

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2040472	(X3) Date Survey Completed 02/20/2019
Name of Provider or Supplier Mary F Holley Md Pc	Street Address, City, State 2001 Gunter Ave, Guntersville, AL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, a review of proficiency testing records, and interviews with the Laboratory Director (LD) and Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the accuracy in interpretation of vaginal wet preparations and sperm count analyses were performed at least twice annually. This affected the survey review period of 9/28/2016 - 2/20/2019. The findings include: 1. During the entrance tour of the laboratory at 11:00 AM on 2/20/2019, TP #1 stated sperm counts and vaginal wet preparations were included in the laboratory's test menu, and were considered PPM (Provider Performed Microscopy) procedures. 2. A review of the proficiency testing records revealed the laboratory was enrolled in API (American Proficiency Institute) for 2016, 2017 and 2018. However, a review of proficiency testing records for Event #3, 2016 and three testing events in 2017 and 2018 revealed the above mentioned tests were not included in these records. Note: Because these analytes are considered CLIA non-regulated analytes, the laboratory may choose to verify the accuracy by another means, other than organized proficiency testing participation. 3. On 2/20/2019 at 1:20 - 1:42 PM, the surveyor inquired of TP #1 if the laboratory was enrolled in proficiency testing for vaginal wet preparations and sperm counts or verified the accuracy by some other method. TP #1 replied the laboratory was not enrolled in proficiency testing for these procedures and had not performed accuracy verifications by any other means. 4. At 4:30 PM on 2/20/2019, the requirements to verify non-regulated analytes at least twice annually was discussed with the Laboratory Director and TP #1.</p>