

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2297548	(X3) Date Survey Completed 06/24/2024
Name of Provider or Supplier Blank Check Labs Llc	Street Address, City, State 140 W Main St, Unit 3, Saxonburg, 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
D0000	An initial certification survey was conducted on 06/24/2024. The laboratory was found to be out of compliance with the following standard: 493.1291 Standard: Test report
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Technical consultant, the laboratory failed to document 3 of 3 patient test reports when hematology testing was performed from 04/05/2024 to the date of survey. Findings include: 1. On the day of survey, 06/24/2024 the laboratory was not able to provide completed test reports for the 3 of 3 post-vasectomy semen analyses performed from 04/05/2024 to 06/24/2024. 2. Interview with the Technical consultant on 06/24/2024 at 3:15 pm confirmed the patient results were reported to the patient over the phone and a completed test report was not available.</p>