

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0719423	(X3) Date Survey Completed 05/19/2026
Name of Provider or Supplier Msu Urology	Street Address, City, State 4660 S Hagadorn Road Suite 600, East Lansing, MI	
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	An complaint investigation was performed on May 19, 2026 at MSU Urology laboratory by the State of Michigan Licensing and Regulatory Affairs Department for complaint intake number MI00155670. During the investigation, it was determined Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: 493.1215 Condition: Hematology. 493.1355 Condition: Laboratories performing PPM procedures; laboratory director. 493.1361 Condition: Laboratories performing PPM procedures; testing personnel.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interviews, the laboratory failed to follow manufacturer's instructions for its urinalysis testing for one (May 2025 to May 2026) of one year reviewed. Findings include: 1. The surveyor observed the laboratory on 5/19/26 at 9:19 am and saw the following waived testing supplies: a. Two Clinitek Status + urinalysis analyzers b. Siemens Multistix 10 SG reagent strips for urinalysis No manufacturers' instructions were found present in the laboratory. 2. An interview on 5/19/26 at 9:33 am with medical assistant #1 revealed the laboratory had not used the control materials present in the laboratory and that they had not performed quality control testing when new bottles of Siemens Multistix were opened. 3. The surveyor requested manufacturers' instructions for the Clinitek Status + and Siemens Multistix 10 SG and any documentation of quality control testing performed between May 2024 and May 2025 on 5/19/26 at 10:44 am. The surveyor was emailed links to external websites and electronic copies of manufacturers' instructions. No documentation of quality control testing was provided. 4. A review of the electronic

copy of the "Siemens Multistix 10 SG" manufacturer's instructions included a section titled "QUALITY CONTROL" stating, "Test negative and positive controls when you first open a new bottle. Water should NOT be used as a negative control." and a section stating, "Test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days. Run QC tests to ensure reagent strips integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match." 5. An interview on 5/19/26 at 11:39 am with the Director of Practices confirmed the manufacturer's instructions provided had been retrieved from the internet and was unsure whether these instructions were available to testing personnel. B. Based on observation, record review, and interview with the Clinic Manager, the laboratory failed to follow manufacturers' instructions to ensure supplies had not exceeded expiration dates for one of six bottles of Siemens Multistix and six of six bottles of Consult Diagnostics McKesson urinalysis control dropper bottles. Findings include: 1. The surveyor observed the laboratory on 5/19/26 at 9:19 am and saw the following expired waived testing materials: a. Three bottles of Consult Diagnostics McKesson urinalysis control level 1 bottles with the expiration date of 1/3/2026. b. Three bottles of Consult Diagnostics McKesson urinalysis control level 2 bottles with the expiration date of 1/4/2026. c. One bottle of Siemens Multistix 10 SG with the expiration date of 4/30/2026. 2. A review of the electronic copy of the "Siemens Multistix 10 SG" manufacturer instructions included a section titled "STORAGE" stating, "Do not use the strips after their expiration date." 3. A review of the "Consult Diagnostics Premium Liquid Urine Controls Dropper Style" package insert included a section titled "Stability and Storage" stating, "McKesson Urine Control is stable until the expiration date stated on the label, when stored between 2 degrees and 8 degrees C." 4. An interview on 5/19/26 at 9:40 am with the Clinic Manager confirmed the above findings.

D5024

HEMATOLOGY
CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

. Based on observation, record review, and interviews, the laboratory failed to establish a competency assessment policy to assess testing personnel performing qualitative post-vasectomy (refer to D5209), failed to verify the accuracy of its qualitative post-vasectomy semen analysis testing (refer to D5217), failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in general laboratory systems (refer to D5291), failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in preanalytic systems (refer to D5391), failed to follow its qualitative post-vasectomy semen analysis test procedure (refer to D5401), failed to have an approved test procedure for the performance of qualitative post-vasectomy semen analysis (refer to D5407), failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in analytic systems (refer to D5791), failed to accurately document test results (refer to D5801), and failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in post analytic systems (refer to D5891).

