

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0965332 | (X3) Date Survey Completed 10/30/2020 |
| Name of Provider or Supplier Bio-Tech Clinical Laboratories Inc | Street Address, City, State 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 unannounced complaint survey, #2020014990, was conducted on 10/28/20 thru 10/30/20 at BioTech Clinical Laboratories. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories. The following Conditions were cited: D3000 Facility Administration 493.1100 D5300 Preanalytic Systems 493.1240 |
| D3000 | <p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow the State of Florida Emergency Rule to report demographics COVID-19 test results immediately to the Department of Health (DOH) for 2,096 Patient reports (See D3009).</p> |
| D3007 | <p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Laboratory Manager the laboratory failed to have sufficient equipment for the PT (Prothrombin Time) and PTT (Partial thromboplastin time) testing performed at the laboratory. The laboratory reports 1169 tests per year for PT and PTT testing. Findings Included: There are 2</p> |

laboratories located at the same physical address (separated by a door), this laboratory and another Certificate of Compliance laboratory (to be referred to as Lab B). During a tour of the laboratory on 10/28/20 at 11:28 AM it was observed there was a ACL Elite Pro coagulation instrument that was located thru the door at Lab B that was being used for this laboratory as well. There was no hours of operation for when this laboratory and Lab B would be using the instrument. Also, there was no policy in place to address if one laboratory had a different lot number and had to change the ISI number causing inaccurate PT-INR results. Interview on 10/28/20 at 6:30 PM the Laboratory Manager confirmed that there was no policies about sharing the instrument with Lab B and confirmed that another instrument is ordered but has not arrived.

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 failed to follow the State of Florida Emergency Rule to report demographics COVID-19 test results immediately to the Department of Health (DOH) for 2,096 Patient reports. Findings Included: Review of Florida Administrative Code Rule 64D-3.031 "Notification by Laboratories" revealed that "To allow follow-up of laboratory findings suggestive of or diagnostic of diseases or conditions in the Table of Notifiable Diseases or Conditions, the form upon which the information will be reported shall be furnished by the laboratory that includes the following information: (a) The Patient's: 1. First and last name including middle initial, 2. Address including street, city, state, and zip code, 3. Phone number, including area code, 4. Date of birth, 5. Sex, 6. Race, 7. Ethnicity (specify if of Hispanic descent or not of Hispanic descent), 8. Pregnancy status if applicable, 9. Social Security number." Interview on 10/29/20 at 6:30 PM with the Laboratory Manager confirmed that the laboratory did not report the necessary demographic information during reporting of COVID-19 results to the DOH.

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 record review and interview with the Laboratory Manager the laboratory failed to get a Test Requisition signed by an authorized person for 15 (1, 2, 3, 4, 5, 7, 8, 10, 11, 13, 16, 17, 18, 19, and 20) out of 20 (1-20) Test Requisitions reviewed (See D5301).

| | |
|---------------------|--|
| <p>D5301</p> | <p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the laboratory failed to get a Test Requisition signed by an authorized person for 15 (1, 2, 3, 4, 5, 7, 8, 10, 11, 13, 16, 17, 18, 19, and 20) out of 20 (1-20) Test Requisitions reviewed. Findings Included: Review of Test Requisitions revealed the following not signed by an authorized person: 1 (dated 06/30/20), 2 (06/30/20), 3 (07/08/20), 4 (07/15/20), 5 (07/16/20), 7 (07/17/20), 8 (07/17/20), 10 (07/23/20), 11 (07/23/20), 13 (07/17/20), 16 (09/28/20), 17 (09/28/20), 18 (09/29/20), 19 (10/13/20), and 20 (no date). The dates of the 5 that had been signed by an authorized person were from: 6 (no date), 9 (no date), 12 (no date), 14 (08/31/20), and 15 (08/11/20). Interview on 10/29/20 at 6:30 PM the Laboratory Manager confirmed that the Test Requisitions signed by an authorized person.</p> |
| <p>D5411</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Medical Technologist the laboratory failed to use disposable reagent tubes for the Zeus Elisa DSX analyzer per the manufacturer's instructions for an unknown amount of time. Findings Included: During a tour of the laboratory on 10/28/20 at 11:28AM it was observed a container with tubes that had been washed. Interview on 10/28/20 at 11:30 AM the Medical Technologist confirmed that they reused the plastic disposable reagent tubes for the Zeus Elisa DSX analyzer that tested for Anti-Nuclear antibody, Mumps, Measles, Rubella, COVID antibody testing, and Quantiferon for tuberculosis. Review of the bag that the tubes come in revealed that they are disposable. The Medical Technologist called Tech Support on 10/28/20 at 1:28 PM. Tech Support confirmed that the manufacturer states that they are one use and disposable.</p> |
| <p>D5415</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by:</p> |

| | |
|---------------------|--|
| | <p>Based on observation and interview with the Laboratory Manager it was observed Hematology stain without an open date or expiration date on the label. Findings Included: During a tour of the laboratory on 10/28/20 at 11:28 AM it was observed a Cameo Hematology Stain pak on the counter without an expiration date or a date opened. Interview on 10/28/20 at 11:45 AM the Laboratory Manager confirmed that the expiration date and the date of open were not on the bottles.</p> |
| <p>D5417</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the Laboratory Manager the laboratory had expired KOH (Potassium Hydroxide) since 07/2020. Findings Included: During a tour of the laboratory on 10/28/20 at 11:28 AM it was observed a bottle of KOH that expired 07/2020. There was no other KOH in the laboratory for use. Interview on 10/28/20 at 12:30 PM the Laboratory Manager confirmed that the expired KOH was used.</p> |
| <p>D5481</p> | <p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Medical Technologist the laboratory reported patients when QC (quality control) was not acceptable for Magnesium testing for 2 days (08/18/20 and 08/19/20) out of 26 days reviewed. Findings Included: Quality Control was reviewed for August 2020 for the following days: 08/01, 08/03, 08/04, 08/05, 08/06, 08/07, 08/08, 08/10, 08/11, 08/12, 08/13, 08/14, 08/15, 08/17, 08/18, 08/19, 08/20, 08/21, 08/22, 08/24, 08/25, 08/26, 08/27, 08/28, 08/29, and 08/31. Review of QC ran for Magnesium revealed on 08/18/20 (4.92) and 08/19/20 (4.96) the level 2 was not in the acceptable range of 3.16 to 3.58. Review of Patients ran revealed 2 patients reported on 08/18/20 and 2 patients reported on 08/19/20. Review of the "QC Corrective Action Daily Log" revealed the QC was not reran. Interview on 10/29/20 at 5:20 PM the Medical Technologist confirmed that the QC was not in range and Patients were reported on 08/18/20 and 08/19/20.</p> |