

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0202741	(X3) Date Survey Completed 04/11/2023
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
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 lack of documentation and interview with the Laboratory Director (LD) , the laboratory failed to verify twice annually the accuracy of Post Vasectomy examinations performed from 03/30/2021 through the date of the survey. Findings include: 1. On the day of survey, 04/11/2023 at 10:00 am, the laboratory could not provide documentation of verification of accuracy for Post Vasectomy examinations (semen analysis for presence or absence) performed from 03/30/2021 through the date of the survey. 2. The LD reported a total of 108 semen analysis examinations were performed annually (CMS116). 3. The LD confirmed the findings above on 04/11 /2023 at 10:00 a.m.</p>
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 record review and interview with the Laboratory Director (LD), the laboratory failed to document a positive and negative control each day patient</p>

specimens were examined for post vasectomy semen check from 03/30/2021 to 04/11/2023. Findings include: 1. Laboratory records reviewed at the time of survey on 04/11/2023 at 09:50 am, revealed the laboratory did not include a negative and positive control, at least once each day patient testing was performed (semen analysis for presence or absence). 2. The LD reported a total volume of 108 tests were performed annually (CMS116). 3. The LD confirmed the above findings on 04/11/2023 at 9:50AM.