D5209	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 a lack of documentation and interview with the Director of Practices, the laboratory failed to establish a competency assessment policy to assess testing personnel performing qualitative post-vasectomy semen analysis for two (May 2024 to May 2026) of two years requested. Findings include: 1. The surveyor requested the laboratory's competency assessment policy on 5/19/26 at 9:27 am and 12:02 pm and it was not provided. 2. An interview on 5/19/26 at 12:02 pm with the Director of Practices confirmed a competency assessment policy was not present.
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 a lack of documentation and interview with the Director of Practices, the laboratory failed to verify the accuracy of its qualitative post-vasectomy semen analysis testing for two (May 2024 to May 2026) of two years requested. Findings include: 1. The surveyor requested documentation of the laboratory's verification of accuracy testing performed between May 2024 and May 2026 for its qualitative post-vasectomy semen analysis testing on 5/19/26 at 9:27 am and 12:04 pm. Documentation was not made available. 2. An interview on 5/19/26 at 12:04 pm with the Director of Practices confirmed verification of accuracy testing performed between May 2024 and May 2026 for its qualitative post-vasectomy semen analysis testing was not available.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Director of Practices, the laboratory failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in general laboratory systems for two (May 2024 to May 2026) of two years requested. Findings include: 1. The surveyor requested the laboratory's quality assessment records from May 2024 to May 2026 on

	5/19/26 at 9:27 am and the records were not made available. 2. An interview on 5/19/26 at 12:02 pm with the Director of Practices confirmed quality assessment records from May 2024 to May 2026 were not present.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Director of Practices, the laboratory failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in preanalytic systems for two (May 2024 to May 2026) of two years requested. Findings include: 1. The surveyor requested the laboratory's quality assessment records from May 2024 to May 2026 on 5/19/26 at 9:27 am and the records were not made available. 2. An interview on 5/19/26 at 12:02 pm with the Director of Practices confirmed quality assessment records from May 2024 to May 2026 were not present.
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 interview with the Director of Practices, the laboratory failed to follow its qualitative post-vasectomy semen analysis test procedure for two (Patients #3 and #5) of five patient test reports reviewed. Findings include: 1. A review of the laboratory's "Qualitative Semen Analysis" test procedure revealed a section titled "Semen Specimen Collection" stating, "Evaluate the specimen within 30 minutes of collection" and "Store at room temperature. Do not place the specimen in the refrigerator. Do not use specimens older than 2 hours." 2. A review of five patient test records showed the following patients had testing completed on specimens more than two hours old: a. Patient #3's record included a note on 3/9/26 at 9:14 am noting the specimen was received, but did not include the time the specimen was collected or the time the testing was completed. The record included a note on 3/9/26 at 4:43 pm, over seven hours later stating, "Pt (patient) has been called and informed." b. Patient #5's record did not include the time of specimen collection. On 5/13/26 at 10:47 am, there was a note stating, "Pt dropped off a semen sample this morning. Placed in Urology lab." Another note dated 5/13/26 4:30 pm, over five hours later, stated "Patient has been contacted and informed that his semen sample is negative for any live sperms cells [sic]." 3. The surveyor requested additional information about the specimen collection, receipt, and testing times for the patients listed above on 5/19/26 at 12:08 pm and it was not provided. 4. An interview on 5/19/26 at 12:54 pm with the Director of Practices indicated additional information for the timeframe of specimen collection to test performance was not present for the patients listed above.

