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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0663183 | (X3) Date Survey Completed 01/13/2021 |
| Name of Provider or Supplier Aids Monitoring Lab | Street Address, City, State Bldg 469 Rooms 12,256-258, Frederick, MD | |
| 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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| D0000 | The Centers for Medicare and Medicaid Services (CMS) Philadelphia Regional Office CLIA Surveyors conducted an announced routine CLIA recertification survey at AIDS MONITORING LAB- LEIDOS BIOMEDICAL RESEARCH, INC on January 13, 2021. The laboratory is on compliance with 42 CFR part 493, Requirement for Laboratories with Standard level deficiencies. |
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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. (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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedure, and interview with Technical Supervisor, the laboratory failed to define step by step procedure of testing by not</p> |

providing a reference or description for the morphology of normal cells in a manual differential performed on a peripheral blood smear. 1. In review of "Performing a Differential on Stained Smears" a description of the morphology of basophils, eosinophils, monocytes, and lymphocytes which are cells reported as a result on a manual differential was missing from the procedure. 2. In an interview on January 13, 2021 at 1:00 PM, Technical Supervisor confirmed that cell descriptions and were not defined in the SOP.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:
Based on review of test report, and interview with Technical Supervisor, the laboratory failed to include units of measure in the test report. 1. In review of "AIDS Monitoring Laboratory, CLIA Test Report" the units of measure were missing for all provided values on sample P234112. 2. In an interview on January 13, 2021 at 12:20 PM, the Technical Supervisor confirmed that the lab has not put units of measure in the test report for all patient samples.