| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>40D0666528 | (X3) Date Survey Completed<br>03/05/2019 |
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| **Name of Provider or Supplier**<br>Imrl Clinical Lab | **Street Address, City, State**<br>Calle Domingo Caceres #11e, Carolina, 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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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2017 to February 2019 and laboratory director interview on March 5, 2019 at 9:38 AM, it was determined that the laboratory failed to maintain the proficiency testing event records. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records were reviewed from February 2017 to February 2018. 2. Review of proficiency testing records from February 2017 to February 2019, showed that the laboratory did not maintain the following proficiency testing event records: March 2019, April 2019, June 2019, July 2019, August 2019, August 2019, October 2019, November 2019 and December 2019. 3. The laboratory director confirmed on March 5, 2019, that the laboratory did not maintain these proficiency testing event records. 4. This deficiency was cited on February 07, 2017. |
| **D3037** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(4) |

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| | Proficiency testing records. Retain all proficiency testing records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on Puerto Rico Proficiency Testing Program (PRPTP) records from February 2017 to February 2019 and laboratory director interview on March 5, 2019 at 9:38 AM, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing Program (PRPTP) records were reviewed from February 2017 to February 2019. 2. The laboratory did not have the proficiency testing scores from March 2018, April 2018, June 2018, July 2018, August 2018, October 2018, November 2018 and December 2018. 3. The laboratory director confirmed on March 5, 2019 at 9:38 AM, that the laboratory did not have these PRPTP testing scores records. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality control records, written procedures review and laboratory director interview on March 5, 2019 at 11:15 AM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of the centrifuges, rotator and microscope instrument each day of use. The findings include: 1. The laboratory did not perform and document the preventive maintenance of the centrifuges (ALC 4218, Clay Adams), rotator (American Rotator 100) and microscope (Nikon) each day of use from January 2017 to March 5, 2019. 2. The testing personnel confirmed on March 5, 2019, that those preventive maintenance were not perform and document from January 1, 2018 to March 5, 2019. 3. The 2019's annual volume records showed that the laboratory processed the following patients specimens: a. urinalysis (microscopic examination) - 4570 specimens b. pregnancy tests - 60 specimens c. syphilis serology - 177 specimens d. complete blood count - 13955 4. This deficiency was cited on February 7, 2017. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of hematology stain quality control records review and laboratory director and testing personnel interview on March 5, 2019 at 11:36 AM, it was determined that the laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. The findings include: 1. The laboratory establish in the procedures manual, that the |

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| | laboratory check, each day of use, the Wright's stain (Wright's ONE Step Satin) used in hematology for intended reactivity to ensure predictable staining characteristics. 2. Review of hematology quality control records showed that the laboratory did not check nor document the reactivity of Wright's stain reagent, each day of use, from January 1, 2018 to March 5, 2019. 3. The laboratory director and general supervisor confirmed on March 5, 2019, that the laboratory did not check nor document the reactivity of Wright's stain reagent from January 1, 2018 to March 5, 2018. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on hematology quality control records review and laboratory director and general supervisor interview on March 5, 2019 at 11:32 AM, it was determined that the laboratory failed to follow the written policies to evaluate twice a year the relationship of the WBC differential examination results performed by the manual method and Coulter AcT 5 Diff AL system. The findings include: 1. The laboratory performed automatic cell differential by Coulter AcT 5 Diff AL hematology system. 2. Quality controls records were reviewed from January 2017 to March 5, 2019. 3. The laboratory director stated on March 5, 2019, that the laboratory did not evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system since February 2017. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on quality assessment (QA) records review and laboratory director interview on March 5, 2019 at 11:48 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment manual showed that for each analytic process a log sheet was designate to keep track of the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic systems: a. to follow written instructions for the preventive maintenance of the centrifuges, rotator and microscope instrument each day of use. Refer to D5429. b. to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. Refer to D5473. c. to follow the written policies to evaluate twice a year the relationship of the WBC differential examination results performed by the manual method and Coulter AcT 5 Diff AL system. |

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| **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 urinalysis and hematology procedures manual, quality control records review from January 2017 to March 5, 2019 and laboratory director and general supervisor interview on March 5, 2019 at 11:55 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5429, D5473 and D5775. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review from January 2017 to March 5, 2019 and laboratory director interview on March 5, 2019 at 11:48 AM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requierements. The finding includes: 1. The laboratory did not evaluate the established Quality Asessment Program to monitor and evaluate the requirement for analytic systems. Refer to D5791. |