

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D2126870	<b>(X3) Date Survey Completed</b> 02/03/2025
<b>Name of Provider or Supplier</b> Uhmp - Portage Urology	<b>Street Address, City, State</b> 3963 Loomis Parkway, Ravenna, OH	
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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to enroll with a proficiency testing (PT) provider for the urine microscopic tests performed in the subspecialty of Urinalysis. This deficient practice had the potential to affect two out of two patient urine microscopic tests performed in this laboratory from 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's "UHPS-CLIN-17.0-Proficiency Testing Policy", unapproved by the Laboratory Director and provided on the date of the complaint investigation, found the following statement: "This Laboratory has implemented and maintains a Proficiency Testing Policy in compliance with CLIA 88 rules and regulations." 2. The Inspector requested the laboratory's 2025 urine microscopic PT documentation from the RNCC. The RNCC confirmed, on 02/03/2025 at 9:52 AM, that the laboratory had not enrolled in urine microscopic proficiency testing in 2025 and was unable to provide the requested documentation on the date of the complaint investigation. The RNCC further confirmed via an electronic mail message on 02/10/2025 at 11:26 AM, the first patient urine microscopic test was conducted on 01/23/2025.</p>
<b>D5209</b>	PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to follow written policies and procedures to assess the competency of the Testing Personnel (TP) for the moderately complex Provider Performed Microscopy (PPM) testing procedures performed in the specialty of Hematology and the subspecialty of Urinalysis. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 02/03/2025 and provided on the date of the complaint investigation revealed two qualified and listed individuals as TP to perform PPM testing procedures. 2. Review of the laboratory's "Competency Testing" policy and procedure, unapproved via signature and date by the Laboratory Director and provided on the date of the complaint investigation revealed the following: "1. UHPS requires annual competency to be completed on every lab test, for each site, every January. 1.1. New hire and internal transfers: 1.1.1. Training and initial competency completion in the first 30 days. 1.1.2. Repeat competency 6 months after date of hire 1.1.3. Repeat competency 1 year from date of hire 1.1.4. Follow annual competency 1.2. Current employees follow annual competency 2.0 Ultimately, the lab director is responsible to ensure that all testing personnel are competent and maintain their competency in order to perform and report accurate and reliable test results." 3. Review of the laboratory's "Physician Performed Microscopy (PPM) and CLIA Waived Point-of-Care Testing, CP-118" policy and procedure, unapproved via signature and date by the Laboratory Director and provided on the date of the complaint investigation revealed the following: "...competency is required to be assessed semiannually the first year and annually thereafter for all physicians and practitioners who perform PPM independently." "7.0 Microscopic procedures performed under the CLIA PPM Certificate: 1. Competency: 1. Privileges to perform the specified microscopy procedures are contingent upon annual competency assessments. Clinical departments are responsible for administering and documenting annual competency assessments, which must be available for accrediting agency review. 2. House staff may perform PPM under direct supervision and may perform PPM independently once competency has been demonstrated.... 3. Annual competency assessments are required for all physicians/LIP's who perform Provider Performed Microscopy (PPM)...." 4. Review of the laboratory's "UHPS-Clin-7.0-Laboratory Competency Policy", unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation found the following: "UHPS requires annual competency to be completed each January. \*A new hire needs initial training and initial competency within the first few weeks of hire. Then 6 months after date of hire competency needs to be performed on every test, then one year from date of hire competency needs performed again. Then the employee can be put into the regular annual competency rotation. \*Current employees that transfer to another UH office must be treated like a new hire and follow the new hire competency timeline, regardless of any previous competency at another office. \*Employees who work at more than one office (site) regardless of whether it is the same physician

