| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 40D0658269 | 01/11/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Imrl Clinical Lab | 724 Ponce De Leon Ave, Hato Rey, PR | |

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 |
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| **D5012** | SYPHILIS SEROLOGY<br>CFR(s): 493.1207<br><br>If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on manufacturer's instructions of Cenogenics VDRL/STS Test, syphilis serology procedures manual, syphilis serology quality control records from January 2, 2018 to January 11, 2019, policy for Laboratory Method Validation of modified FDA cleared tests and laboratory director and testing personnel interview on January 11, 2019 at 10:35 AM, it was determined that the laboratory failed to meet the requirements for syphilis serology (quantitative Venereal Disease Research Laboratories - VDRL test) from January 2, 2018 to January 11, 2019. The findings include: 1. The laboratory did not perform the quantitative VDRL in accordance with the manufacturer's instructions of Cenogenics VDRL/STS Test. Refer to D5403. 2. The laboratory did not establish the analytical sensitivity (detection limits) of the Cenogenics VDRL/STS Test (modified FDA cleared test) prior reporting patient VDRL quantitative tests. Refer to D5423. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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. |

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| | (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.<br><br>This STANDARD is not met as evidenced by:<br>Based on manufacturer's instructions of Cenogenics VDRL/STS Test, syphilis serology procedures manual, syphilis serology quality control review and laboratory director and testing personnel interview on January 11, 2019 at 10:32 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when perform the quantitative VDRL (Venereal Disease Research Laboratories) patient specimen were tested and reported for VDRL method quantitative tests from January 2, 2018 to January 11, 2019. The findings include: 1. The laboratory performed Venereal Disease Research Laboratories (VDRL) by Cenogenics VDRL /STS. 2. The syphilis serology quality control records were reviewed since January 2, 2018 to January 11, 2019. 3. The Cenogenics VDRL /STS manufacturer's instruction establishes that the laboratory for the quantitative VDRL procedures to report in terms of the greatest serum dilution that produces a Reactive (not Weakly Reactive) result. 4. The syphilis serology (VDRL) testing records showed that the laboratory performed and reported the following dilutions (> 1:64) for 16 out of 16 patients specimens for VDRL quantitative tests from January 2, 2018 to January 11, 2019: Id # 26648926 (4/9 /18), # 26648937 (4/9/18), # 15260946 (4/16/18), # 662662 (5/9/18), # 26748541 (6/15 /18), # 26756308 (6/20/18), # 26823558 (8/7/18), # 26823590 (8/7/18), # 26837466 (8 /15/18), # 26904838 (9/28/18), # 26915717 (10/5/18), # 26925199 (10/11/18), # 26961850 (11/5/18), # 26992216 (11/29/18), # 27004954 (12/7/18) and # 27024141 (12/27/18). The laboratory reported the higher dilution of 1:64 dills without knowing if the patients is reactive at a higher dilution. 5. From January 2, 2018 to January 11, 2019, the laboratory processed and reported 1,930 patient samples for VDRL . 6. The laboratory director confirmed on January 11, 2019, that the laboratory reported the higher dilution of 1:64 dills without knowing if the patients is reactive at a higher dilution those days. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on policy for Laboratory Method Validation of modified FDA cleared tests, syphilis serology procedures manual, syphilis serology quality control records review and laboratory director and testing personnel interview, it was determined that the laboratory failed to establish the analytical sensitive (detection limits) of the Cenogenics VDRL /STS Test (modified FDA cleared test) prior reporting patient VDRL quantitative tests from January 2, 2018 to January 11, 2019. The findings include: 1. The laboratory modified the quantitative VDRL test procedures (Cenogenics VDRL/STS Test) when 16 out of 16 patients specimen were tested and reported for VDRL quantitative tests from January 2, 2018 to January 11, 2019. Refer to D5403. 2. The laboratory policy for Laboratory Method Validation showed that the laboratory must establish the analytic sensitivity (detection limits) for the performance characteristic of the modified FDA cleared test. 3. The laboratory director confirmed on January 11, 2019, that the laboratory did not modified the quantitative VDRL tests procedures, but the testing personnel failed to follow the manufacturer's instruction to perform the quantitative VDRL test procedures (Cenogenics VDRL/STS test) from January 2, 2018 to January 11, 2019. 4. The laboratory processed and reported 1,930 patient's tests by Cenogenics VDRL/STS Test. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on Cenogenics VDRL /STS Test manufacturer's instructions, syphilis serology quality control records from January 2, 2018 to January 11, 2019, Laboratory Method Validation of modified FDA cleared test, test report records review and laboratory director and testing personnel interview on January 11, 2019 at 10:35 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to comply with the analytic system requirements. Refer to D6093. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on Cenogenics VDRL /STS Test manufacturer's instructions, syphilis serology quality control records from January 2, 2018 to January 11, 2019, Laboratory Method Validation of modified FDA cleared test and laboratory director and testing personnel interview on January 11, 2019 at 10:35 AM, it was determined that the laboratory director failed to ensure that the analytic requirements for syphilis serology (quantitative VDRL tests) are established and maintained to assure the quality of laboratory services provided. Refer to D5012. |

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| **D6177** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1495(b)(3)<br><br>Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on Cenogenics VDRL /STS Test manufacturer's instructions, syphilis serology quality control records from January 2, 2018 to January 11, 2019, Laboratory Method Validation of modified FDA cleared test and laboratory director and testing personnel interview on January 11, 2019 at 10:35 AM, it was determined that the testing personnel failed to follow manufacturer's instructions for the analytic requirements for syphilis serology (quantitative VDRL tests) are established and maintained to assure the quality of laboratory services provided. Refer to D5403. |