

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0202741	(X3) Date Survey Completed 03/30/2021
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 quality control record review and interview with the Laboratory Director on (03/30/2021), the laboratory failed to document all Quality Control procedures performed for sperm morphology examination. Findings include: 1. Quality Control documentation was not found for 66 sperm morphology examination tests performed from 08/30/2018 through the date of survey. 2. During the survey, the Laboratory Director, confirmed that Quality Control was not documented each day of patient testing for sperm morphology examination.</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 (PT) record review and interview with the Laboratory Director 03/30/ 2021 at the time of inspection, the director failed to ensure an approved corrective action plan was followed to prevent recurrence of the semen analysis 2019 proficiency testing failure (Events 1 & 2). Findings include: 1. Review</p>

of proficiency records at the time of inspection revealed the following: 2019 Event 1 Sperm Count - quantitative - 0% Sperm Motility - 0% 2019 Event 2 Sperm Morphology - 0% Sperm Motility - 0% Sperm Count - quantitative - 0% 2. During the survey at 11:00 03/30/2021, the Laboratory Director confirmed the above finding.