group must have competency completed at each office (site). \*Thereafter; evaluations will be performed annually in accordance with our UH policy." 5. Further review of the laboratory's policy and procedure manual, unapproved via signature and date by the Laboratory Director and provided on the date of the complaint investigation revealed a blank "UHMSO Waived-PPMP Laboratory Testing Form". 6. The Inspector requested the laboratory's 2023, 2024 and 2025 competency assessment documentation for Testing Personnel (TP) #1 and TP#2 from the RNCC. The RNCC confirmed the laboratory did not conduct competency assessments on TP#1 and TP#2 in 2023, 2024 and 2025 and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 9:52 AM.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to establish and conduct blind test accuracy verification (TAV) activities, at least twice annually, for the post-vasectomy presence or absence of sperm testing procedures in the specialty of Hematology. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy semen specimens tested between 02/03/2023 through 02/03/2025. Findings Include: 1. Review of the laboratory's "UHPS-CLIN-17.0-Proficiency Testing Policy", unapproved by the Laboratory Director and provided on the date of the inspection, did not find any mention of TAV instructions. 2. The Inspector requested the laboratory's TAV policy and procedure and 2023, 2024 and 2025 documentation of blind TAV for the post-vasectomy presence or absence of sperm test procedures performed from the RNCC. The RNCC confirmed the laboratory did not establish a TAV policy and procedure, the laboratory did not enroll in a proficiency testing module or conduct any TAV activities in 2023, 2024 and 2025 to date for the post-vasectomy presence or absence of sperm test procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/03/2025 at 9:52 AM.

**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 record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to ensure that written post-vasectomy presence or absence of sperm, urine microscopic and microscope and centrifuge maintenance/service policies and procedures were established and available to the laboratory personnel for the testing conducted in the specialty of Hematology and the subspecialty of Urinalysis. This deficient practice had the potential to affect 396 out of 396 patient post-

vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the complaint investigation did not find any post-vasectomy presence or absence of sperm, urine microscopic and microscope and centrifuge maintenance/service policies and procedures. 2. The Inspector requested the laboratory's post-vasectomy presence or absence of sperm, urine microscopic and microscope and centrifuge maintenance/service policies and procedures from the RNCC. The RNCC confirmed the laboratory did not establish written post-vasectomy presence or absence of sperm, urine microscopic and microscope and centrifuge maintenance/service policies and procedures and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 9:52 AM.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to establish step-by-step performance of the procedure instructions, specimen collection, labeling, storage, preservation, processing, criteria for specimen acceptability and rejection, preparation of slides and controls used in testing, control procedures, corrective action to take when control results fail to meet the laboratory's criteria for acceptability, interpretation of the results, limitations of the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable for post-vasectomy presence or absence of sperm and urine microscopic. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's "UHPS-CLIN-12.0-Laboratory Procedure Book Policy", unapproved by the Laboratory Director and provided on the date of the complaint investigation, found the following statements:

