Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2116443	03/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Igenomedx Inc	2040 Babcock Road, Suite 201, San Antonio, TX	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on laboratory policy, proficiency testing (PT) records, and confirmed in interview, the laboratory director and testing personnel failed to attest to the routine integration of PT samples into the patient workload for 18 of 18 PT events in 2024 and 2025. Findings included: 1. Review of laboratory policy, "Proficiency Testing Policy" (Approved by the laboratory director on 01/23/2025) revealed the following: " ...A. Test Methodology: ...Testing personnel will sign the attestation sheet documenting the proficiency testing samples were tested in the same manner as patient specimens." 2. Review of laboratory PT records in 2024 and 2025 revealed the laboratory director and testing personnel failed to document attestation of routine integration of PT samples into the patient workload for the following 18 of 18 PT events in 2024 and 2025: 2024 a. PT Event: Gastrointestinal Panel Survey (GIP) 5; Event A b. PT Event: GIP 5; Event B c. PT Event: GIP 5; Event C d. PT Event: C. trachomatis and N. gonorrhoeae by Nucleic Acid (HC) 6; Event A e. PT Event: HC 6; Event B f. PT Event: HC 6; Event C g. PT Event: Infectious Disease, Respiratory Panel Survey (IDR); Event A h. PT Event: IDR; Event B i. PT Event: IDR; Event C 2025 j. GIP 5; Event A k. GIP 5; Event B l. GIP 5; Event C m. PT Event: HC 6; Event A n. PT Event: HC 6; Event B o. PT Event: HC 6; Event C p. PT Event: IDR; Event A q. PT Event: IDR; Event B r. PT Event: IDR; Event C The laboratory was asked to provide documentation of attesting to the above PT samples integrated into the patient workload, and no documentation was provided. 3. In an interview on 03/02/2026 at 0948 hours in the laboratory conference room, technical supervisor-1 (TS-1), confirmed the laboratory director and testing personnel failed to attest to the routine

	integration of PT samples into the patient workload for 18 of 18 PT events in 2024 and 2025.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records and staff interview, the laboratory failed to have documentation of performing twice annual accuracy assessments in 2024 and 2025 for 15 of 15 analytes tested on the Olympus AU400. The findings included: 1. A review of the the laboratory's test menu identified the following 15 tests were performed on the Olympus AU400: Nitrite pH Specific gravity Urine Creatinine 6-acetylmorphine Amphetamine Barbiturates Benzodiazepines Buprenorphine Cannabinoids Cocaine EDDP Methamphetamine Opiates Oxycodone 2. A review of the laboratory's records from 2024 and 2025 determined the laboratory failed to have documentation of performing twice annual accuracy assessments for the identified analytes for 4 of 4 events in 2024 and 2025. 3. General supervisor number 1 (as listed on Form CMS 209) stated the accrediting agency stated twice annual competency assessments were not required for tests that were reported out qualitatively in an interview conducted on 03/02/2026 at 1145 hours in the conference room. This confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policy, twice annual accuracy assessments, and confirmed in interview, the laboratory failed to document evaluation of all unsatisfactory scores for one of two events in 2025. Findings included: 1. Review of laboratory policy, "Proficiency Testing Policy" (Approved by the laboratory director on 01/23/2025) revealed the following: " ...F. For tests that are not tested in a formal proficiency testing program, a verification system is in place. Acceptable methods of evaluating accuracy and reliability include the following: Every 6 months, the laboratory sends five specimens to a CLIA certified laboratory for comparison with its own results." 2. Review of laboratory molecular twice annual accuracy assessments in 2025 revealed the following unsatisfactory scores: Sexually Transmitted Infection Event 2; July 2025 a. Sample: E37-STI-1 Target: Ureaplasma parvum Performance: Not Acceptable b. Sample: E37-STI-4 Target: Ureaplasma parvum Performance: Not Acceptable c. Sample: E37-STI-5 Target: Ureaplasma urealyticum Performance: Not Acceptable d. Sample: E37-STI-5 Target: Ureaplasma parvum Performance: Not Acceptable e. Sample: E37-STI-6 Target: Ureaplasma urealyticum Performance: Not Acceptable The laboratory was asked to provide documentation of evaluation of the above unsatisfactory scores in 2025, and no documentation was provided. 