Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0965332	10/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bio-Tech Clinical Laboratories Inc	9000 Nw 15th St Unit 1, Doral, FL	

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	An announced CLIA recertification survey was conducted at BIO-TECH CLINICAL LABORATORIES from 10/06/2025 to 10/29/2025 The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory was not in compliance with Federal licensure requirements to perform testing for the ABO Group and Rh Factor since 02/15/2024. The findings included: 1-The Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) signed by the owner on 09/30/2025, obtained during survey showed the laboratory performed testing in the following specialties/subspecialties: Microbiology (Bacteriology, Mycology, Parasitology and Virology), Diagnostic Immunology (Syphilis Serology and Diagnostic Immunology), Chemistry (Routine Chemistry, Urinalysis and Toxicology), Hematology and Immunohematology. 2-Review of the laboratory test menu showed the laboratory performed testing for the analytes ABO typing and Rh Factor. 3-Review of the Food and Drug Administration (FDA) web site for CLIA testing complexity showed that since 2007, the FDA has classified the reagents: ALBAclone Blood Grouping Reagent ABO group and Rh Factor as moderate complexity under Immunohematology specialty. 4-Review of the Certificate of Compliance for this laboratory revealed that the laboratory did not have included the Immunohematology specialty/subspecialty ABO Group & Rh Group. 5-During an

	interview on 10/08/2025 at 02:30 PM, Testing Personnel #1 confirmed the laboratory did not have the Immunohematology specialty/ subspecialty ABO Group & Rh Group.
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 record review and staff interview, the laboratory failed to test 2 out of 5 patients reviewed within the acceptable timeframe for urine culture. Findings included: 1-Review of the Microbiology Procedure Manual signed by the Laboratory Director on 10/06/2025 in section "BIO-TECH CLINICAL LABORATORY"," Patient instructions for Urine Collection (Routine Urinalysis and Culture" revealed, that in section "Storage" stated "Specimen should be delivered as soon as possible to Biotech Clinical Laboratory, if a delay of more than two hours is expected, refrigerate the sample. Maximum refrigeration time for routine urinalysis and routine culture is 24 hours." 2-Review of policy: "SPECIMEN TRANSPORT GUIDE", in section" SPECIMEN REJECTION CRITERIA" in section "Unacceptable specimens" stated: "... Twenty-four hours specimens are unacceptable for bacterial culture." 3-Review of patient reports, worklist reports, and final patient reports revealed that the following cases were tested outside of the acceptable timeframe established in the procedure: Patient #1 (Collected 10/25/2023, received 10/27/2023, plated 10/28/2023 final 10/30 /2023). This patient was plated at 72 hours of collection date. Patient #2 (Collected 10 /26/2023, received and plated 10/30/2023, final 11/01/2023). This patient was plated 96 hours after collection) 4-Review of Microbiology rejection log for October 2023, revealed that the laboratory had no specimens rejected. 5-During an interview on 10/06 /2025 at 12:20 PM, the Testing Personnel #5 confirmed that the patients listed above were tested outside of the acceptability criteria for urine culture.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-

	threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 observation, record review and staff interview, the laboratory failed to follow the Microbiology Procedure Manual of documenting the Microbiology worksheet daily for 15 out of 15 cases set-up on 10/03/2025. Findings included: 1-During the laboratory tour on 10/06/2025 at 11:40 AM, the surveyor observed that the laboratory had the worklist for 15 cases plated on 10/03/2025 with results of the culture, review of worksheet for the cases set-up on 10/03/2025, revealed that the worksheet for the 15 cases failed to have the set-up date, the culture media used, the 24 hours result. 2-Review of the procedure manual for Microbiology signed by the Laboratory Director on 10/06/2025 revealed that the laboratory had a policy "MICROBIOLOGY WORKSHEET", that stated that the "approved worksheet to be used on daily basis" 3-During an interview on 10/06/2025 at 12:06 PM, Microbiology Testing Personnel confirmed that the laboratory failed to document the daily worksheet for 15 out of 15 cases set-up on 10/03/2025.
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 observation, record review and staff interview, the laboratory failed to follow manufacturer's instructions for storage temperature of the Bio-Rad Liquicheck Immunoassay Plus Controls, Bio-Rad Liquid Assayed Multiqual Control 1 and 3 and Biorad Liquicheck Therapeutic Drug Monitoring Control 1, 2 and 3 controls for 238 out of 277 days reviewed in 2024 and 2025. Findings included: 1-During the laboratory tour on 10/06/2025 at 10:30 AM, the surveyor observed that the laboratory had stored in a freezer with identification 2507000764, the following controls: 1 box Bio-Rad Liquicheck Immunoassay Plus Controls (Levels 1, 2 and 3) Lot # 85360, Bio-Rad Liquid Assayed Multiqual Control 1(Lot# 46021) and Control 3 (Lot# 46023) and Bio-Rad Liquicheck TDM Control 1 (Lot # 1002901), Control 2 (Lot#1002902 and Control 3 (Lot# 1002903). 2-Review of the manufacturer instructions revealed the following statement in the section "STORAGE AND STABILITY" "This product will be stable until the expiration date when stored unopened at -20 to -70C." 3-Review of freezer log for 2024 and 2025, revealed the following: a) Temperature Log for freezer identified as Norlane 2024 (main lab), this freezer broke in 11/18/2025, this log had a temperature range of -15C to -25C. The laboratory moved the controls to another freezer identified as WB414600140 with a range of -15C to -25C. b) Review of the

	temperature log for this freezer from 11/18/2024 to 06/05/2025 revealed the following days the stored temperatures were outside of the acceptable range: 11/19/2024 to 11/27 /2024, 11/29/2024 to 11/30/2024, 12/02/2024, 12/03/2024, 12/04/2024, 12/06/2024, 12 /10/2024 to 13/13/2024, 12/16/2024 to 12/19/2024, 12/23/2024, 12/24/2024, 12/30 /2024, 12/31/2024, 01/02/2025 to 01/17/2025, 01/20/2025 to 02/08/2025, 02/11/2025 to 03/22/2025, 03/26/2025 to 04/14/2025, 04/17/2025 to 05/02/2025, 05/06/2025 to 05 /17/2025, 05/19/2025 to 05/23/2025, 05/19/2025 to 06/05/2025. c) On 06/06/2025, the laboratory implemented the freezer identified 2507000764 with a range of -20C, in this freezer the laboratory stored the controls of reference, the following dates the temperatures were outside of the acceptable range: 06/06/2025 to 07/05/2025, 07/08 /2025, 07/09/2025, 07/14/2025 to 07/21/2025, 07/27/2025 to 08/04/2025, 08/07/2025 to 08/18/2025, 08/21/2025 to 08/27/2025, 08/29/2025 to 09/10/2025, 09/11/2025 to 09 /21/2025, 09/23/2025 to 10/06/2025. 4-During an interview on 10/06/2025 at 2:30 PM, the Testing Personnel #A confirmed that temperature records of the freezer used for the storage of the controls listed above were outside of the acceptable temperature ranges as per the manufacturer instructions in the days listed above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 observation, record review and staff interview, the laboratory used REMEL Thayer Martin Modified (TMM) agar plate expired since 10/01/2025 to test one patient on 10/03/2025. Findings included: -During the laboratory tour on 10/06/2025 at 10:35 AM, the surveyor observed that the laboratory had one plate of TMM agar plate with Lot number 297679 expired since 10/01/2025 on the Microbiology counter. Review of Microbiology incubator revealed that the laboratory had one labeled plate of the TMM agar media with Patient # 1 (P#1) in the incubator. -Review of Microbiology worklist for 10/03/2025, revealed that P#1, was collected on 10/02 /2025, and plated on 10/03/2025. During an interview on 10/06/2025 at 10:45 AM, Testing Personnel # 5 confirmed that the laboratory used the expired culture plate. 49641 Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions for incubation time for the QuantiFERON from October 4, 2025 to October 6, 2025 for 28 samples tested. Findings included: 1-During a tour of the laboratory on 10/06/2025 at 10:30 AM observed incubation logs posted in front of the LAB-LINE L-C incubator for QuantiTIFERON specimens in the specialty of Immunology, that exceeded 24 hours of incubation for 10/04/2025 - 10/06/2025 sample ID 1015386-387, 1015399-408, 1015409-420, and 1015430-433. 2- Record review of QuantiFERON TB GOLD PLUS insert PN 1095849 Rev 02 states that "QFT-Plus tubes Incubate at 37C +1 C for 16 to 24 Hours." 3- Review of the QuantiFERON Procedure signed by the Laboratory Director on 01/23/2023 states on page 3 bulleted "Incubate at 37 C +1 C for 16 to 24 Hours." 4- During an interview on 10/06/2025 at approximately 10:40 AM, TP4 confirmed not removing samples from incubation on 10/05/2025 exceeding 24-hour incubation over weekend.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)

