

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0202741	(X3) Date Survey Completed 08/30/2018
Name of Provider or Supplier James R Bollinger Md Lab	Street Address, City, State 21 Industrial Blvd, Ste 203, Paoli, PA	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Laboratory Quality Control record review and interview with the Office Manager and Laboratory Director, on the date of the survey (08/30/2018), the laboratory failed to document Quality Control each day patients specimens were examined for sperm morphology, from 03/29/2017 through 08/30/2018. Findings include: 1. Laboratory Quality Control records reviewed at the time of survey (10:30 08/30/2018), revealed the Laboratory did not include sperm morphology controls, at least once each day patients specimens were examined for sperm morphology. 2. 37 sperm morphology tests were preformed from 03/29/2017 through 08/30/2018. 3. During the survey, the Office Manager, confirmed that sperm morphology controls are not documented.</p>
D6092	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on WSLH Proficiency testing record review and interview with the Office</p>

Manager and Laboratory Director on (08/30/2018), at the time of inspection, the Laboratory Director failed to ensure an approved corrective action was followed to prevent recurrence of the 2018 semen analysis proficiency testing failure (Event 1). Findings include: 1. Reviewed WSLH Proficiency testing records at the time of inspection (10:00 08/30/2018), revealed the following: 2018 Event 1 Quantitative Sperm Count - 50% 2. Corrective action was not documented for WSLH Proficiency testing 2018 Event 1. 3. During the survey the Director confirmed the above findings.