3. During an interview on 03/02/2026 at 1115 hours in the laboratory conference room, the technical supervisor (TS-1) confirmed the laboratory failed to document evaluation of all unsatisfactory scores for one of two events in 2025.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: i. Based on review of the laboratory's policies, review of patient test records from February 6, 2026 to February 23, 2026 and staff interview, the laboratory failed to have a mechanism in place to ensure samples were delivered to the laboratory within acceptable temperature ranges for 9 of 9 days. The findings included: 1. A review of the laboratory's policy titled "Toxicology Sample Stability, Storage and Rejection" determined the laboratory had the following defined sample stability and storage requirements: a) Urine drug screen and validity testing: 18 - 25C for 8 days 2 - 8C for 8 days b) Urine drug LCMS Confirmation testing: 18 - 25C for 14 days 2 - 8C for 14 days 2. A sampling of patient samples received from February 6, 2026 to February 23, 2026 determined the laboratory failed to have a mechanism in place to assess the temperature of samples received by the laboratory to ensure they meet the laboratory's requirements. They were: a) 02/06/2026 Sample ID: 2602090030 b) 02/09/2026 Sample ID: 2602090036 c) 02/10/2026 Sample ID: 2602100003 Sample ID: 2602100004 d) 02/11/2026 Sample ID: 2602110007 e) 02/12/2026 Sample ID: 2602120010 Sample ID: 2602120009 f) 02/13/2026 Sample ID: 2602130007 Sample ID: 2602130006 Sample ID: 2602130001 g) 02/19/2026 Sample ID: 2602190019 Sample ID: 2602190013 h) 02/20/2026 Sample ID: 2602230004 i) 02/23/2026 Sample ID: 2602230021 3. General supervisor number 1 (as listed on Form CMS 209) confirmed the laboratory did have a mechanism in place to ensure samples maintained the required temperatures during transport to the laboratory in an interview conducted on 03/02/2026 at 1445 hours in the conference room. 44278 ii. Based on surveyor observation, review of laboratory policy, and confirmed in interview, the laboratory failed to have a mechanism in place to ensure samples were delivered to the laboratory within acceptable temperature ranges for ten of ten randomly reviewed patient specimens in 2026. Findings included: 1. During a tour of the facility on 03/02 /2026 at 1100 hours, the surveyor observed the following ten molecular patient specimens received in the laboratory from Fedex shipping services: Received Date: 03 /02/2026 a. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020010 b. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020009 c. Sample Type: Nasopharyngeal Swab /Respiratory PCR; Sample Identification (ID): 2603020008 d. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020007 e. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020006 f. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020005 g. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020004 h. Sample Type: Nasopharyngeal Swab /Respiratory PCR; Sample Identification (ID): 2603020003 i. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020002 j. Sample Type: Nasopharyngeal Swab/Respiratory PCR; Sample Identification (ID): 2603020001 The testing person was asked if the sample temperatures were recorded upon receipt in the laboratory. The testing personnel stated she did not record the

	temperature of samples, and the temperature was not monitored during shipping. 2. Review of laboratory policy, "Stability Assay RPP" (Approved by the laboratory director on 09/22/2019) revealed the following sample stability requirements: Respiratory Pathogen Panel Stability Assay RPP Instrument: QuantStudio Nasopharyngeal Swabs: 2-8 C for 14 days 3. During an interview on 03/02/2026 at 1105 hours in the laboratory conference room, the technical supervisor (TS-1) confirmed the laboratory failed to have a mechanism in place to ensure samples were delivered to the laboratory within acceptable temperature ranges for ten of ten randomly reviewed patient specimens in 2026. Word Key C- Celsius
