

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2297548	(X3) Date Survey Completed 05/13/2026
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies, competency assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to follow the established procedure used to assess the competency of 1 of 1 Technical Consultant (TC) for their supervisory responsibilities performed from 06/24/2025 to 05/13/2026. Findings include: 1. On the day of survey, 5/13/2026 at 9:45 am, review of CA records revealed the laboratory failed to follow the established procedure used to assess the competency of the TC for their supervisory responsibilities performed from 06/24/2025 to 05/13/2026. 2. Review of the laboratory's Quality Management Plan revealed the following, " 9.6 Personnel Competency: Competency of General and Technical supervisors is assessed by other Technical or General Supervisors and documented on a Personnel Competence Assessment Form. Competency is assessed initially, at 6 months then yearly as long as the individual is listed as CLIA personnel." 3. The laboratory failed to provide CA records for 1 of 1 TC (CMS 209, personnel #2, dated 05/04/2026) for their supervisory responsibilities performed from 06/24/2025 to 05/13/2026. 4. The laboratory performed 9 hematology tests in 2025 (CMS-116, estimated annual volume dated 05/04/2026). 5. The TC confirmed the findings above on 5/13/2026 at 10:15 am.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>(e)(12) Ensure that policies and procedures are established for monitoring individuals</p>

who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of competency assessment (CA) records and interview with the Technical Consultant (TC), the laboratory director (LD) failed to ensure 1 of 1 testing personnel (TP) maintained their competency to perform qualitative semen analysis (hematology) examinations from 06/24/2024 to 05/13/2026. Findings include: 1. On the day of survey, 5/13/2026 at 9:45 am, review of CA records revealed the LD failed to assess the competency of 1 of 1 TP (CMS 209, personnel #2, dated 05/04/2026) that performed qualitative semen analysis examinations (hematology) from 06/24/2024 to 05/13/2026. 2. The laboratory failed to provide documentation for the following CA records performed for 1 of 1 TP: - 6 month CA (2024) - Annual CA (2025) 3. The laboratory performed 9 hematology tests in 2025 (CMS-116, estimated annual volume, dated 05/4/2026). 4. The TC confirmed the findings above on 5/13/2026 at 10:15 am.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality management policy and interview with the Technical Consultant (TC), the laboratory director (LD) failed to ensure established ongoing quality assessments (QA), were maintained to assure the quality of laboratory services and to identify failures in quality as they occurred for 2 of 2 years from 06/24/2024 to 05/13/2026. Findings include: 1. Blank Check Labs LLC-Quality Management Plan stated, "8 Assessments: 8.1 Policy: The laboratory performs ongoing quality assessments such as: Participate in internal and external audits. 8.2 Internal Assessments: 8.2.1 Internal Audits: - Process and operating procedures - Personnel competency assessments (ensuring all are completed per the set schedule) - Personnel Training - Equipment - Handling of samples - Quality control and validation of results - Recording and reporting practices" 2. On the day of the survey, 05/13/2026 at 9:30 am, the laboratory could not provide documentation of the ongoing QA (internal audits) performed for 2 of 2 years from 06/24/2024 to 05/13/2026. 3. The TC confirmed the findings above on 05/13/2026 at 10:15 am.