Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1069375	11/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bio-Techne Corporation	2150 Woodward St Ste 100, Austin, 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
D0000	The Asuragen Clinical Services laboratory's announced validation survey on 11/05 /2025 was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the laboratory's study, the laboratory's policies and procedures, client collection instructions, patient reports, presurvey paperwork, and interview, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems in Chemistry for six of six specimens collected between December 2023 to March 2025. (see D5311).
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: Based on the laboratory's study, the laboratory's policies and procedures, client collection instructions, patient reports, presurvey paperwork, and interview, the laboratory failed to ensure blood specimens in transport were maintained at ambient temperature (18-25 degrees Celsius (C)) during transportation for its lab developed test (LDT) fragile X messenger ribonucleoprotein-1 (FMR1) gene polymerase chain reaction using capillary electrophoresis (PCR/CE) for six of six specimens collected between December 2023 to March 2025. Findings follow. A1. Review of the document titled Frozen EDTA Blood Tubes as a Viable Xpansion Interpreter Sample Type, SOP-003610A001 Rev 04 09/26/2017, did not include specimen transport conditions. A2. Additional studies for transport temperatures were requested on November 5, 2025 at 1735 hours but not provided. B. Review of the laboratory's policy and procedure titled Xpansion Interpreter Test Procedure Version 16, 11/12 /2024, under 7. Specimen Information stated, "7.1 Specimen Types, Collection, and Shipping Requirements 7.1.1. >1ml blood samples should be collected in vacutainer tubes containing EDTA. Samples should be shipped overnight in ambient conditions." The ambient temperature was not defined in the policy and procedure. C. Review of the client instructions titled Specimen Collection Manual Version 5, 03/26/2025, under Whole Blood stated, "6. Need for special handling between time of collection and time received by the laboratory Blood specimen should be stored at 2-8 C until shipping overnight to Asuragen. Blood specimens should be shipped Monday-Thursday to limit transit time. Samples may be shipped at ambient temperature. Sample must arrive within 7 days of collection, unless previously frozen." The ambient temperature was not defined in the client instructions. D. Random review of test reports of EDTA blood specimens showed the date of collection and received dates: Specimen ID Date collected Date received 1. 55557 12/12/2023 12/27/2023 2. 55688 12/29/2023 01/10/2024 3. 57226 04/18/2024 05/17/2024 4. 57227 04/29/2024 05/17/2024 5. 60118 03/07/2025 03/27/2025 6. 60119 03/10/2025 03/27/2025 E. Review of the paperwork for the condition blood samples were received showed those listed above were received under "ambient" conditions, with "no dry ice". The ambient temperature was not defined. F. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual volume of 3200. G. Interview with the Director of Laboratory Operations/ Technical Supervisor #2 on November 5, 2025 at 1735 hours confirmed they do not have a mechanism to ensure ambient temperatures were exceeded in transport and did not perform transport studies.
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 the manufacturer's instructions, laboratory's policy and procedure, humidity charts, testing records, test reports, and interview, the laboratory failed to ensure humidity was within manufacturer's specifications for its lab developed test (LDT) fragile X messenger ribonucleoprotein-1 (FMR1) gene polymerase chain reaction using capillary electrophoresis (PCR/CE) for 16 out of 148 testing dates reviewed from January - February 2024 and 2025 and June - July 2024 and 2025. Findings follow. A. Review of the Applied Biosystems 3500 or 3500xL Genetic Analyzer Site Preparation Guide, publication number 4401689 revision C, stated under Operating conditions "15 to 30 degrees Celsius (C) (59 to 86 degrees Fahrenheit (F)) (Room temperature should not fluctuate +/- 2 C during an instrument run) 20 to 80% relative humidity, noncondensing." B. Review of the GeneAmp PCR System 9700 User's Manual, 06/2010, under Setting Up your Laboratory stated at Operating Temperature, "The instrument will meet performance specifications when the ambient temperature is 15 C to 30 C (59 to 86 F) and the ambient relative humidity is 20% to 80%. C. Review of the laboratory's policy and procedure titled Isenix Advance Remote Monitoring Systems Basic Operations Version 11, 08/30/2022, under Table 1 at 5.5 System Maintenance defined Room Relative Humidity as 10%-75%. D. Review of the daily humidity charts showed humidity exceeded manufacturer's recommendations on 16 out of 148 testing dates reviewed. Testing date % Humidity 1. 01/09/2024 17.46% 2. 01/10/2024 18.30% 3. 01/16/2024 9.24% 4. 01/17/2024 9.28% 5. 01/18/2024 18.60% 6. 01/19/2024 12.20% 7. 01/06/2025 9.80% 8. 01/07/2025 6.70% 9. 01/13 /2025 9.00% 10. 01/14/2025 11.62% 11. 01/15/2025 16.10% 12. 01/22/2025 9.40% 13. 01/23/2025 8.10% 14. 01/24/2025 6.4% 15. 02/19/2025 10.6% 16. 02/20/2025 5.00% E. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual volume of 3200. F. Interview with the Director of Laboratory Operations/ Technical Supervisor #2 on November 5, 2025 at 1515 hours confirmed the findings.