Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2006925	04/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Quality Lab One	1325 Ogden Ave, Downers Grove, 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: Based on review of laboratory records, direct observation, lack of documentation and interview with testing personnel (TP 1), the laboratory failed to enroll in proficiency testing (PT) challenges for four of four microbiology subspecialties (Bacteriology, Mycology, Parasitology and Virology) for the Sexually Transmitted Diseases (STD), Urinary Tract Infections (UTI), Respiratory Pathogens 1 and Respiratory Pathogens 2, molecular panels performed. Findings include: 1. On 04/23/2025, at 1:31 p.m., the surveyor observed four of four microbiology molecular profile kits: (BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX STI Profile Kit (LOT CK-04102025-001, EXP: 03/2026) and the BioPathogenix qPLEX Urinary Tract Profile Kit (LOT CK-04102025-001, EXP: 03/2026) stored in the laboratory freezer marked "Freezer 1". 2. Review of laboratory records and lack of documentation revealed the laboratory failed to enroll in proficiency testing challenges for the following sub-specialties: Bacteriology - 42 analytes performed as listed below: a) Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma hominis, Ureaplasma urealyticum, Mycoplasma genitalium, Ureaplasma parvum, Staphylococcus aureus, Acinetobacter baumannii,

	Enterococcus faecalis, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, Enterobacter cloacae, Proteus mirabilis, Morganella morganii, Citrobacter freundii, Proteus vulgaris, Klebsiella aerogenes, Enterococcus faecium, Providence stuartii, Serratia marcescens, Staphylococcus saprophyticus, Streptococcus agalactiae, AmpC Resistance Marker (ampC), Methicillin Resistance Marker (mecA, femA), Quinolone and fluoroquinolone Resistance Marker (QnrB, QnrA), Vanomycin Resistance Marker (vanA1, vanA2, vanB), Carbapenem Resistance Marker (NDM, KPC, VIM/IMP-7), ESBL Resistance Marker (SHV, TEM, CTX-M group 1, CTX-M group 2), and Macrolide Resistance Marker (mefA, ErmA, ErmB); Mycology - Seven analytes performed as listed below: b) Candida tropicalis, Candida krusei, Candida albicans, Candida glabrata, Candida auris, Candida lusitaniae, Candida parapsilosis; Virology - 44 analytes performed as listed below: c) Influenza A, Influenza B, Human Respiratory Syncytial Virus A, Human Respiratory Syncytial Virus B, Influenza C, Influenza A/H3, Influenza A/H1-2009, Human Coronavirus OC43, Human Coronavirus 229E, Human Coronavirus NL63, Human Coronavirus HKU1, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human enterovirus, Human metapneumovirus A/B, MERS, SARS, Human bocavirus, Human rhinovirus, Human parechovirus, Human adenovirus 3, Coxiella burnetiid, Pneumocystis jirovecii, Moraxella catarrhalis, Klebsiella pneumoniae, Streptococcus pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella longbeach, Legionella pneumophila, Haemophilus influenzae, Haemophilus influenzae B, Bordetella parapertussis, Bordetella pertussis, Bordetella holmesii, Group A Strep, Group B Strep, Group C & G Strep, Staphylococcus aureus, PVL (Panton-Valentine leukocidin), mecA (Methicillin resistance in Staphylococcus aureus), and van A/B (Vancomycin resistance); Parasitology - one analyte performed as listed below: d) Trichomonas vaginalis 3. On 04/23/2025, at 3:17 p.m., TP 1 confirmed the laboratory did not have PT enrollment records available during the time of survey.
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on surveyor's direct observation, review of laboratory records, and interview with testing personnel (TP 1), the laboratory failed to maintain a uni-directional workflow for molecular amplification procedures to prevent potential cross-contamination in specimen processing, preparation, amplification, and detection of four of four microbiology analyte panels for Sexually Transmitted Diseases (STD), Urinary Tract Infections (UTI) and Respiratory Pathogens 1 and 2. Findings include: 1. On 04/23/2025, at 11:53 a.m., direct observation during a laboratory tour with TP 1 revealed the laboratory failed to maintain a uni-directional workflow for the molecular amplification of STD, UTI and Respiratory Pathogens 1 and 2: a) The transfer of patient samples to the patient testing plates and the addition of positive and negative control samples to the patient testing plates all performed in one biosafety cabinet (BSC) "Pro-Lab Diagnostics Serial No. BSC13A1909211"; b) Patient sample preparation and sample amplification utilizing the "QuantStudio 5 Real-Time PCR Instrument ...SN: 272531573" all conducted in the same laboratory space. 2. On 04/23

