

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0705173	<b>(X3) Date Survey Completed</b> 02/13/2018
<b>Name of Provider or Supplier</b> Lozito Medical Associates	<b>Street Address, City, State</b> 484 Lafayette Ave, Hawthorne, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to evaluate results when the laboratory received an unacceptable score in PT performed with the College of American Pathologists (CAP) in 2017. The finding includes: 1. There was no review or evaluation documented when the laboratory received an unacceptable result for Throat Culture (TC) sample TC-03 in the first event of 2017. 2. The OM confirmed on 2/13/18 at 10:00 am that the laboratory did not perform and document an evaluation of unacceptable PT performance.</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Office Manager (OM), the laboratory failed to meet the analytic system requirements for Throat Culture (TC) testing. The findings include: 1. The laboratory failed to have a</p>

	<p>Procedure Manual approved, signed and dated by the Laboratory Director. Cross refer to D 5407. 2. The laboratory did not have criteria for acceptable Room Temperature and Humidity for patient testing. Cross refer to D 5413. 3. The laboratory did not perform Quality Control (QC) on TC plates. Cross refer to D 5477. 4. The laboratory did not perform QC on bacitracin discs used on TC plates. Cross refer to D 5479.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to have an approved, signed and dated PM by the Laboratory Director (LD) from 12/17/15 to the date of the survey. The OM confirmed on 2/13/18 at 10:15 am the LD did not sign the PM. This was cited on the previous survey dated 12/17/15.</p>
<p><b>D5413</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Temperature Records (TR) and interview with the Office Manager (OM), the laboratory failed to monitor and record the temperature and humidity of the room where Throat Culture testing was performed from 12/17/15 to the date of the survey. The OM confirmed on 2/13/18 at 10:15 am that room and humidity temperature was not monitored and recorded. This was cited on the previous survey dated 12/17/15.</p>
<p><b>D5477</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to check QC on each batch of Selective Strep Agar (SSA) used for Throat Culture testing from 12/17/15 to the date of the survey. The findings include: 1. The laboratory did not check SSA for: a. Ability to support growth. b. Ability to select or inhibit specific organisms c. Sterility of media. 2. The OM confirmed on 2/13/18 at 10:30 am that the laboratory did not perform the above mentioned QC checks.</p>
<p><b>D5479</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(5)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to follow the manufacturer's specification for performing QC on Bacitracin Discs used in Throat Cultures from 12/17/15 to the date of survey. The finding includes: 1. The manufacturer's instructions required QC for each new lot number however the laboratory had no documented evidence QC was performed on any Bacitracin lot received after the last survey. 2. The OM confirmed on 2/13/18 at 10:40 am that the laboratory did not perform QC. This was cited on the previous survey dated 12/17/15.</p>
<p><b>D5803</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Patients Medical Records (PMR), Test Results (TR) and interview with the Office Manager (OM), the laboratory failed to have TR in five out of ten PMR reviewed from 12/17/15 to the date of the survey. The OM confirmed on 2/13/18 at 11:20 am that the TR was not in all the PMR .</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Office Manager (OM), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 12/17/15 to the date of survey. The OM confirmed on 2/13/18 at 11:30 am that the TRD was not on the FR.</p>
<b>D5891</b>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to have a procedure to verify manually entered Throat Culture results into electronic medical records for accuracy from 12/17/15 to the date of survey. The OM confirmed on 2/13/18 at 11:10 am that the laboratory did not have the procedure mentioned above. This was cited on the previous survey dated 12/17/15.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 12/17/15 to the date of survey. The findings include: 1. The LD failed to ensure that Quality Control and Quality Assessment programs were established and maintained. Cross refer to D 6020 and 6021. 2. The LD failed to ensure that prior to testing patients' samples all Testing Personnel (TP) had the appropriate education. Cross refer to D 6029. 3. The LD failed to ensure that all TP were competent and retain their competency to process specimens, perform test procedures and report patient results. Cross refer to D 6030. These were cited on the previous survey dated 12/17/15.</p>
<b>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Office Manager (OM), the Laboratory Director failed to ensure that a QC program was established for laboratory services provided from 12/17/15 to the date of the survey. The OM confirmed on 2/13/18 at 10:20 am the LD did not ensure a QC plan was established. This was cited on the previous survey dated 12/17/15.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on lack of a Quality Assessment (QA) program and interview with the Office Manager (OM), the Laboratory Director failed to ensure that a QA program was established from 12/17/15 to the date of survey. The OM confirmed on 2/13/18 at 10:15 am that the laboratory did not have a QA program. This was cited on the previous survey dated 12/17/15.</p>
<p><b>D6029</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Files (PF) and interview with the Office Manager (OM), the Laboratory Director failed to have education records for one out of three Testing Personnel from 12/17/15 to the date of the survey. The OM confirmed on 2/13/18 at 9:40 am that all TP did not have education records. This was cited on the previous survey dated 12/17/15.</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for</p>

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Office Manager (OM), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements for Testing Personnel (TP) from 12/17/15 to the date of the survey. The OM confirmed on 2/13/18 at 10:00 am that a CA procedure was not established for TP. This was cited on the previous survey dated 12/17/15.