

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D0317885	<b>(X3) Date Survey Completed</b>  01/04/2022
<b>Name of Provider or Supplier</b>  Yazoo Family Medicine Pa Db a Yazoo City Med Clinic	<b>Street Address, City, State</b>  805 East 15th Street, Yazoo City, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of QA (quality assessment) logs and proficiency testing records from 10/15/19 through the day of survey and interview with the testing personnel (TP)#1 at 3:00 p.m. on 1/4/22, the laboratory failed to verify the accuracy of urine microscopic testing at least twice annually for 2021. Findings Include: 1. Review of the proficiency records for 2021 revealed no proficiency testing for urine microscopic had been performed. 2. Review of the QA logs revealed there was no documentation of verification of accuracy on urine microscopic analysis performed in 2021. 3. An interview with TP #1 at 3:00 p.m. on 1/4/22 confirmed that accuracy had not been verified in 2021 for urine microscopic analysis.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory testing personnel records available on 1/4/22, the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with testing personnel (TP) #1 (as listed on CMS-209), the laboratory director had not ensured that TP #1 had received appropriate documented training prior to performing moderate complexity testing offered in the clinic laboratory. Findings Include: 1. Based on lack of training documentation available the day of survey, TP #1 had no training prior to performing moderate complexity testing on patients beginning in May 2021. 2. Interview with TP #1 at 3:30 p.m. on 1/4/22 confirmed that no initial training for TP #1 had been documented for moderate testing performed in the laboratory.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the CMS 209 personnel form, lack of qualifying documentation, and interview with TP#1 and office manager at 10:30 a.m. on 1/4/22, the laboratory does not have a technical consultant who meets the qualification requirements of 493.1411 of this subpart.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for

"laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:  
Based on review of the CMS 209 personnel form, lack of qualifying documentation available and interview with the TP #1 and the office manager, the laboratory did not have an individual designated as technical consultant who meets the qualification requirements of 493.1411 of this subpart from May 2021 through January 4, 2022.

**D6049**

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:  
Based on review of laboratory testing records from 10/15/19 through 1/4/22 and interview with TP #1 as listed on the Centers of Medicare & Medicaid Services 209 form at 2:30 p.m. on 1/4/22, laboratory records had not been documented as reviewed by a technical consultant as required. Findings Include: 1. Review of the laboratory records from 5/28/21 (when the previous Technical Consultant resigned) through 1/4/22 revealed the following records were not documented as reviewed by a technical consultant: a. Cell Dyne Emerald hematology maintenance b. Cell Dyne Emerald hematology quality control (QC) c. Cell Dyne Emerald hematology calibration records d. Temperature records (room, refrigerator, freezer) e. Vitros 350 chemistry maintenance f. Vitros 350 chemistry QC g. Vitros 350 chemistry calibration records h. Access 2 endocrinology maintenance i. Access 2 endocrinology QC j. Access 2 endocrinology calibration records k. Proficiency testing results for the 2nd and 3rd events of 2021 2. Interview with the TP#1 at 2:30 p.m. on 1/4/22 confirmed there was no documented review of these records by a technical consultant during this time period.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of testing personnel records from 10/15/19 through 1/4/22, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and interview with TP #1 and the office manager, a technical consultant (TC) failed to evaluate and document the performance semiannually of TP #1 who was performing

moderate complexity testing during the first year of employment. Findings include: 1. Review of the personnel records for TP #1 revealed there was no semiannual laboratory evaluation/competency documented as performed by a technical consultant during the first year of testing patients using moderate complexity testing. TP #1 began employment in May 2021 as a laboratory testing personnel. 2. An interview with the TP #1 and office manager at 3:00 p.m. on 1/4/22 confirmed the semiannual evaluation/ competency was not performed on TP#1.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on review of laboratory testing personnel (TP) records including the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with TP #1 listed on the CMS 209 form and the office manager, the technical consultant failed to evaluate annually and document the performance of testing personnel #2 who is responsible for performing moderate laboratory testing. Findings include: 1. Based on laboratory personnel records available for review on the day of survey, there were no annual evaluations/competencies performed by the technical consultant on TP #2 since the last survey, 10/15/19. The evaluations available the day of survey were signed as performed by non-lab personnel. 2. Interview with TP #1 and the office manager confirmed no annual evaluation/competencies for TP #2 had been documented as performed by the technical consultant for the years 2019, 2020 and 2021.