	/2025, at 3:17 p.m., TP 1 confirmed all testing was conducted in the same laboratory space.
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 review of laboratory records, direct observation, lack of documentation and interview with the laboratory manager (LM) and testing personnel (TP 1), the laboratory failed to establish a written procedure manual for testing four of four high complexity microbiology molecular profile kits BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile and the BioPathogenix qPLEX Urinary Tract Profile Kit (refer to D5401); failed to record the temperatures of the laboratory freezer marked "Freezer 1" and laboratory refrigerator marked "Maximum Refrigerator - Refrigerator 1" for the storage of four of four high complexity microbiology molecular profile kits, BioPathogenix qPLEX Respiratory Pathogen 1 Profile, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit and the BioPathogenix qPLEX Urinary Tract Profile Kit and one BPX DUO Direct-Detect Kit, EXP: 08102025 (refer to D5413); failed to establish the performance specifications for four of four high complexity microbiology molecular profiles using the BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile and the BioPathogenix qPLEX Urinary Tract Profile kits utilizing the QuantStudio 5 Real - Time PCR Instrument (Serial Number: 272531573) (refer to D5423).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 records, direct observation, lack of documentation and interview with the laboratory manager (LM), the laboratory failed to establish a written procedure manual for testing four of four high complexity microbiology molecular profile kits (BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile and the BioPathogenix qPLEX Urinary Tract Profile Kit). Findings include: 1. On 04/23/2025, at 1:31 p.m., the surveyor observed four microbiology molecular profile kits: BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit (Lot

	CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX STI Profile Kit (LOT CK-04102025-001, EXP: 03/2026) and the BioPathogenix qPLEX Urinary Tract Profile Kit (LOT CK-04102025-001, EXP: 03/2026) stored in the laboratory freezer marked "Freezer 1". 2. Review of laboratory records revealed no documentation of the required procedures for testing: a) 42 of 42 bacteriology analytes (Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma hominis, Ureaplasma urealyticum, Mycoplasma genitalium, Ureaplasma parvum, Staphylococcus aureus, Acinetobacter baumannii, Enterococcus faecalis, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, Enterobacter cloacae, Proteus mirabilis, Morganella morganii, Citrobacter freundii, Proteus vulgaris, Klebsiella aerogenes, Enterococcus faecium, Providence stuartii, Serratia marcescens, Staphylococcus saprophyticus, Streptococcus agalactiae, AmpC Resistance Marker (ampC), Methicillin Resistance Marker (mecA, femA), Quinolone and fluoroquinolone Resistance Marker (QnrB, QnrA), Vanomycin Resistance Marker (vanA1, vanA2, vanB), Carbapenem Resistance Marker (NDM, KPC, VIM/IMP-7), ESBL Resistance Marker (SHV, TEM, CTX-M group 1, CTX-M group 2), and Macrolide Resistance Marker (mefA, ErmA, ErmB); b) Seven of seven mycology analytes (Candida tropicalis, Candida krusei, Candida albicans, Candida glabrata, Candida auris, Candida lusitaniae, Candida parapsilosis); c) 44 of 44 virology analytes (Influenza A, Influenza B, Human Respiratory Syncytial Virus A, Human Respiratory Syncytial Virus B, Influenza C, Influenza A/H3, Influenza A/H1-2009, Human Coronavirus OC43, Human Coronavirus 229E, Human Coronavirus NL63, Human Coronavirus HKU1, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human enterovirus, Human metapneumovirus A/B, MERS, SARS, Human bocavirus, Human rhinovirus, Human parechovirus, Human adenovirus 3, Coxiella burnetiid, Pneumocystis jirovecii, Moraxella catarrhalis, Klebsiella pneumoniae, Streptococcus pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella longbeach, Legionella pneumophila, Haemophilus influenzae, Haemophilus influenzae B, Bordetella parapertussis, Bordetella pertussis, Bordetella holmesii, Group A Strep, Group B Strep, Group C & G Strep, Staphylococcus aureus, PVL (Panton-Valentine leukocidin), mecA (Methicillin resistance in Staphylococcus aureus), and van A/B (Vancomycin resistance); d) One of one parasitology analyte (Trichomonas vaginalis). 3. On 04/23 /2025 at 11:53 a.m., the LM confirmed via telephone interview, no procedure manual was available on-site for surveyor review.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to record the

