

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0892482	(X3) Date Survey Completed 10/14/2021
Name of Provider or Supplier Wt Medical Associates DbA West Tennessee Medical	Street Address, City, State 243 Jim Adams Drive, Paris, TN	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview, the laboratory director and testing personnel failed to sign attestation statements for three of nine events in 2019 and 2020. The findings include: 1. Review of the laboratory's proficiency testing records revealed the following: no signature of the laboratory director on the attestation page for proficiency testing events 19 event three, and 2020 events two and three; no testing personnel signatures on the attestation page for proficiency testing events 2019 event three. 2. Interview with the lead testing person on 10/14/2021 at approximately 1pm confirmed proficiency testing attestations were not signed by the lab director and testing personnel for three of nine PT events reviewed in 2019 and 2020.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the lead testing person,</p>

	<p>the laboratory failed to retain control assay sheets for six of fifteen control lots reviewed. The findings include: 1. Review of the laboratory's quality control records revealed lot numbers 069500, 079500 and 089500 in use on 03.08.2021; lot numbers 068100, 078100, and 088100 in use on 09.22.2021. No quality control assay sheets for the six lot numbers were retained. 2. Interview on 10/14/2021 at 1pm with the lead testing person confirmed the laboratory failed to retain control assay sheets for six of fifteen lots in 2021.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with the lead testing person, the laboratory director failed to review proficiency testing reports for three of nine proficiency testing events in 2020 and 2021. The findings include: 1. Review of the laboratory's proficiency testing records revealed no review of the proficiency testing performance evaluation report for proficiency testing events 2020 event three, and 2021 events one and two. 2. Interview with the lead testing person on 10/14/2021 at approximately 1pm confirmed the laboratory director failed to ensure review of the proficiency performance evaluation reports in 2020 and 2021 for three of nine proficiency testing events.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to have a qualified technical consultant (Refer to D6033).</p>
<p>D6034</p>	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory documents, laboratory personnel records, and interview with the laboratory director, the laboratory failed to have a technical consultant who qualified with training and experience since 2020 to survey date. The findings include: 1. Review of laboratory quality assessment and testing personnel documents revealed the laboratory director was performing technical consultant duties including quality assessment activities and testing personnel competency assessments beginning in 2020. 2. Review of laboratory personnel records revealed no documented laboratory experience for the laboratory director. 3. Interview on 10/14/2021 at approximately 1pm with the laboratory director confirmed the laboratory director did not have the required experience to qualify as a technical consultant, but was performing technical consultant duties since taking over laboratory director duties in 2020.

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 testing personnel competency assessments, patient complete blood count (CBC) test reports, and interview with the lead testing person, the technical consultant failed to perform annual competency for one of four annual competencies in 2020. The findings include: 1. Review of testing personnel competency assessments revealed one of four annual competencies were not performed in 2020. No annual competency was completed for the lead testing person. 2. Review of patient CBC test reports revealed patient testing for CBC performed by the lead testing person on 12/28/2020 for patient number 77599. 3. Interview with the lead testing person on 10/14/2021 at approximately 1pm confirmed the technical consultant failed to evaluate competency on the lead testing person in 2020 with patient testing performed.