

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0256801	<b>(X3) Date Survey Completed</b>  03/10/2023
<b>Name of Provider or Supplier</b>  Harbin Clinic, Llc - Main Office	<b>Street Address, City, State</b>  101 Redmond Road, Rome, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 10, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the laboratory tour and staff interview, the laboratory failed to ensure the fire extinguisher was inspected, the last inspection date was May 2019. The Findings include: 1. Laboratory tour revealed that the fire extinguisher was last inspected in May 2019. There were 3 fire extinguisher's with the same date. 2. During an interview with the General Supervisor on March 10, 2023 at 12:45 PM, in the General Supervisor's office, confirmed the fire extinguishers were last inspected May 2019.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 laboratory policy and procedure manual (SOP) review and staff interview,</p>

the laboratory failed to have the appropriate person evaluate the competency for Testing Personnel(TP). The Findings include: 1. Competency documents revealed the annual competencies were performed but not reviewed by the Laboratory Director for Testing Personnel #1-10 (CMS-209) for 2021 and 2022, as stated in the SOP. 2. During an interview with the General Supervisor (CMS-209) on March 10, 2023 at 1:00 PM, in the breakroom, confirmed that competencies were performed for the Testing Personnel (TP), but the competencies were not evaluated by the Laboratory Director, as stated from the SOP.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist for 2021 (January 2021- December 2021) and 2022 (January-December 2022), and thus far 2023 (January-March 2023). 2. During an interview with the General Supervisor (CMS 209), on March 10, 2023 at 1:15 PM, in the General Supervisor's office, confirmed the lack of a QA checklist for 2021, 2022, and thus far 2023.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals 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 documents and staff interview, the Laboratory Director(LD) failed to ensure competency records for the Testing Personnel were performed, reviewed, and documented. The Findings include: 1. Competency documents revealed that the Laboratory Director failed to perform competencies for 2021 and 2022 for all Testing Personnel (TP) 2. During an interview with the General Supervisor (CMS-209) on March 10, 2023 at 1:25PM, in the General Supervisor's office, confirmed that the Laboratory Director (LD) did not perform competency on the Testing Personnel(TP) for 2021 and 2022.