	temperatures of the laboratory freezer marked "Freezer 1" and laboratory refrigerator marked "Maximum Refrigerator - Refrigerator 1" for the storage of four of four high complexity microbiology molecular profile kits BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit, BioPathogenix qPLEX Urinary Tract Profile Kit and one BPX DUO Direct-Detect Kit, EXP: 08102025. Findings include: 1. During a tour of the laboratory on 04/23/2025 at 11:53 a.m., the surveyor observed four high complexity microbiology molecular profile kits (BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit, BioPathogenix qPLEX Urinary Tract Profile Kit) in the laboratory freezer marked "Freezer 1". 2. Review of the four microbiology molecular profile kits listed in Finding 1 revealed the temperature range requirements as listed below: a) BioPathogenix qPLEX Respiratory Pathogen Profile Kits 1 and 2 (Lot CK-04102025-001, EXP: 03/2026) - Temperature range: -10 to - 30 degrees Celcius b) BioPathogenix qPLEX STI Profile Kit (LOT CK-04102025-001, EXP: 03/2026) - Temperature range: -10 to - 30 degrees Celcius c) BioPathogenix qPLEX Urinary Tract Profile Kit (LOT CK-04102025-001, EXP: 03/2026) - Temperature range: -10 to - 30 degrees Celsius 3. On 04/23/2025, at 1:10 p.m., surveyor direct observation also revealed reagents stored in the laboratory refrigerator marked, "Maximum Refrigerator - Refrigerator 1". a) BPX DUO Direct-Detect Kit, EXP: 08102025, TEMPERATURE RANGE: 2 to 4 degrees Celcius 4. Review of laboratory records and lack of documentation revealed no records to monitor the temperature ranges for laboratory "Freezer 1" and laboratory "Refrigerator 1". 5. On 04/23/2025, at 2:33 p.m., TP 1 stated that the laboratory was not documenting the daily temperatures of the freezer marked "Freezer 1" and refrigerator marked, "Maximum Refrigerator - Refrigerator 1".
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory records, laboratory tour, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to establish the performance specifications for four of four high complexity microbiology molecular profiles using the BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile and the BioPathogenix qPLEX Urinary Tract Profile kits utilizing the QuantStudio 5 Real - Time PCR Instrument (Serial Number: 272531573). Findings include: 1. During a tour of the laboratory on 04/23/2025 at 11:53 a.m., the surveyor observed four of four high complexity microbiology molecular profile kits in the laboratory freezer "Freezer 1": a) BioPathogenix qPLEX Respiratory Pathogen 1

	Profile (Lot CK-04102025-001, EXP: 03/2026) b) BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit (Lot CK-04102025-001, EXP: 03/2026) c) BioPathogenix qPLEX STI Profile (LOT CK-04102025-001, EXP: 03/2026) d) BioPathogenix qPLEX Urinary Tract Profile (LOT CK-04102025-001, EXP: 03/2026). 2. The surveyor also observed a total of 80 small blue top samples marked "UTI, STI, RPR V1 and RPR V2". 3. The tour of the laboratory also revealed a QuantStudio 5 Real - Time PCR Instrument (Serial Number: 272531573). 4. Review of laboratory records revealed no documentation of Accuracy, Precision, Analytical sensitivity, Analytical specificity to include interfering substances, Reportable range of test results for the test system, Reference intervals (normal values), and any other performance characteristics required for adequate test performance for the four profile kits listed in Finding 1. 5. On 04/23/2025 at 2:01 p.m., TP 1 described the 80 samples listed in Finding 2 as extractions for the validation study. The validation study was not on-site for surveyor review.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with testing personnel (TP 1), the laboratory failed to ensure the training of one of one testing personnel (TP 1) listed on the CMS - 209 form for testing high complexity microbiology molecular profile kits BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit and the BioPathogenix qPLEX Urinary Tract Profile Kit. Findings include: 1. On 04/23/2025, at 1:31 p.m., the surveyor observed four of four microbiology molecular profile kits: BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX STI Profile Kit (LOT CK-04102025-001, EXP: 03/2026) and the BioPathogenix qPLEX Urinary Tract Profile Kit (LOT CK-04102025-001, EXP: 03/2026) stored in the laboratory freezer marked "Freezer 1". 2. On 04/23/2025, at 3: 17 p.m., TP 1 stated the laboratory failed to have training records available for the microbiology profile kits listed in Finding 1.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 (a) Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. (b) All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of laboratory records, direct observation, lack of documentation and interview with the laboratory manager (LM) and testing personnel (TP 1), the

