

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D2108368	(X3) Date Survey Completed 03/10/2020
Name of Provider or Supplier Webster Health Serv Db a Kilmichael Fam Med Clinic	Street Address, City, State 301 Lamar Street, Kilmichael, MS	
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	<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 laboratory personnel documented annual evaluations /competencies and interview with the Technical Consultant (TC) at 4:00 pm on 3/10 /20, the laboratory failed to follow written policies to assess competency of the TC competency at least annually performed by the laboratory director. The annual competency/evaluation available on the day of survey for the TC was attesting laboratory testing competency rather than her duties as technical consultant. Findings include: 1. Based on review of the personnel competency available for the TC on the day of survey, there was no competency evaluation performed that covered the duties of the TC in the lab. 2. Interview with the TC listed on the Centers for Medical & Medicaid Services (CMS) 209 form at 4:00 p.m. confirmed that the competency available included only testing personnel duties and not the TC duties and responsibilities actually performed for the laboratory. 2. Based on review of the personnel records the day of survey 3/10/2020, the laboratory director failed to evaluate the technical consultant at least annually.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor review of the written laboratory procedure manual and interview with the Technical Consultant (TC) listed on the Centers for Medicare and Medicaid (CMS) 209 personnel form on the day of survey 3/10/20 at 3:30 pm, the laboratory director failed to ensure that a comprehensive Quality Assessment (QA) program designed to monitor and evaluate the overall quality of the total testing process (general laboratory, preanalytic, analytic and postanalytic systems) was established, maintained and followed to assure the quality of the laboratory services was provided. Findings include: 1. Review of the laboratory procedure manual revealed there was no QA program available for review. 2. Interview with the TC revealed that no QA program had been established. The laboratory director had not ensured that there was a written QA program that included the practices or issues related to the following when applicable to the test procedure: 1. Patient confidentiality. 2. Specimen integrity. 3. Complaint investigations. 4. Communications. 5. Personnel competency (education, training, evaluation). 6. Proficiency testing or QA activities. 7. Specimen submission, handling, and referral. 8. Establishment and verification of method performance specifications. 9. Control procedures. 10. Review and documentation of the effectiveness of corrective actions taken to resolve problems. 11. Monitoring and evaluating the accuracy and completeness of the laboratory test reports. 12. Performance and periodic review of quality control, proficiency testing, and patient results. 13. Specifications of which qualified personnel will conduct QA reviews and how often these reviews will be conducted, systems and retention of QA records. 14. Revision of policies and procedures necessary to prevent recurrence of problems. 15. Discussion of laboratory QA reviews with appropriate testing personnel. 16. Documentation of QA activities.