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 the laboratory's procedures for testing performed on the LC-MS /MS, review of urine confirmation results from February 2026, review of oral fluid confirmation results from October 2025 - December 2025, and staff interview, the laboratory failed its procedures for not reporting patient results when the sample had exceeded stability for 2 of 2 samples. The findings included: 1. The laboratory's procedure titled "Measurement of Pain Management Drugs in Urine via LC-MS/MS" (dated 05/19/2021) under the section titled "Specimen Rejection Criteria" stated: "If the specimen is collected less than 14 days but more than 7 days, 7-aminoclonazepam test should not be ordered." 2. The laboratory's procedure titled "Measurement of Pain Management Drugs in Oral Fluid via LC-MS/MS (dated 11/21/2023) under the section titled "Specimen Rejection Criteria" stated: "If the specimen is collected less than 14 days but more than 7 days, test(s) for Bupropion/cocaine/Olanzapine /Lorazepam should not be ordered." 3. A review of urine confirmation results from February 2026 identified the following result for which 7-aminoclonazepam should not have been ordered, tested, or reported: Sample: 2602100003 collection date: 02/04 /2026 received date: 02/10/2026 test date: 02/13/2026 elapsed time: 9 days 4. A review of oral fluid results from October 2025 - December 2025 identified the following result for which bupropion, cocaine, olazapine, and lorazepam should not have been ordered, tested, or reported: Sample: 2511120010 collection date: 11/10 /2025 received date: 11/12/2025 test date: 11/18/2025 elapsed time: 8 days 5. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings after his review of the records during interviews conducted on 03/03/2026 at 1050 hours and 1205 hours in the conference room. He stated the stability of the identified drugs had been exceeded and should not have been reported.
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:
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of calibration material currently in use in the laboratory on 03/03/2026 at 1100 hours in the laboratory, review of the laboratory's procedure for Urine Drug Confirmation via LC-MS/MS, and staff interview, the laboratory failed to label 8 of 8 calibration materials with preparation and expiration dates. The findings included: 1. Surveyor observation of calibration material in use in the laboratory on 03/03/2026 at 1100 hours identified 8 vials of calibration material labeled "1" through "8". No other documentation was seen on the vials or the rack in which the vials were stored. 2. The laboratory's procedure titled "Measurement of Pain Management Drugs in Urine via LC-MS/MS (signed 06/01/2021) under the section titled "6.3. Working Calibrator Stock" stated: "There are eight levels of Working Calibration Stock (WCS) in total...The prepared WCS should be stored from 2 to 8C. Stable for five days." 3. General supervisor number 1 (as listed on Form CMS 209) confirmed the vials were not labeled a required during an interview conducted on 03/03/2026 at 1240 hours in the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's AU400 maintenance records from January 2024 to December 2025, and staff interview, the laboratory failed to have documentation of performing weekly maintenance 59 of 97 times, monthly maintenance 10 of 24 times, and 3 month maintenance 12 of 12 times. The findings included: 1. A review of the laboratory's AU400 maintenance records from January 2024 to December 2025 identified the manufacturer required the following maintenance: a) weekly - Perform a W2 - Perform a photocal - Perform a photometer - Wash pre-dilution bottle - Levy-Jennings Review b) Monthly - Clean probe wash wells - Clean mix bar wash well - Clean wash nozzles - Clean water tank - Clean water filter - Clean sample probe filter c) 3 months - Replace wash solution - Clean air filters 2. Further review of the maintenance records from January 2024 to December 2025 identified the laboratory failed to have documentation of performing the following maintenance: a) Weekly

