

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0900756	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Daniel Jaller, Md Pc	Street Address, City, State 15245 Shady Grove Road Ste 315, Rockville, MD	
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 laboratory procedure manual review, and interview with the laboratory staff and laboratory director (LD), the laboratory did not ensure that the procedure for staining blood slides for analysis accurately reflected the current practice in the laboratory. Findings: 1. The laboratory prepares blood slides for staining with Giemsa stain to test for the presence or absence of Babesia parasites. 2. During an interview at 9:15 am, the laboratory staff stated that they stain the prepared blood slides for 20 minutes with the Giemsa stain. 3. A review of the laboratory procedure manual showed that the procedure for staining slides states, "stain with diluted Giemsa for 30 minutes in a coplin jar." 4. During an interview on 11/6/19 at 10:30 AM, the LD stated that staining time can vary and confirmed that the procedure manual needed to be updated to reflect the current practice in the laboratory.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on laboratory procedure manual and record review, and interview with the laboratory director (LD), the laboratory did not ensure that reagents used in the laboratory were not of substandard quality. Findings: 1. The laboratory uses a buffer solution to prepare Giemsa stain for staining blood slides for identification of blood parasites. The laboratory procedure manual states, "Commercially prepared buffer solution or pH controlled mineral water is used in the lab. The pH of the solution is checked and must measure in the range of 7.2 - 7.4, otherwise we have to open a new buffer solution and check the pH for adequacy." 2. A review of slide staining records from October, 2018 to October, 2019 showed that 19 out of 35 times the pH of the buffer was out of range; and 3. Eight of 35 times the pH of the buffer was not recorded. 4. During an interview on 11/6/19 at 10:30 AM the LD confirmed that the pH of the buffer used for making Giemsa stain was out of range and stated that the range needed to be updated in the procedure manual.