	The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of patient testing during competency evaluation for three testing personnel (TP) out of five TP in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 10/06/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant, Technical Consultant (TC), Technical Supervisor (TS) and General Supervisor (GS) for Chemistry, Hematology and Immunology specialties. The laboratory had five testing persons (TP#1, TP#2, TP#3, TP#4 and TP#5). 2-Review of personnel records yearly competency for TP#2 revealed that the direct observation of patient testing with the DxH560 and ACL Elite Pro in the Hematology specialty, with the AU460 in Chemistry specialty, and DXS I in the Immunology specialty was observed by TP#1 on 07/24/2025. TP#1 had no delegation letter to do competency. 3- Review of personnel records yearly competency for TP#3 revealed that the direct observation of patient testing with the DxH560 and ACL Elite Pro in the Hematology specialty, with the AU460 in Chemistry specialty, and DXS I in the Immunology specialty was observed by TP#1 on 08/19/2025. TP#1 had no delegation letter to do competency. 4- Review of personnel records yearly competency for TP#4 revealed that the direct observation of patient testing with the DxH560 and ACL Elite Pro in the Hematology specialty, with the AU460 in Chemistry specialty, and DXS I in the Immunology specialty was observed by TP#1 on 05/01/2025. TP#1 had no delegation letter to do competency. 5- During an interview on 10/06/2025 at 10:44 AM, the TS/GS admitted did not perform the direct observation of patient testing during competency for TP#2 on 07/24/2025, TP#3 on 08/19/2025 and TP#4 on 05/01/2025.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to do direct observation of performance of instrument and function check during competency evaluation for three out of five testing personnel (TP) in 2025. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 10/06/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant, Technical Consultant (TC), Technical Supervisor (TS) and General Supervisor (GS) for Chemistry, Hematology and Immunology specialties. The laboratory had five testing persons (TP#1, TP#2, TP#3, TP#4 and TP#5). 2-Review of personnel records annual competency for TP#2 revealed that the direct observation of performance of instrument and function check with the DxH560 and ACL Elite Pro in the Hematology specialty, with the AU460 in Chemistry specialty, and DXS I in the Immunology specialty was observed by TP#1 on 07/24/2025. TP#1 had no delegation letter to do competency. 3- Review of personnel records annual competency for TP#3, revealed that the direct observation of performance of instrument and function check with the DxH560 and ACL Elite Pro in the

	Hematology specialty, with the AU460 in Chemistry specialty, and DXS I in the Immunology specialty was observed by TP#1 on 08/19/2025. TP#1 had no delegation letter to do competency. 4- Review of personnel records annual competency for TP#4 revealed that the direct observation of performance of instrument and function check with the DxH560 and ACL Elite Pro in the Hematology specialty, with the AU460 in Chemistry specialty, and DXS I in the Immunology specialty was observed by TP#1 on 05/01/2025. TP#1 had no delegation letter to do competency. 5- During an interview on 09/15/2025 at 11:53 AM, the TS/GS admitted did not perform direct observation of performance of instrument and function check during competency for TP#2 on 07/24/2025, TP#3 on 08/19/2025 and TP#4 on 05/01/2025.