	laboratory failed to allow the surveyor to assess documentation of enrollment in proficiency testing for four of four microbiology subspecialties (Bacteriology, Mycology, Parasitology and Virology) for the Sexually Transmitted Diseases (STD), Urinary Tract Infections (UTI), Respiratory Pathogens 1 and Respiratory Pathogens 2, molecular panels performed; failed to establish a written procedure manual for testing four of four microbiology subspecialties (Bacteriology, Mycology, Parasitology and Virology) utilizing molecular profile kits (BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit and the BioPathogenix qPLEX Urinary Tract Profile Kit); failed to provide documentation of recorded temperatures of the laboratory freezer marked "Freezer 1" and laboratory refrigerator marked "Maximum Refrigerator - Refrigerator 1"; failed to provide documentation for the establishment of performance specifications for the BioPathogenix qPLEX Respiratory Pathogen 1 Profile kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile kit, BioPathogenix qPLEX STI Profile kit and the BioPathogenix qPLEX Urinary Tract Profile kit utilizing the QuantStudio 5 Real - Time PCR Instrument (Serial Number: 272531573); failed to provide training documentation of testing personnel (TP 1) listed on the CMS - 209 form for testing high complexity microbiology molecular profile kits BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit and the BioPathogenix qPLEX Urinary Tract Profile Kit within a reasonable timeframe. (Refer to D8103).
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, lack of documentation and interview with the laboratory manager (LM) and testing personnel (TP 1), the laboratory failed to allow the surveyor to assess documentation of enrollment in proficiency testing for four of four microbiology subspecialties (Bacteriology, Mycology, Parasitology and Virology) for the Sexually Transmitted Diseases (STD), Urinary Tract Infections (UTI), Respiratory Pathogens 1 and Respiratory Pathogens 2, molecular panels performed; failed to establish a written procedure manual for testing four of four microbiology subspecialties (Bacteriology, Mycology, Parasitology and

	Virology) utilizing molecular profile kits (BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit and the BioPathogenix qPLEX Urinary Tract Profile Kit); failed to provide documentation of recorded temperatures of the laboratory freezer marked "Freezer 1" and laboratory refrigerator marked "Maximum Refrigerator - Refrigerator 1"; failed to provide documentation for the establishment of performance specifications for the BioPathogenix qPLEX Respiratory Pathogen 1 Profile kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile kit, BioPathogenix qPLEX STI Profile kit and the BioPathogenix qPLEX Urinary Tract Profile kit utilizing the QuantStudio 5 Real - Time PCR Instrument (Serial Number: 272531573); failed to provide training documentation of testing personnel (TP 1) listed on the CMS - 209 form for testing high complexity microbiology molecular profile kits BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit, BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit, BioPathogenix qPLEX STI Profile Kit and the BioPathogenix qPLEX Urinary Tract Profile Kit within a reasonable timeframe. Findings include: 1. On 04/23/2025, at 11:30 a.m., an initial survey was conducted as requested by the lab director. The following items were not provided for surveyor review as requested: a) documentation of enrollment in proficiency testing challenges for testing for four of four microbiology subspecialties (Bacteriology, Mycology, Parasitology and Virology) utilizing molecular profile kits: BioPathogenix qPLEX STI Profile (LOT CK-04102025-001, EXP: 03/2026) the BioPathogenix qPLEX Urinary Tract Profile (LOT CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX Respiratory Pathogen 1 (Lot CK-04102025-001, EXP: 03 /2026), BioPathogenix qPLEX Respiratory Pathogen 2 (Lot CK-04102025-001, EXP: 03/2026) (refer to D2000); b) established procedure manual for testing four of four microbiology subspecialties (Bacteriology, Mycology, Parasitology and Virology) utilizing molecular profile kits: BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX STI Profile Kit (LOT CK-04102025-001, EXP: 03/2026) and the BioPathogenix qPLEX Urinary Tract Profile Kit (LOT CK-04102025-001, EXP: 03 /2026 (refer to D5401); c) recorded temperatures of the laboratory freezer marked "Freezer 1" and laboratory refrigerator marked "Maximum Refrigerator - Refrigerator 1" used for the storage of: - BioPathogenix qPLEX Respiratory Pathogen Profile Kits 1 and 2 (Lot CK-04102025-001, EXP: 03/2026) - Temperature range: -10 to -30 degrees Celsius - BioPathogenix qPLEX STI Profile Kit (LOT CK-04102025-001, EXP: 03/2026) - Temperature range: -10 to -30 degrees Celsius - BioPathogenix qPLEX Urinary Tract Profile Kit (LOT CK-04102025-001, EXP: 03/2026) - Temperature range: -10 to -30 degrees Celsius - BPX DUO Direct-Detect Kit, EXP: 08102025, TEMPERATURE RANGE: 2 TO 4 degrees Celsius (Maximum Refrigerator - Refrigerator 1) (refer to D5413); d) establishment of performance specifications for the BioPathogenix qPLEX Respiratory Pathogen 1 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX Respiratory Pathogen 2 Profile Kit (Lot CK-04102025-001, EXP: 03/2026), BioPathogenix qPLEX STI Profile (LOT CK-04102025-001, EXP: 03/2026) and the BioPathogenix qPLEX Urinary Tract Profile (LOT CK-04102025-001, EXP: 03/2026) kits utilizing the QuantStudio 5 Real - Time PCR Instrument (Serial Number: 272531573) (refer to D5423); e) training documentation of testing personnel (TP 1) (refer to D6102). 2. On 04/23/2025, at 3:17 p.m., TP 1 confirmed the requested documentation listed in Finding 1 was not available for surveyor review during the time of survey.