	January 2024 missing 3 of 5 weeks February 2024 missing 2 of 4 weeks March 2024 missing 3 of 4 weeks April 2024 missing 2 of 4 weeks May 2024 missing 2 of 4 weeks June 2024 missing 2 of 4 weeks July 2024 missing 3 of 5 weeks September 2024 missing 2 of 4 weeks October 2024 missing 2 of 4 weeks November 2024 missing 3 of 5 weeks December 2024 missing 4 of 5 weeks January 2025 missing 4 of 5 weeks February 2025 missing 3 of 4 weeks March 2025 missing 3 of 5 weeks April 2025 missing 2 of 4 weeks May 2025 missing 3 of 5 weeks June 2025 missing 4 of 5 weeks July 2025 missing 4 of 5 weeks August 2025 missing 2 of 4 weeks October 2025 missing 2 of 4 weeks November 2025 missing 2 of 4 weeks December 2025 missing 2 of 4 weeks b) monthly January 2024 missing February 2024 missing March 2024 missing August 2024 missing January 2025 missing April 2025 missing May 2025 missing August 2025 missing October 2025 missing November 2025 missing c) 3 Month none documented in 2024 and 2025 3. The general supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 03/02 /2026 at 1530 hours in the conference room.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on the columns used on the LC-MS/MS analyzer, review of the laboratory's procedures for urine confirmation and for oral confirmation testing on the LC-MS /MS, and staff interview, the laboratory failed to have documentation of establishing criteria to evaluate when columns required changing. The findings included: 1. The laboratory currently used the following columns for LC-MS/MS testing: a) Thermoscientific Accucore Biphenyl b) Phenomenex Luna HPLC/UHPLC Column 2. A review of the laboratory's procedures titled "Measurement of Pain Management Drugs in Urine via LC-MS/MS (Urine Drug Confirmation - Panel A), Measurement of Pain Management Drugs in Urine via LC-MS/MS (Urine Drug Confirmation - Panel B), and Measurement of Pain Management Drugs in Oral Fluid Drug Confirmation - Panel C) determined the laboratory failed to have criteria defined which could indicate column deterioration and the need for column change. 3. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 03/03/2026 at 1020 hours in the conference room.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 review of the laboratory's policies, review of the laboratory's calibration and control records for testing performed on the Olympus AU400 analyzer, review of the laboratory's records in 2024 and 2025, and staff interview, the laboratory failed to have documentation of performing calibration verification in 2024 and 2025 for 4 of 4 tests. The findings included: 1. A review of the laboratory's calibration and control records for validity testing performed on the Olympus AU400 analyzer determined the following five assays utilized 2 calibrators and 2 levels of quality control, and thus required calibration verification: Axion Diagnostics Test True pH Assay Axion Diagnostics Test True Creatinine Assay Axion Diagnostics Test True Nitrite Assay Axion Diagnostics Test True Specific Gravity Assay 2. A review of the laboratory's records from 2024 and 2025 determined the laboratory failed to have documentation of performing calibration verification every six months in 2024 and 2025. 3. General supervisor number 1 (as listed on Form CMS 209) stated in an interview conducted on 03/03/2026 at 0925 hours in the conference room that the laboratory did not perform calibration verification on the quantitative assays because the laboratory modified the quantitative results into qualitative prior to reporting. This confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control plan, review of the laboratory's quality assessment plan, review of the laboratory's quality control records for the Olympus AU400 analyzer from 2024 and 2025, and staff interview, the laboratory failed to have documentation of monitoring quality control values over time for 4 of 4 analytes. The findings included: 1. The laboratory's quality control plan titled "General Laboratory Quality Control" (date: 6/1/2021) under the section titled "Laboratory Quality Control" stated: "Data is reviewed and maintained in the department as well as review of Levy-Jennings and statistical analysis.", and "QC, over a period of time, will be reviewed for statistical analysis, shifts and trends." 2. The laboratory's quality assurance plan titled "Quality Management Systems (dated: 6 /1/2021) under the section titled "Quality Control review" stated: "Levy-Jennings

