

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0692370	<b>(X3) Date Survey Completed</b> 01/16/2019
<b>Name of Provider or Supplier</b> International Medical Laboratory	<b>Street Address, City, State</b> 15 Corporate Park, Irvine, CA	
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>D2098</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the third quarter (Q3-2017) of the College Of American Pathologists (CAP) proficiency testing records, random patient sampling test results from 09/01/2017 to 12/02/2018, and interview with the technical consultant on 01/16/2019 (survey date), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Sex hormone-binding globulin (SHBG) analyte. The findings included: a. Q3-2017, CAP reported an unsatisfactory score of 0% for Sex hormone-binding globulin (SHBG). b. The testing laboratory technical consultant confirmed (401/16/2018 14:30) that the laboratory received the above unsatisfactory proficiency testing score of 0% for (SHBG) testing. c. The accuracy, quality, and reliability of patient results reported during the period of the Q3, 2017 proficiency testing could not be assured. c. The laboratory's testing declaration (01/11/2019) estimated 30,000 endocrinology tests (includes the SHBG analyte) reported annually.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, ten (10) random patient sampling test records and an interview with the laboratory technical consultant and bacteriology technical superior, it was determined that the laboratory failed to follow the laboratory's written policy and procedure manual. The findings included: a. Review of the laboratory's Bacteriology policy for the workup and identification of pathogens following the guidelines entitled "TSI - Biochemical Reactions" and "Staph Identification Chart" (see tables for details) showed that the laboratory testing personnel failed to follow the laboratory's policies and procedures. The laboratory bacteriology workup log sheets lacked documentation that biochemical reactions or assays were performed and that only visual morphological notations were transcribed when bacterial organisms were identified and reported. b. For two (2) patient test records sampled on 04/18/2018 and 04/25/2018 the laboratory's bacteriology workup sheet lacked notations of biochemical reactions performed on bacteriological organisms identified. Date ID# Result 4/18/18 485746 Pseudomonas aeruginosa 4/25/18 486816 SCN c. The technical consultant and bacteriology technical superior confirmed on 01/16/2019 14:20 that the laboratory did not follow the laboratory's written policies and procedures. d. The laboratory's testing declaration (5/21/20015) estimated 14,000 bacteriology tests reported annually.

**D6122**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on reviews of laboratory personnel documents and patients test records, the lack of laboratory documents, and an interview with the technical consultant and technical superior for the procedures for assessing competency (accuracy, quality, and reliability of results) in test performance, the laboratory failed to include monitoring of recording and reporting of test results. See D5401