

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0897266	(X3) Date Survey Completed 11/16/2023
Name of Provider or Supplier Caballero Family Healthcare Group, Pllc	Street Address, City, State 1920 Kirby Pkwy Suite 202, Germantown, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of final patient test reports laboratory procedure, and staff interview, the laboratory failed to follow the urine microscopic reporting protocol for the white blood cell per high power field (WBC/hpf), red blood cell per high power field (RBC/hpf), and bacteria per high power field (Bact/hpf) for three of three patients reviewed from 2023. The findings include: 1. Review of final patient test reports for urine sediment microscopic exam revealed the following: Patient #50376 reported 09/15/2023 WBC/hpf 10-20, Bact/hpf 10-20 Patient #10669 reported 03/08/2023 WBC/hpf 0-10, RBC/hpf 0-5 Patient #11615 reported 10/03/2023 WBC/hpf 0-10, RBC/hpf 0-5 2. Review of the laboratory procedure titled "Urine Sediment Microscopic Exam" section "Elements to Report" revealed the following: WBC: (average 10 hpf count) 0-2, 5-10, 20-40, or >100. WBC clumps should be noted. RBC: (average 10 hpf count) 0-2, 5-10, 20-40, or >100. Bacteria: reported as few, moderate, or many (per hpf). 3. Interview on 11/16/2023 at 1:00 pm with the technical consultant confirmed the laboratory failed to follow the reporting protocol for urine sediment microscopic examination in 2023.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from</p>

the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the log used for recording wet prep results, the final patient test report, and staff interview, the laboratory failed to ensure manually entered test results for wet prep were accurately entered into the final patient test report for one of two patients reviewed from 2023. The findings include: 1. Review of the laboratory's manual log for recording wet prep revealed a hyphae result of 0/hpf on 05/03/2023 for patient 55726. 2. Review of the final patient test report revealed the hyphae was reported as 1+. 3. Interview on 11/16/2023 at 1:00 pm with the technical consultant confirmed the laboratory failed to ensure wet prep results were accurately entered from the manual patient log into the patient chart for patient 55726 on 05/03/2023.