"Each procedure must include step by step operating instructions." "Each procedure must include specimen collection requirements." "Each procedure must include interpretation of the results." "Each procedure must include Quality Control requirements." "Each procedure must include limitations of test." "This book must be kept on site and available to staff, physicians and inspectors at all times." 2. Further review of the laboratory's "UHPS-CLIN-12.0-Laboratory Procedure Book Policy", unapproved by the Laboratory Director and provided on the date of the complaint investigation, did not find step-by-step performance of the procedure instructions, specimen collection, labeling, storage, preservation, processing, criteria for specimen acceptability and rejection, preparation of slides and controls used in testing, control procedures, corrective action to take when control results fail to meet the laboratory's criteria for acceptability, interpretation of the results, limitations of the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable for post-vasectomy presence or absence of sperm and urine microscopic testing. 3. The Inspector requested the laboratory's post-vasectomy presence or absence of sperm and urine microscopic policies and procedures from the RNCC. The RNCC confirmed that the laboratory did not establish post-vasectomy presence or absence of sperm and urine microscopic policies and procedures and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 9:52 AM.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the RN Clinical Coordinator (RNCC), the Laboratory Director failed to ensure that policies and procedures for Provider Performed Microscopy Procedures (moderately complex) in the specialty of Hematology and the subspecialty of Urinalysis were established, approved via signature and date before implementation and available to the laboratory personnel. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the complaint investigation, did not find the Laboratory Director's approval via signature and date on any of the laboratory's policies and procedures. 2. Further review of the laboratory's policies and procedures provided on the date of the complaint investigation did not find any mention of post-vasectomy presence or absence of sperm, urine microscopic and microscope and centrifuge maintenance/service policies and procedures. 3. The Inspector requested the laboratory's approved policies and procedures via signature and date by the Laboratory Director from the RNCC. The RNCC confirmed the laboratory did not establish post-vasectomy presence or absence of sperm, urine microscopic and microscope and centrifuge maintenance/service policies and procedures, the Laboratory Director did not approve any of the laboratory's policies and procedures via signature and date and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 9:52 AM.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(b) 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 instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 record review, direct observation and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to define criteria, monitor and document maintenance and service activities of the microscope and centrifuge utilized for Provider Performed Microscopy Procedures (PPMP) performed in the specialty of Hematology and subspecialty of Urinalysis. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 02/03/2025 and provided on the date of the complaint investigation revealed the laboratory performed post-vasectomy presence or absence of sperm and urine microscopic testing utilizing a microscope and centrifuge. 2. Review of the laboratory's policies and procedures, unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation did not find any maintenance and service policies and procedures for the microscope and centrifuge. 3. Direct observation of the laboratory's Olympus BH2 microscope (serial number; 003676) found one Environmental Services (ES) sticker affixed to the microscope with the following documentation: ES Done 4/23, Due 4/24 4. Direct observation of the laboratory's centrifuge (serial number; 48713) found two ES stickers affixed to the centrifuge with the following documentation: ES Done 4/21, Due 4/22 ES Done 4/23, Due 4/24 5. Review of the laboratory's "Microscope Cleaning Log" provided on the date of the complaint investigation revealed microscope cleaning was only documented on seven out of 31 days in January 2025 with eight out of 31 days of documented patient PPMP testing performed. 6. The Inspector requested the laboratory's maintenance and service policies and procedures, approved by the Laboratory Director via signature and date, and their 2023, 2024 and 2025 microscope and centrifuge maintenance and service documentation from the RNCC. The RNCC confirmed the laboratory did not establish and define maintenance and service policies and procedures, did not monitor and document maintenance for their microscope in 2023 and 2024 and for their centrifuge in 2023, 2024 and 2025. The RNCC further confirmed the laboratory previously contracted with B&B Microscopics for annual service, however the microscope and centrifuge were not serviced in 2024 and 2025, as required, and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 11:35 AM.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to establish and demonstrate performance specifications for the urine microscopic testing which were not provided by the manufacturer to include accuracy, precision and any other performance characteristics required for accurate and reliable test performance in the subspecialty of Urinalysis before reporting patient test results. This deficient practice had the potential to affect two out of two patient urine microscopic tests performed since the implementation of testing on 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's policies and procedures, unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation, did not find any performance specification instructions for urine microscopic testing procedures performed. 2. The Inspector requested the laboratory's policy and procedure for performance specification activities and the laboratory's performance specification documentation conducted prior to implementing patient urine microscopic testing on 01/23/2025 from the RNCC. The RNCC confirmed the laboratory did not establish a policy and procedure for urine microscopic testing and performance specifications, did not conduct and document any performance specification activities and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 9:55 AM.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Director and RN Clinical Coordinator (RNCC), the laboratory failed to conduct and document a negative and positive quality control for the qualitative post-vasectomy presence or absence of sperm and urine microscopic testing procedures. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's "Specimen Collection and Handling, CLIA-3" policy and procedure, unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation, found the following: "Quality Control (QC) 1. Quality Control is performed and documented on all laboratory tests prior to patient testing. Document on corresponding quality control log. 2. The frequency of Quality Control...is required either daily, weekly or with each test... 4.

Complete action plan for all out of range quality controls. 5. Verify acceptable range for each quality control material... 7. All vials are marked clearly with: 7.1. Open date 7.2. Expiration date... 7.3. Initials of person who opened and performed the QC..." 2. The Inspector requested the laboratory's 2023, 2024 and 2025 post-vasectomy presence or absence of sperm QC and 2025 urine microscopic QC documentation from the Laboratory Director and RNCC. The Laboratory Director stated "either the sperm are there or they're not" and confirmed on 02/03/2025 at 9:33 AM that no QC had been conducted for post-vasectomy presence or absence of sperm testing. The RNCC confirmed the laboratory did not conduct and document any urine microscopic QC and was unable to provide the requested documentation on the date of the complaint investigation on 02/03/2025 at 9:55 AM.

**D5485**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(h)

(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. (a) The laboratory must check the following for positive and negative reactivity using control organisms:

