

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2164229	(X3) Date Survey Completed 12/09/2025
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 December 9, 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:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 the American Proficiency Institute (API) records for years 2024 and 2025 and an interview with testing personnel (TP), the lab director failed to attest that proficiency test (PT) samples were tested the same as patient specimens. Findings: 1. Review of API attestations for 2024 (events 1, 2, & 3) and 2025 (events 1 & 2) revealed the lab director did not sign the attestation statements. 2. Interview with TP #1 (CMS Form 209) in the breakroom on December 9, 2025 at 1:03 PM confirmed the finding.</p>
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:</p>

Based on review of the Standard Operating Procedure (SOP), Quality Assurance (QA) records, and interview with the testing personnel (TP) the lab director failed to establish a safety standard operation procedure for the eyewash. Findings: 1. Review of the 2024 and 2025 QA records and SOP showed the laboratory lacked an eyewash maintenance procedure. Eyewash logs did not include documented quality checks by testing personnel from July 10, 2025, through December 2, 2025, and the laboratory director did not document review signatures for 2024 or 2025. 2. During a laboratory tour on December 9, 2025, at 3:00 PM, it was identified that the eyewash had been placed on a contaminated sink used for urine disposal. 3. Interview in the laboratory on December 9, 2025, at 3:00 PM, with the back office manager and TP#1 (CMS Form 209) confirmed the laboratory did not meet required eyewash safety and maintenance standards

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on Review of the American Proficiency Institute (API) proficiency testing (PT) documents provided and an interview with testing personnel (TP), the laboratory failed to maintain copies of all PT evaluation reports. Findings: 1. Review of API documents provided (submitted results) revealed the laboratory failed to maintain copies of 2024 (events 1,2, and 3) and 2025 (events 1 and 2) evaluation reports. NO evaluation reports were provided or on file in the laboratory. No documentation of review was provided. 2. Interview with TP #1 (CMS form 209), in the breakroom, on 12/09/2025, at 1:03 PM confirmed the aforementioned finding.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the Standard Operations Procedure (SOP), observation during the lab tour, and interview with testing personnel (TP) the laboratory failed to adhere to the procedure for processing urine samples. The laboratory lacked procedures for all testing processes in the laboratory. Findings: 1. A Review of the SOP revealed that the testing personnel is to "place urine sample into the centrifuge and spin for 5 minutes." 2. During the laboratory tour, on December 9, 2025, at 3:00 PM, TP #1 (CMS 209 form) was observed in the laboratory stopping the centrifuge before the 5 minute timer was complete. TP #1 (CMS 209 form) was also observed lifting the hood of the centrifuge while it was still spinning, and stopping the centrifuge rotor with her hand. 3. Review of the SOP revealed there was no written policy and procedure for the examination of post vasectomy specimens. 4. Interview with TP#1 (CMS form 209) in the laboratory on December 9, 2025 at 3:00 PM confirmed the aforementioned findings.

<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on Standard Operating Procedure (SOP) review and staff interview, the laboratory failed to maintain manufacturers instructions or follow established written procedures. Findings include: 1. SOP review revealed the laboratory is not following written procedures for Quality Control (QC) of complete urinalysis or the equipment maintenance protocol (no eyewash procedure established). 2. Package inserts were not available to review for QC or Multistix. 3. Interview with the testing personnel (TP) #1 on 12/09/2025 at approximately 1:03 p.m.confirmed the lack of following the laboratory SOP or manufacturers instructions for the aforementioned procedures.</p>
<p>D5465</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g)</p> <p>(d)(8) Test control materials in the same manner as patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) documents from 2024 and 2025, observation during laboratory tour, and staff interviews, the laboratory failed to monitor the accuracy and precision of complete urinalysis testing over time. Testing personnel did not test urinalysis quality control materials in the same manner as patient specimens. . Findings: 1. Review of the Quality Control documents (Clinitek Thermal Printouts) from January 2024 to December 9, 2025 revealed missing QC log sheets with acceptable reporting ranges. Document review also revealed no urine microscopic QC was being performed. 2. Observation during the laboratory tour revealed 30 of 30 patients had been run without QC acceptable ranges and without microscopic QC. 3. During an interview, on December 9, 2025, at 1:03 PM in the breakroom, TP#1 (CMS Form 209) confirmed the TP were unaware of the requirement for the log sheets with acceptable ranges or the performance of microscopic urinalysis QC testing.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records from American Proficiency Institute (API) and staff interview, the laboratory director (LD) failed to ensure PT results were printed and reviewed upon receipt from the PT agency. Findings include: 1. Review of API PT records for 2024 (Events 1, 2, and 3) and 2025</p>

	<p>(events 1 and 2) revealed NO evaluation reports were provided or on file in the laboratory. No documentation of review was provided. 2. Interview with the back office manager and TP # 1 (CMS form 209) on December 9, 2025 at 1:03 PM in the breakroom confirmed the aforementioned findings.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and an interview with the back office manager, the Laboratory Director (LD) failed to ensure all testing personnel received proper training before testing and reporting patient samples. Findings: 1. Review of the testing personnel documents for years 2024 and 2025 revealed 1 of 2 TP did not have documented training. TP #1 (see CMS-209 Form) did not have documented training on file. 2. Interview with the back office manager on 12/09/2025 at 3:00 PM in the breakroom confirmed the aforementioned findings.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedure (SOP) and staff interview the Laboratory Director (LD) failed to review and sign the Urinalysis procedure manual available to testing personnel. Findings: 1. Review of the SOP revealed the procedure was last signed and reviewed on 06/25/2015 by previous LD. 2. Review of the SOP revealed no evidence of review by the current LD. 3. Interview on 12/09/2025 at 3:00 PM in the breakroom confirmed the aforementioned findings.</p>
<p>D6032</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>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 specify, in writing the duties and responsibilities of each person engaged in the performance of the preanalytic,</p>

	<p>analytic, and postanalytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. No documentation of duties and responsibilities were available for the LD, Technical Consultant, Clinical Consultant, and Testing Personnel. 2. Interview with the back office manager and TP#1 (CMS 209) in the breakroom on Decemeber 9, 2025 at 1:03 PM confirmed the SOP did not contain a duties and responsibilities policy and procedure.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) documents and an interview with the back office manager, the Technical Consultant (TC) failed to ensure all testing personnel received semi-annual competency evaluations. Findings: 1. Review of the testing personnel documents for years 2024 and 2025 revealed 1 of 2 TP did not have documented semi-annual competency. TP #1 (See CMS-209 Form) did not have documented semi annual competency on file. 2. Interview with the back office manager on 12/09/2025 at 3:00 PM in the breakroom confirmed aformentioned finding.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel(TP) documents and staff interview , the laboratory director (LD) also serving as the Technical Consultant (TC) failed to perform annual competency on all testing personnel. Findings include: 1. Review of personnel records (October 1, 2024 to October 31, 2025) revealed TP #1 (CMS-209 form) did not have annual competency performed for year 2024 and 2025. 2. Interview with TP#1 (CMS 209 form) on December 9, 2025 at 1:03 PM in the breakroom, stated she had not been evaluated for competency annually for years of 2024 and 2025.</p>