

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0666419	(X3) Date Survey Completed 04/21/2021
Name of Provider or Supplier American Bio-Clinical Laboratories	Street Address, City, State 2730 N Main St, Los Angeles, CA	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency for one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency for one of one Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for the one of one Technical Supervisor who performed microscopic evaluations in 2019, 2020 and to the date of the survey in 2021. Technical Supervisor includes: - Laboratory Director/Technical Supervisor 3. During an interview on April 21, 2021 at 12:30 PM Laboratory Director/Technical Supervisor confirmed these findings.</p>
D5659	<p>CYTOLOGY CFR(s): 493.1274(e)(6)</p> <p>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on review of laboratory policies and procedures, final test reports and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for issuing a corrected report. 2. The Survey Team randomly identified one of one corrected report from April 19 thru April 21, 2021, which did not indicate the basis for the correction on the report. Corrected report includes: - N21-01922 3. During an interview on April 20, 2021 at 4:15 PM the Cytology Manager stated that there was not a reason for the correction on the report. 4. During an interview on April 21, 2021 at 12:30 PM the Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency for one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5209.</p>
<p>D9999</p>	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.</p>