Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0965332	09/30/2021
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	A recertification survey conducted on 09/29/2021 to 09/30/2021 found that BIO-TECH CLINICAL LABORATORIES INC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following conditions were cited: -D5400. Analytic Systems. -D6076 Laboratory Director
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 observation, record review and interview, the laboratory failed to validate the use of Clinitek 500 to read the results of urine strips URS-10 from Teco. Refer to D5423
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other

	materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation record review and interview, the laboratory failed to have a step-by-step procedure manual for Hologic Panther instrument available onsite at the time of survey. The findings included: During an observation of the laboratory on 09/29 /2021 at 10:00 AM revealed a Hologic Panther instrument used for molecular testing. Review of Hologic Panther procedure revealed there was no step-by-step instruction guide on how to use the Hologic Panther instrument. During an interview on 09/30 /2021 at 11:00 AM with testing personnel, she confirmed there was no procedure manual for Hologic Panther instrument available onsite.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to perform validation of the reading of Urine Reagent strips for Urinalysis, from Teco Diagnostics (URS-10) with Clinitek 500 reader; from 09/24/2021 to 09/29/2021. The findings include: -During the laboratory tour on 09/29/2021 at 1:20 PM the surveyor observed a bottle of Teco Urine strips (URS-10) with a opened date of 09/24/2021 placed at the side of the Clinitek 500 instrument. The surveyor also observed print outs results with date 09/29/2021. No other brand of urine strips found in the laboratory. -Review of the package insert for the Urine Reagent strips for Urinalysis from Teco Diagnostics stated that: "Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. No calculations or laboratory instruments are required." -Record review revealed that the laboratory received the URS-10 strips on 09/21/2021 and started using on 09/24/2021 and a total of 24 patients were tested from 09/24/2021 to 09/29/2021. During an interview on 09 /29/2021 at 1:30 pm, with Technical Consultant confirmed that the laboratory started using the URS-10 strips on 09/24/2021 and failed to follow manufacturer instructions

	for interpretation of the results and instead used the Clinitek 500 reader without performing a validation.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation , record review and interview , the laboratory director failed ensure the laboratory to perform validation of the reading of Urine Reagent strips for Urinalysis from Teco Diagnostics (URS-10) with Clinitek 500 reader from 09/24/2021 to 09/29/2021 (see D6095)
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory director failed to ensure that the validation of the reading of Urine Reagent strips for Urinalysis from Teco Diagnostics (URS-10) with Clinitek 500 reader was performed. During the period from 09/24/2021 to 09/29/2021. The findings included: Refer to D5423-Based on observation, record review and staff interview, the laboratory failed to perform validation of the reading of Urine Reagent strips for Urinalysis from Teco Diagnostics (URS-10) with Clinitek 500 reader from 09/24/2021 to 09/29/2021.