This STANDARD is not met as evidenced by:  
Based on record review and interviews with the Laboratory Director and RN Clinical Coordinator (RNCC), the laboratory failed to establish and document an alternative quality control (QC) mechanism when commercial QC materials were not available for post-vasectomy presence or absence of sperm and urine microscopic testing procedures. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's policies and procedures, unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation did not find any alternative QC instructions when commercial QC materials were not available. 2. The Inspector requested the laboratory's alternative QC policy and procedure when commercial QC material was not available and their 2023, 2024 and 2025 post-vasectomy presence or absence of sperm and 2025 urine microscopic QC documentation from the RNCC. The RNCC confirmed the laboratory did not conduct and document any QC or alternative QC activities when commercial QC material was not available for the post-vasectomy presence or absence of sperm and urine microscopic testing procedures performed and was unable to provide the requested documentation on the date of the complaint investigation The interview occurred on 02/03/2025 at 9:55 AM.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:  
 Based on record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to maintain an information or record system that included the time of specimen receipt into the laboratory and the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability for the post-vasectomy presence or absence of sperm and urine microscopic tests performed. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's policies and procedures, unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation did not find policies and procedures for post-vasectomy presence or absence of sperm and urine microscopic tests. 2. The Inspector requested the laboratory's 2023 and 2024 UHSP Patient Microscopic Result Logs and a sample of five patient requisitions, intermediate test results logs and the corresponding final reports for post-vasectomy presence or absence of sperm and urine microscopic testing in 2023, 2024 and 2025 from the RNCC. The RNCC confirmed on 02/03/2025 at 12:11 PM that the test orders were not entered in the EPIC electronic medical record system as required and therefore no final test reports were available. The RNCC further confirmed the test and test results were only indicated within the patient visit notes. The RNCC was unable to provide the requested documentation on the date or within seven days of the complaint investigation. 3. The Inspector requested the laboratory's policies and procedures for post-vasectomy presence or absence of sperm and urine microscopic testing, including test order entry, result entry (test name, specimen type, date/time of receipt, date/time of result) and the condition and disposition of patient specimens that do not meet the laboratory's criteria for acceptability from the RNCC. The RNCC confirmed the laboratory did not establish policies and procedures for post-vasectomy presence or absence of sperm and urine microscopic testing, including test order entry, result entry (test name, specimen type, date/time of receipt, date/time of result) and the condition and disposition of patient specimens that do not meet the laboratory's criteria for acceptability and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 12:11 PM.

**D5805**

**TEST REPORT**  
 CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
 Based on record review and an interview with the RN Clinical Coordinator (RNCC), the laboratory failed to ensure the laboratory had test reports that indicated the patient's name and unique patient identifier, test report date, test performed, specimen source (when appropriate), test result and any information regarding the condition and

disposition of specimens that do not meet the laboratory's criteria for acceptability for the post-vasectomy presence or absence of sperm and urine microscopic testing performed. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's policies and procedures, unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation did not find instructions for entering laboratory test orders into their computer system and for test reports. 2. The Inspector requested the laboratory's 2023 and 2024 UHSP Patient Microscopic Result Logs and a sample of five patient requisitions, intermediate test results logs and the corresponding final reports for post-vasectomy presence or absence of sperm in 2023, 2024 and 2025 and urine microscopic testing in 2025 from the RNCC. The Inspector and RNCC reviewed the five sampled January 2025 patient microscopic test records and final test reports. The RNCC confirmed on 02/03/2025 at 12:11 PM that the test orders were not entered in the EPIC electronic medical record system as required, the test and test results were only indicated within the patient's visit notes, therefore no final test reports were available and was unable to provide the requested documentation on the date or within seven days of the complaint investigation.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the RN Clinical Coordinator (RNCC), the Laboratory Director failed to ensure that quality control (QC) and quality assessment (QA) programs were maintained to assure the quality of post-vasectomy presence or absence of sperm and urine microscopic testing procedures performed in the specialty of Hematology and the subspecialty of Urinalysis. This deficient practice had the potential to affect 396 out of 396 patient post-vasectomy presence or absence of sperm tests performed between 02/03/2023 through 02/03/2025 and two out of two urine microscopic tests performed between 01/23/2025 through 02/03/2025. Findings Include: 1. Review of the laboratory's policies and procedures, unapproved by the Laboratory Director via signature and date and provided on the date of the complaint investigation, did not find policies and procedures for post-vasectomy presence or absence of sperm and for urine microscopic testing to include the number, type and frequency of QC and the monitors and frequency of QA activities. 2. The Inspector requested the laboratory's 2023, 2024 and 2025 QC and QA documentation for post-vasectomy presence or absence of sperm and 2025 QC and QA documentation for urine microscopic testing from the RNCC. The RNCC confirmed the laboratory did not perform and document any QC testing or QA activities for the post-vasectomy presence or absence of sperm and urine microscopic testing in 2023, 2024 and 2025 and was unable to provide the requested documentation on the date of the complaint investigation. The interview occurred on 02/03/2025 at 9:52 AM.