	graphs are reviewed weekly and monthly by viewing the LIS graphing reports." And, "Lab Director or Technical Supervisor will document review on the Quality Control Review form as well as communication, education, and recommendations." 3. A review of the laboratory's quality control records from January 2024 to December 2025 identified the following lots of quality control materials were used to assess the accuracy of Specific gravity, creatinine, pH and Nitrite: a) Axiom Diagnostic A3 Control Lot: 012022 Lot: 010723 Lot: 011024 Lot: 011325 b) Axiom Diagnostic A3 Control Lot: 030923 Lot: 079523 Lot: 011124 Lot: 071324 Lot: 011425 c) Axiom Diagnostic T13 Control Lot: 021123 Lot: 080823 Lot: 021224 Lot: 081024 Lot: 020825 d) Axiom Diagnostic T14 Control Lot: 031123 Lot: 090723 Lot: 031624 Lot: 090524 Lot: 031025 3. A review of the laboratory's quality control records determined the laboratory failed to have documentation of monitoring the quantitative quality control values over time in 2024 and 2025. 4. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview on 03/03/2026 at 0943 hours in the laboratory. He stated the Olympus analyzer was able to create Levy-Jennings graphs to monitor quality control values, but could not provide documentation of it being performed in 2024 and 2025.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) (d)(3)(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, manufacturer's instructions, and confirmed in interview, the laboratory failed to utilize two control materials every day of patient testing on the Kingfisher system, during the extraction phase, for ten of ten days reviewed in January 2026. Findings included: 1. During a tour of the facility on 03/02/2026 at 0915 hours, the surveyor observed one KingFisher Flex Extraction System available for patient sample extraction. 2. Review of laboratory policy, "Analytic Protocol for Urinary Tract Infection Panel" (Approved by the laboratory director on 01/23/2025) revealed the following: " ...2. Sample Genomic Material Extraction UltraPure Distilled Water (Negative Control)" Review of laboratory policy, "Analytic Protocol for Sexually Transmitted Infection Panel Urine (STI-Urine)" (Approved by the laboratory director on 01/23/2025) revealed the following: " ...2. Sample Genomic Material Extraction UltraPure Distilled Water (Negative Control)" Review of laboratory policy, "Analytic Protocol for Wound Panel" (Approved by the laboratory director on 01/23/2025) revealed the following: " ...2. Sample Genomic Material Extraction UltraPure Distilled Water (Negative Control)" 3. Review of manufacturer's instructions, "TrueMark Enteric Select Panels User Guide" (Publication Number: MAN0029144) revealed the following: " ...2. Methods Nucleic acid extraction guidelines ...The TaqMan Universal Extraction Control Organism (B. atrophaeus) (BA process control) must be used to verify the efficacy of sample preparation and the absence of inhibitors in the real-time PCR reaction. Use nuclease free water containing 1X solution of the BA process control as the negative control." The laboratory was asked if the above negative control solution was used in the extraction phase of patient testing. The laboratory stated only distilled water was used in testing the above panels as a negative control material. 4. Random review of laboratory quality control documentation, revealed the following days the laboratory failed to document two levels of control materials during the extraction phase of testing in January 2026: a. 01/12/2026 b. 01/13/2026 c. 01/14/2026 d. 01/15

	/2026 e. 01/16/2026 f. 01/19/2026 g. 01/20/2026 h. 01/21/2026 i. 01/22/2026 j. 01/23 /2026 5. In an interview on 03/03/2026 at 0932 hours in the laboratory conference room, the laboratory failed to utilize two control materials every day of patient testing on the Kingfisher system, during the extraction phase, for ten of ten days reviewed in January 2026.