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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 18D0975396 | (X3) Date Survey Completed 04/18/2023 |
| Name of Provider or Supplier Dr John Howard Jr Md Psc | Street Address, City, State 2200 E Parrish Ave Suite 202b, Owensboro, KY | |
| 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 |
|---------------------------|--|
| D0000 | A recertification survey was conducted on 04/18/2023 and the facility was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited. |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, personnel records and interview, the laboratory failed to establish a written policy to assess employee competency for 2 of 2 tests (CBC hematology and bilirubin chemistry) performed in the laboratory. Findings included: Review of the laboratory procedure manual revealed there was not a written policy or procedure that revealed how employee competency would be assessed. In an interview on 04/18/2023 at 2:15 PM, Testing Personnel (TP) #1 stated the laboratory did not have a written policy or procedure on how employee competency was evaluated.</p> |
| D5293 | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> |

This STANDARD is not met as evidenced by:
Based on review of quality assurance records, the laboratory's procedure manual, and interview, the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. Findings included: Review of quality assurance records, and the laboratory's procedure manual, revealed there were no written procedures that specified the necessary steps that would be taken to identify and correct problems, efforts to prevent recurrences, and necessary procedures to prevent reoccurrence of problems in the laboratory. In an interview on 04/18/2023 at 2:30 PM, Testing Personnel (TP) #1 stated the laboratory did perform correction actions; however, the corrective actions were not documented. TP #1 confirmed the laboratory did not have quality assurance policies and procedures to indicate how the laboratory adequately assessed and identified problems in the laboratory.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview of testing personnel, the Technical Consultant (TC) failed to assess the six mandated competency assessment criteria for 1 of 1 testing personnel (TP) for Hematology and Routine Chemistry test procedures performed in the laboratory. Findings included: 1. A review of testing personnel records of 2021, 2022, and April 2023 revealed that an assessment was performed for moderately complex procedures in the laboratory, but the assessment did not address the six competency mandated criteria for performing for the specialties of Hematology and Routine Chemistry. 2. Review of annual competency assessment evaluation, dated 03/08/2010 for TP#1 revealed the evaluation did not address the following required six criteria for competency assessment: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. Direct observations of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f. Assessment of problem-solving skills. 3. An interview with the office manager and TP#1 in the office on 4/18/2023 at 2:30 PM confirmed that annual competencies did not contain the six competency assessment criteria for testing personnel in the specialties of Hematology and Routine Chemistry and were not being performed by the TC. A concurrent document review revealed the lab used a standing document to evaluate competency. TP and Laboratory Director signed the standing competency document annually.