

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0442414	(X3) Date Survey Completed 06/06/2018
Name of Provider or Supplier Campbell Medical Clinic	Street Address, City, State 413 West Grand, Campbell, MO	
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
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology and urinalysis test reports for 2018, the approved procedure manual and interview with the technical consultant, the laboratory failed to ensure pertinent reference intervals (normal values) were available for interpretation. Reference intervals included on two of two test reports differed from those stated in the approved procedure manual. Findings: 1. Review of two selected test test reports for May 2018 revealed the following differences between reference intervals included on test reports and those stated in the approved procedure manual: Reference intervals included on hematology and urinalysis test reports from May 2018: Hematology: White blood cells (WBC) 4.8 - 11.4 Urinalysis: Urine white blood cells (UWBC) 0-2 Urine red blood cells (URBC) 0-2 Reference intervals revised /effective April 7, 2011 and stated in the approved procedure manual in use; Hematology: White blood cells (WBC) 4.5 - 10.5 Urinalysis: Urine white blood cells (UWBC) 0-4 Urine red blood cells (URBC) 0-1 2. Interview with the technical consultant on June 7, 2018 at 10:00 AM confirmed reference intervals on test reports differed from those stated in the approved procedure manual.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation of the urinalysis centrifuge, review of the approved urinalysis procedure manual, laboratory's literature references and interview with the technical consultant, the director failed to ensure testing personnel performed urine microscopic examinations as required for accurate and reliable results. Findings: 1. Observation of the urinalysis centrifuge revealed a speed setting of 1000 revolutions per minute (RPM) for 10 minutes. 2. Review of the approved urinalysis procedure manual revealed the laboratory centrifuges 12 milliliters (ml) urine for 2 minutes at a speed between 2900 and 3500 RPMs. 3. Review of the laboratory's literature reference (Clinical Diagnosis Management by Laboratory Methods) states, " pour exactly 10 ml of urine into a graduated disposable centrifuge tube. Centrifuge at 2000 RPM for 5 minutes." 4. On interview June 6, 2018 at 10:00 AM, the technical consultant agreed the speed setting on the centrifuge was too slow and the step by step procedure manual for processing urine for microscopic examination differed from the laboratory literature reference stated in the approved procedure. Interview confirmed, the laboratory director failed to ensure testing personnel processed urine for accurate microscopic examinations.