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records for the Olympus AU400 analyzer from 2024 and 2025, and staff interview, the laboratory failed to have documentation of verifying 59 of 59 new lots of control material prior to use. The findings included: 1. A review of the laboratory's quality control records from January 2024 to December 2025 identified the following lots of quality control materials were placed into use: a) Axiom Diagnostic A3 Control Lot: 012022 Lot: 010723 Lot: 011024 Lot: 011325 b) Axiom Diagnostic A3 Control Lot: 030923 Lot: 079523 Lot: 011124 Lot: 071324 Lot: 011425 c) Axiom Diagnostic T13 Control Lot: 021123 Lot: 080823 Lot: 021224 Lot: 081024 Lot: 020825 d) Axiom Diagnostic T14 Control Lot: 031123 Lot: 090723 Lot: 031624 Lot: 090524 Lot: 031025 e) Immunalysis THC Low Control Lot: E50761 Lot: E52102 Lot: E52984 Lot: E54202 Lot: E55108 Lot: E57008 f) Immunalysis THC High Control Lot: E50762 Lot: E52103 Lot: E52985 Lot: E54203 Lot: E55109 Lot: E57009 g) Immunalysis Oxycodone Low Control Lot: E49849 Lot: E52098 Lot: E51558 Lot: E53774 Lot: E55415 Lot: E56503 h) Immunalysis Oxycodone High Control Lot: E49820 Lot: E52097 Lot: E51559 Lot: E53775 Lot: E55416 Lot: E56504 i) Immunalysis Ethyl Glucuronide Low Control Lot: E49952 Lot: E51780 Lot: E52578 Lot: E52969 Lot: E53796 Lot: E54469 Lot: E55444 Lot: E56156 j) Immunalysis Ethyl Glucuronide High Control Lot: E49953 Lot: E51781 Lot: E52579 Lot: E52970 Lot: E53797 Lot: E54470 Lot: E55445 Lot: E56157 2. A review of the laboratory's quality control records from 2024 and 2025 determined the laboratory failed to have documentation of verifying the identified lots prior to use. 3. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview on 03/03/2026 at 1045 hours in the laboratory.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, laboratory quality control (QC) records in 2025 and 2026, patient final reports and confirmed in interview, the laboratory failed to document acceptable QC prior to reporting patient results for one of ten days reviewed in December 2025, and one of six days in February 2026. Findings included: 1. During a tour of the facility on 03/02/2026 at 0925 hours, the surveyor observed the following two QuantStudio Real-Time PCR analyzers on the laboratory counter available for patient testing: a. QuantStudio 1 Serial Number: 278871107 b. QuantStudio 2 Serial Number: 285881361 2. Review of laboratory policy, "Quality Control General Laboratory Policy" (Approved by the laboratory director on 08/23/2025) revealed the following: "Policy Quality control and calibrations are performed on a regular and routine basis in accordance with CLIA regulations. Purpose: Quality Control is performed in this laboratory to provide an ongoing system for assessing the reliability and accuracy of instruments, systems and methods. ...Acceptability of Quality Control and Calibration Qualitative tests Controls are acceptable when the observed results are expected (positive or negative)" Further review of laboratory policy, "Analytic Protocol for Respiratory Pathogen Panel" (Approved by the laboratory director on 08/23/2025) revealed the following: " ...4 Quality Control Protocol 4.1 Every plate has 3 types of controls- Positive Control, Negative Control, and RNAse P. ...4.6 After each experiment has run, if any of the three types of Quality Controls give an undesired result, the results are rejected and the samples are re-run." 3. Review of laboratory Respiratory Pathogen Panel QC documentation in 2025 and 2026, revealed the following days the laboratory failed to document acceptable QC: a. December 26, 2025 Unacceptable Control: Positive Control (PC); IAV (Influenza A Virus) Corrective Action Documentation: "12/26 /2025: Obvious positives reported" b. February 11, 2026 Unacceptable Control: Positive Control; IAV (Influenza A Virus) Corrective Action Documentation: "2/11 PC low amp/failed; reported obvious positives" The laboratory was asked for documentation of acceptable positive control prior to reporting patient results. No documentation was provided. 4. Review of patient final reports on the above days in 2025 and 2026, revealed the following patients reported with no acceptable QC documented: 12/26/2025 a. Sample ID: 2512260003 IAV Result: Positive b. Sample ID: 2512260005 IAV Result: Positive c. Sample ID: 2512260013 IAV Result: Positive d. Sample ID: 2512260014 IAV Result: Positive 02/11/2026 e. Sample ID: 2602110005 IAV Result: Positive f. Sample ID: 2602110006 IAV Result: Positive g. Sample ID: 2602110012 IAV Result: Positive h. Sample ID: 2602110021 IAV Result: Positive 5. In an interview on 03/03/2026 at 0932 hours in the laboratory conference room, the laboratory failed to document acceptable QC prior to reporting patient results for one of ten days reviewed in December 2025, and one of six days in February 2026.
