

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2164229	(X3) Date Survey Completed 11/01/2023
Name of Provider or Supplier Harbin Clinic Urology	Street Address, City, State 504 Redmond Road, Nw, 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 November 01, 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:
D3011	<p>FACILITIES 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 document review and staff interview during the lab tour, the laboratory failed to document inspections of the eyewash bottles and flush eyewash equipment was not installed in the laboratory to protect against accidental chemical and biohazard facial contamination as required by CLIA from 2021 to 2023. Findings: 1. The review of maintenance records revealed that the laboratory failed to document inspections of the eyewash bottles and there was NO eyewash flush equipment installed in the lab to protect against accidental biohazard and chemical contamination from 2021 to 2023. 2. Interviews with the office manager and General staff (TP #1 CMS 209) at 12:00 PM on 11/01/2023 confirmed the laboratory failed to document inspections of the eyewash bottles and NO flush eyewash equipment was present at the time of survey.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems</p>

identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

A review of the procedure manual and an interview with the office manager director, the laboratory failed to have a Quality Assurance (QA) policy for the laboratory specific to the specialty of Provider Performed Microscopy (PPM) and Urinalysis in 2021 thru 2023. Findings: 1.) Procedure manual review revealed that the clinic does not have a Quality Assurance (QA) policy specific to (PPM) and Urinalysis testing, currently performed in the laboratory. 2.) An interview with the office manager and staff (TP# 1 CMS 209) at approximately at 12:05 PM, on 11/01/2023 in the break room, confirmed that the clinic did not have a written (QA) policy, specific to the current testing performed.

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, on a monthly or quarterly basis, as required. Findings: 1. Laboratory QA documents review revealed the laboratory failed to have a monthly or quarterly quality checklist from 2021 thru date of survey (11/01/2023). 2. Daily maintenance logs including Room Temperature, Humidity and Refrigerator logs, had inadequate normal ranges (RT) or location documented. 3. The laboratory did not have evidence of maintenance log review by lab director or designee from 2021 thru date of survey (11/01/2023). 3. An interview with the office manager and (TP#1 CMS 209), on 11/01/2023, at 12:20 PM in the break room confirmed the lack of a QA checklist and inadequate laboratory oversight in 2021 thru date of survey (11/01/2023).

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on documents review and interview with the office manager, the Lab Director (LD) failed to ensure that Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory in 2022 as required by Clinical Laboratory

Improvement Amendments (CLIA). Findings: 1. Standard Operating Procedures (SOP), QA, proficiency testing (PT) and maintenance logs (Room Temperature, Refrigerator and QC) review revealed the Lab Director, who is also the Technical Consultant (TC), did NOT make ALL Quality Assurance aspects in the laboratory were reviewed and corrective action performed in this case for unsatisfactory (PT) results in Events #2 and #3 in 2022. 2. An interview with the laboratory's office manager and staff in the conference room on 10/26/2023, at approximately 12:30 PM, confirmed the LD failed to ensure proper oversight of the laboratory to solve problems as they occurred in 2022.