simplex Virus 2 4. Mycobacterium abscessus/chelonae 5. Mycobacterium marinum 6. Mycobacterium fortuitum 7. Mycobacterium avium complex 8. Cutibacterium spp 9. Clostridium septicum 10. Clostridium novyi 11. Clostridium perfringens 12. Burkholderia spp 13. Acinetobacter baumannii 14. Enterobacter cloacae complex 15. Escherichia coli 16. Proteus spp 17. Citrobacter freundii complex 18. Klebsiella oxytoca 19. Klebsiella pneumoniae 20. Streptococcus saprophyticus 21. Streptococcus agalactiae 22. Enterococcus spp 23. Serratia marcescens 24. Morganella morganii 25. Streptococcus pyogenes 26. Pseudomonas aeruginosa 27. Providencia stuartii 28. Klebsiella aerogenes 29. Staphylococcus aureus 30. Staphylococcus epidermidis l) Sigmoida Series Nail Panel 1. Malassezia restricta 2. Malassezia globose 3. Malassezia furfur 4. Aspergillus terreus 5. Aspergillus fumigatus 6. Aspergillus flavus 7. Aspergillus niger 8. Fusarium oxysporum 9. Trichophyton mentagrophytes/interdigitale 10. Trichophyton verrucosum 11. Trichophyton violaceum 12. Trichophyton rubrum 13. Trichophyton tonsurans 14. Trichophyton mucoides 15. Trichophyton terrestre 16. Trichophyton soudanense 17. Epidermophyton floccosum 18. Trichosporon asahii 19. Malassezia sympodialis 20. Microsporum canis 21. Microsporum audouinii 22. Microsporum gypseum 23. Candida krusei 24. Candida glabrata 25. Candida albicans 26. Candida parapsilosis 27. Candida auris 3. Interview with TP #1 on 09/24/2024, at 5:07 pm, confirmed that each thermal cycler platform performed all twelve above-mentioned molecular assays and that instrument #4 (Applied Biosystems) performed only Claro assays. 4. Review of laboratory records of verification of performance revealed that the laboratory failed to perform verification of performance for three of four thermal cycler platforms. Instrument: Verification Completed: 1 Yes 2 No 3 No 4 No 5. Interview with TP #1 on 09/24/2024, at 5:09 pm, confirmed that three of four of their molecular thermal cycler platforms did not have verification of performance completed prior to patient testing.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(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 test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	Based on review of laboratory policies and procedures, lack of documentation, the laboratory's test volume worksheet, and interview with testing personnel (TP) #1; the laboratory failed to include at least one control material that is capable of detecting errors through the extraction process for 12 of 12 molecular assays performed from 2023 through the date of survey, 09/25/2024. Findings include: 1. Review of the laboratory's test volume worksheet revealed the following twelve molecular assays performed: a) Chlamydia trachomatis, Neisseria gonorrhea, Trichomonas vaginalis Assay Set b) Claro Series Bacterial Vaginosis c) Claro Series Candida Vaginitis d) Claro Series Covid Direct Method e) Claro Series Respiratory Multiplex f) Sigmoida Gastroenteritis Panel g) Sigmoida Respiratory Pathogen Panel (RPP) h) Sigmoida Sexually Transmitted Infection (STI) Panel i) Sigmoida Antibiotic Resistance (ABR) Panel j) Sigmoida Urinary Tract Infections (UTI) Panel k) Sigmoida Series Wound Infection Panel l) Sigmoida Series Nail Panel 2. Review of the laboratory's policy and procedure manual revealed an extraction kit procedure entitled, "Claro Series RNA /DNA Extraction Kit", which lacked any reference to the use of quality control (QC) materials utilized through the extraction phase of molecular testing. 3. Review of the above-mentioned molecular assays' procedures revealed that 12 of 12 molecular procedures failed to address the use of control material utilized through the extraction phase of molecular testing (See also D5401 and D5403). 4. Upon a tour of the laboratory on 09/24/2024, at 5:07 pm, TP #1 confirmed that no QC material was utilized through the extraction process for 12 of 12 molecular assays performed.
D5503	BACTERIOLOGY CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP) #7; the laboratory failed to check gram stains for positive and negative reactivity using control organisms at least each week of use for years reviewed, 2023 through the survey date of 09/25/2024. Findings include: 1. Review of laboratory records revealed a lack of documentation of weekly gram stain positive and negative reactivity. 2. Interview with TP #7 on 09/25/2024, at 1:24 pm, stated that gram stain positive and negative reactivity was performed each day of patient testing, but was not documented anywhere in the laboratory.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation and interview with testing personnel (TP) #1; the laboratory failed to have a system in place that twice a year evaluates and defines the comparison of test results between four of four thermal

