

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0915945	(X3) Date Survey Completed 09/15/2022
Name of Provider or Supplier Isabella Martire Md	Street Address, City, State 8343 Cherry Lane, Laurel, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory testing area and interview with the office manager (OM), the laboratory failed to provide an eyewash station within the work area. Findings: 1. OSHA regulation 29 CFR 1910.151(c) requires that "where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use." 2. The area where the laboratory was performing hematology testing was toured during the survey and no eyewash station was observed. 3. During the survey on 09/15/2022 at 11:15 AM, the OM confirmed that there is no eyewash station within the laboratory where testing is performed.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on record review and interview with the office manager (OM), the laboratory failed to have written policies and procedures for entering and reporting patient test results. Findings: During the survey on 09/15/22 at 11:15 AM, the OM confirmed that the laboratory's procedure manual did not have written post analytical policies and procedures for scanning the test results into the electronic medical record system, attaching the result to the patients medical record, and storing the original results in a separate binder.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on review of daily quality control (QC), monthly quality assurance (QA) records, and interview with the office manager (OM), the laboratory's QA plan did not include a mechanism to monitor, evaluate and assess the QC results for shifts and trends. Findings: 1. The QC results are printed each day of testing and reviewed to ensure they are within acceptable limits. 2. The QC section on the monthly QA worksheet confirms that temperatures are taken and recorded, reagents and controls have not exceeded their expiration date, instrument maintenance was performed and documented, and remedial action was performed and documented. 3. The review of the QC results did not include a review of the results in a monthly chart or graph so that shifts and trends could be viewed and remedial action taken when needed. 4. During the survey on 09/15/2022 at 11:15 AM, the OM confirmed that the QC results were not evaluated for shifts and trends on a monthly basis.