

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0256801	(X3) Date Survey Completed 04/15/2025
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 April 15, 2025. 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:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, the laboratory failed to document corrective actions for missed or failed scores in endocrinology and routine chemistry. Findings: 1. Review of the endocrinology analytes revealed the 2025 event #1 Parathyroid hormone (PTH) scored as 80% (sample IAS-02 result was unacceptable)--no corrective actions documented. 2. Review of the routine chemistry analytes revealed: 2023 event #3 Uric acid was scored 0% (samples CH-11 thru CH-15 results were unacceptable), Phosphorus (phos) was scored 80% (sample CH-14 was unacceptable)--no corrective actions documented. 3. Review of the routine chemistry analytes revealed: 2024 event #3 Direct bilirubin (DBIL) scored 80% (sample CH-14 result was unacceptable)--no corrective actions documented. 4. Review of the routine chemistry analytes revealed: 2025 event #1 unsaturated iron-binding capacity (UIBC) scored 80% (sample CH-02 result was unacceptable), Vitimin D 25 Hydroxy (Vit D25 OH) scored 80% (sample IAS-02 was unacceptable) --no corrective actions documented. 5. Interview with GS#4 (CMS 209) on 4/15/25 at 4 PM in the review office confirmed the afformentioned findings.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p>

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on validation studies review and staff interview, the Laboratory Director (LD) failed to approve the documentation on the MicroScan DXM-90 installed on 7/11/23 before the analyzer was used for patient testing. Findings include: 1. Validation studies review reveals the LD failed to review and approve the data on the MicroScan DXM-90 (SN#10563) installed on 7/11/23 before the analyzer was used for patient testing. 2. Interview with GS# 3 on 4/15/25 at 1:32 p.m. in the review office confirmed the finding above.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions 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 review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to fulfill the duties of LD and technical supervisor (TS) by delegating duties and responsibilities to qualified personnel. Findings include: 1. SOP review of Policy Subject: "Medical laboratory director's deligated duties" revealed the LD failed to specify in writing the duties and responsibilities to qualified personnel. Duties and responsibilities of the LD and TS (CMS 209) were delegated to personnel employed as general supervisor (GS on CMS 209 form). The LD is listed on the CMS 209 Report as fulfilling the duties of LD, TS, and CC (clinical consultant). 2. Interview with GS1 (CMS 209) in the review office on 4/15/25 approximately 4:00 p.m. confirmed the aforementioned finding.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:

Based on Microbiology policy and procedure (SOP) review and staff interview, the Laboratory Director (LD) failed to ensure an approved SOP was available as required. Findings include: 1. An SOP review revealed the last approval of the Microbiology or the BD Max SOP by the Laboratory Director occurred on 6/28/19. 2. Interview with GS#3 (CMS 209), in the review office, on 4/15/25, at approximately 3:00 p.m., confirmed the lack of the LD's recent approval of the Microbiology/BD MAX SOP.