| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D0915945 | 03/17/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Isabella Martire Md | 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 |
|---|---|
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on remote record review and phone interview with the office manager and laboratory director (LD), the laboratory did not establish written policies and procedures for assessing the testing personnel as defined in subpart M- CFR 493.1413 (b)(8) through (9): Findings: 1. The laboratory's written procedure manual did not include all the required elements for evaluating the competency of the testing personnel and assuring that they maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to: direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills; and evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. 2. Evaluations must be performed at six months and annually thereafter unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. 3. During the remote survey phone interview on 03/17/2021 at 3:00 |

| | |
|---|---|
| | PM, the LD confirmed that the policies and procedure manual did not include a written training program along with worksheets for the documentation of the of the training of the testing personnel who perform laboratory testing. |
| **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 remote review of quality control (QC) and monthly quality assurance (QA) records and phone interview with the office manager and laboratory director (LD), 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 remote survey phone interview on 03/17/2021 at 3:00 PM, the LD confirmed that the QC results were not evaluated for shifts and trends on a monthly basis. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on remote review of testing personal qualifications and competency evaluations and phone interview with the office manager and laboratory director (LD), the LD did not ensure that the testing person (TP) working in the lab met the minimum educational requirements. Findings: 1. The educational documentation submitted for the only TP was not from the United States. Individuals who have degrees from foreign institutions must have an evaluation of their credentials to determine the equivalency of their education to an education obtained in the United States (U.S.). 2. During the remote survey phone interview on 03/17/2021 at 3:00 PM, the LD confirmed that the credential of the TP had not been evaluated to ensure that they met the minimum requirements of a High School diploma to be employed as a TP. |