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. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, and confirmed in interview, the laboratory failed to document comparisons twice yearly between two

	instruments performing the same test, for two of two events in 2024 and two of two events in 2025. Findings included: 1. During a tour of the facility on 03/02/2026 at 0925 hours, the surveyor observed the following two QuantStudio Real-Time PCR analyzers on the laboratory counter available for patient testing: a. QuantStudio 1 Serial Number: 278871107 b. QuantStudio 2 Serial Number: 285881361 The laboratory technical supervisor (TS-1) stated respiratory, urinary tract infection, sexually transmitted infection and wound panels were processed on both analyzers. 2. Review of laboratory documentation revealed the laboratory failed to include instrument comparisons in their analytic policies. The laboratory was asked to provide instrument comparisons in 2024 and 2025 for the above QuantStudio analyzers performing the same tests, and no documentation was provided. 3. In an interview on 03/02/2026 at 1216 hours in the laboratory conference room, the technical supervisor (TS-1) stated instrument comparison studies were not performed on the above analyzers in 2024 and 2025. This confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's toxicology temperature logs from January 2025 to December 2025, and staff interview, the laboratory failed to have documentation of performing corrective actions when room humidity levels were outside the laboratory's established acceptability range on 56 of 254 days. The findings included: 1. A review of the laboratory's toxicology temperature logs from January 2025 to December 2025 determined the laboratory established a acceptable room humidity range of 40 - 80%. 2. Further review of the toxicology temperature logs from January 2025 to December 2025 identified the following days where the documented room humidity levels were outside the acceptable range and the laboratory failed to have documentation of performing corrective actions: Date Humidity (%) 1/2 34 1/6 25 1/7 25 1/8 24 1/9 26 1/10 31 1/13 31 1/14 29 1/15 28 1/16 29 1/17 28 1/20 28 1/21 25 1 /22 30 1/23 27 1/24 29 1/27 39 1/31 30 2/13 34 2/14 30 2/17 31 2/19 29 2/20 28 2/21 27 2/27 35 2/28 30 3/4 24 3/5 28 3/6 30 3/10 29 3/11 26 3/13 30 3/17 34 3/24 31 4/7 30 4/8 35 5/12 31 10/30 29 10/31 28 11/10 38 11/26 32 11/28 30 12/1 34 12/2 29 12/3 30 12/4 35 12/5 33 12/8 33 12/9 31 12/10 39 12/11 30 12/15 29 12/16 31 12/18 38 12 /19 28 12/22 39 3. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 03/02/2026 at 1545 hours in the conference room.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's General Laboratory Quality Control plan, review of the laboratory's Quality Management Systems plan, review of the laboratory's

	records, and staff interview, the laboratory director failed to ensure the laboratory's quality control plan and quality assessment plans were established and followed. The findings included: 1. A review of the laboratory's General Laboratory Quality Control Plan (signed 6/1/2021) and the laboratory's Quality Management Plan (signed 6/1 /2021) revealed the laboratory director failed to ensure the plans were established or followed as evidenced by: a) The laboratory director failed to ensure the quality management plan established attestation statements were signed (refer to D2009). b) The laboratory director failed to ensure the quality control plan established twice annual accuracy assessments were performed for 4 of 4 analytes in 2024 and 2025 (refer to D5217). c) The laboratory director failed to ensure the quality management plan was followed for corrective actions being documented for failed proficiency testing results (refer to D5221). d) The laboratory director failed to ensure the quality management plan was followed to monitor the transport and/or shipment of samples to the laboratory to ensure acceptable temperatures were not exceeded (refer to D5311). e) The laboratory director failed to ensure the quality control plan was followed concerning labeling calibration materials (refer to D5413). f) The laboratory director failed to ensure the quality management plan was followed for the documentation of preparation and expiration dates on calibrators (refer to D5415) g) The laboratory director failed to ensure the quality control plan was followed requiring the documentation of equipment maintenance (refer to D5429). h) The laboratory director failed to ensure the quality control plan established the criteria for the determination of degradation to columns used for LC-MS/MS testing (refer to D5433). i) The laboratory director failed to ensure the quality control plan established calibration verification was performed on the Olympus AU 400 analyzer (refer to D5439). j) The laboratory director failed to ensure the quality control plan was followed by monitoring control values over time to detect possible shifts and/or trends (refer to D5441). k) The laboratory director failed to ensure the quality control plan was followed by testing two levels of quality control material each day of patient testing (refer to D5453). l) The laboratory director failed to ensure the quality control plan established control materials were verified prior to use (refer to D5469). m) The laboratory director failed to ensure the quality control plan was followed by ensure controls values were acceptable prior to reporting patient results (refer to D5481). n) The laboratory director failed to ensure the quality management plan defined requirements for instrument comparisons (refer to D5775). o) The laboratory director failed to ensure the the quality control plan established documentation of corrective actions when room humidity levels exceeded acceptable ranges (refer to D 5785).