	cycler platforms used for 172 molecular organisms/analytes in the years of 2023 through the survey date, 09/25/2024. Findings include: 1. During a tour of laboratory on 09/24/2024, at 4:45 pm, four molecular thermal cycler platforms used for molecular LDT assays were observed. Instrument: Serial Number: 1) Bio-Rad CFX96 785BR30385 2) Bio-Rad CFX96 785BR27254 3) Bio-Rad CFX96 785BR28729 4) Applied Biosystems 2750110055 2. Review of laboratory records found the laboratory lacked documentation for instrument-to-instrument test result comparisons for four of four thermal cycler platforms used for 172 molecular organisms/analytes. 3. An interview with TP #1 on 09/24/2024 at 5:07 pm, confirmed that no policy /procedure or documents/results of instrument-to-instrument test result comparison were available nor had been performed.
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 laboratory policy and procedure manual, direct observation, review of laboratory records, the Federal Casper Report 0096D, College of American Pathologist (CAP) proficiency testing (PT) records, laboratory test volume worksheet, lack of documentation, and interviews with the laboratory director (LD) and testing personnel (TP) #1; the laboratory director failed to provide the overall management and direction to maintain proper laboratory operation. Findings include: 1. The LD a) failed to ensure the laboratory was enrolled in appropriate PT testing challenges for 21 of 21 regulated analytes for the subspecialty of routine chemistry and two of two regulated analytes for the specialty of hematology, regarding coagulation, and b) failed to maintain method accuracy testing procedures for 17 of 17 non-regulated analytes for the subspecialty of routine chemistry and nine of nine non-regulated analytes for the subspecialty of toxicology. See D6088. 2. The LD failed to ensure the performance specifications for 12 of 12 laboratory developed test (LDT) molecular assays, including 172 organisms/analytes, on three of four molecular platforms. See D6095. 3. The LD failed to ensure an approved and complete procedure manual was available for all aspects of the testing process. See D6106.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual, the Federal Casper Report 0096D, College of American Pathologist (CAP) proficiency testing (PT) records, laboratory test volume worksheet, lack of documentation, and interview with the laboratory director (LD); the LD a) failed to ensure the laboratory was enrolled in appropriate PT testing challenges for 21 of 21 regulated analytes for the subspecialty of routine chemistry and two of two regulated analytes for the specialty of hematology, regarding coagulation, for the year 2024, affecting 22,344 patients (See D2000), and

	b) failed to maintain method accuracy testing procedures for 17 of 17 non-regulated analytes for the subspecialty of routine chemistry and nine of nine non-regulated analytes for the subspecialty of toxicology for the year of 2024, affecting 21,525 patients (See D2003).
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, test volume worksheet, and interview with testing personnel (TP) #1; the laboratory director failed to ensure the performance specifications for 12 of 12 laboratory developed test (LDT) molecular assays, including 172 organisms/analytes, on three of four molecular platforms. See D5423.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manuals, test volume worksheet, lack of documentation, and interview with the laboratory director (LD); the LD failed to ensure an approved and complete procedure manual was available for all aspects of the testing process. See D5401 and D5403.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records, lack of documentation, and interview with the laboratory director; the laboratory failed to ensure 1 of 13 testing personnel were qualified for high complexity testing. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned

an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of laboratory personnel records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to ensure 1 of 13 testing personnel (TP) was qualified for high complexity testing. Findings include: 1. Review of personnel educational documentation revealed 1 of 13 TP, TP #5, failed to

	have qualifying documentation for high complexity testing prior to reporting test results. 2. On survey date 09/25/2024, at approximately 5:30 pm, the LD notified the surveyor that they had spoken to TP #5 and were in process of requesting to receive necessary foreign equivalency documentation to qualify TP #5 as a high complexity TP. 3. As of 10/10/2024, at 5:35 pm, no foreign equivalency documentation had been provided to the surveyor to qualify the individual as a high complexity TP.