

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0397620	<b>(X3) Date Survey Completed</b>  12/06/2018
<b>Name of Provider or Supplier</b>  Tc Fam Med Clintonville	<b>Street Address, City, State</b>  370 S Main Street, Clintonville, WI	
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>D6019</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with testing personnel, the laboratory director did not ensure testing personnel followed the corrective action plan developed in response to an unacceptable erythrocyte sedimentation rate (ESR) result. Findings include: 1. Review of the API (American Proficiency Institute) results for the first hematology PT event in 2018 showed the laboratory reported the ESR result for sample SRB-01 as 3 mm/hr (millimeters/hour). The PT provider accepted results between 52 and 80 mm/hr. The "Performance Review and Corrective Action Documentation" for this event includes a comment dated April 30, 2018: "Lab Director suggested verifying any ESR with a low value - repeat testing at another facility". 2. Interview with testing personnel, staff A, on December 6, 2019 at 10:45 AM confirmed the laboratory did not implement the corrective actions suggested by the laboratory director and confirmed the director did not ensure the corrective action plan was followed.</p>