

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0256801	(X3) Date Survey Completed 01/10/2019
Name of Provider or Supplier Harbin Clinic, Llc - Main Office	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 10, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and interview with the laboratory general supervisor (GS), the laboratory testing personnel (TP) and lab director (LD) failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the PT test records of 2017 revealed: LD and TP failed to sign the Immunology Event #2; LD failed to sign Chemistry Core Event #2 & #3; LD failed to sign Immunology Event #3; LD failed to sign Microbiology Event #3. 2. Review of the PT test records of 2018 revealed: TP failed to sign the Microbiology Event #1; LD failed to sign Chemistry Core Events #1, #2, & #3. 3. Interview with the GS on 1/10/19 in her office at approximately 3 PM, confirmed the absence of the aforementioned signatures for the 2017-2018 PT attestations.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's</p>

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on maintenance document review and staff interview, the laboratory failed to monitor and document room temperature and humidity as required. Findings include; 1. Maintenance document review revealed there were no temperature or humidity logs for the laboratory area for 2017, 2018, and 2019 thus far. 2. An interview with Staff #1 (CMS 209) in the general supervisor's office on 1/10/19 at approximately 3:30 p.m. confirmed the laboratory area room temperature and humidity were not monitored nor documented for 2017, 2018, and 2019 thus far.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to delegate TP assessment responsibilities to qualified TP as required. Findings include: 1. TP competency document review all TP competencies (initial, 6-month, annual) for 2017 and 2018 were performed by unqualified TO due to lack of educational qualifications. 2. An interview with Staff #1 (CMS 209) in the general supervisor's office on 1/10/19 at approximately 3:30 p.m. confirmed the aforementioned competencies were performed by unqualified TP.