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 interview with the Director of Practices, the laboratory failed to have an approved test procedure for the performance of qualitative post-vasectomy semen analysis for two (May 2024 to May 2026) of two years reviewed. Findings include: 1. A review of the laboratory's "Qualitative Semen Analysis" policy revealed a lack of laboratory director's approval, signature, or date of initiation. 2. An interview on 5/19/26 at 11:39 am with the Director of Practices confirmed the laboratory director had not approved the "Qualitative Semen Analysis" test procedure.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Director of Practices, the laboratory failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in analytic systems for two (May 2024 to May 2026) of two years requested. Findings include: 1. The surveyor requested the laboratory's quality assessment records from May 2024 to May 2026 on 5/19/26 at 9:27 am and the records were not made available. 2. An interview on 5/19/26 at 12:02 pm with the Director of Practices confirmed quality assessment records from May 2024 to May 2026 were not present.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Practices, the laboratory failed to accurately document test results for two (Patient #2 and #3) of five patient test reports reviewed. Findings include: 1. A review of five patient test reports revealed the following: a. Patient #2's test report included a note dated 7/16/25 stating, "Patient brought PVSA (post-vasectomy semen analysis) to the clinic today. The

	specimen was received by [staff name redacted]. Urology staff member [staff name redacted] was informed. Patient is s/p (status post) vasectomy from {{2/21/25}} at the {{Office}}. Specimen was plated by [medical assistant #3], and [testing personnel #1] was informed that the slide is ready to be assessed. Specimen was {{negative positive}} for motile semen [sic]. Patient informed 7/16/25 9:54." It is unclear what the patient's test results were. b. Patient #3 had a note under "All Conversations" dated 3/9/26 9:14 am stating, "Semen sample: Patient brought PVSA to the clinic today. The specimen was received by [staff member name redacted]. Urology staff member [staff member name redacted] was informed. Patient is s/p vasectomy from at the office on 10/23/2025 [sic]" and a note dated 3/9/26 4:43 pm stating, "Pt (patient) has been called and informed." There was no documentation of the results of the post-vasectomy semen analysis. 2. An interview on 5/19/26 at 12:08 pm with the Director of Practices confirmed the above findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Director of Practices, the laboratory failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in post analytic systems for two (May 2024 to May 2026) of two years requested. Findings include: 1. The surveyor requested the laboratory's quality assessment records from May 2024 to May 2026 on 5/19/26 at 9:27 am and the records were not made available. 2. An interview on 5/19/26 at 12:02 pm with the Director of Practices confirmed quality assessment records from May 2024 to May 2026 were not present.
D5980	PPM LABORATORY DIRECTOR CFR(s): 493.1355 The laboratory must have a director who meets the qualification requirements of 493.1357 and provides overall management and direction in accordance with 493.1359. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to have a laboratory director for eight (October 2025 to May 2026) months since the laboratory director vacated the position. Findings include: 1. The surveyor requested a completed Form CMS-116 signed by the laboratory director on 5/19/26 at 9:27 am. 2. A review of Form CMS-116 completed revealed the name of the laboratory director on the form did not match the name of the laboratory director listed on the current Certificate of Provider Performed Microscopy Procedures. Further review revealed the Form CMS-116 was not signed. 3. An interview on 5/19/26 at 10:52 am with the Director of Practices revealed the provider listed on the current Certificate of Provider-Performed Microscopy had vacated their position with the medical practice and confirmed the laboratory had not notified the state agency of a change in laboratory director. 4. An interview on 5/19/26 at 12:07 pm with the Director of Practices indicated the provider listed on the current Certificate of Provider-Performed Microscopy had vacated their

	position with the medical practice as of 9/30/25. 5. An interview on 5/19/26 at 12:54 pm with the Director of Practices confirmed there was a lack of documentation that the provider listed on Form CMS-116 completed for the complaint survey had agreed to serve as the laboratory director. Based on observation, record review, and interviews, the laboratory director failed to ensure verification of accuracy was performed at least twice annually for its qualitative post-vasectomy semen analysis testing (refer to D5983 A), failed to ensure test results were accurately documented (refer to D5983 B), failed to ensure personnel performing specimen processing for qualitative post-vasectomy semen analysis were qualified as testing personnel (refer to D5987), and failed to evaluate the competency of testing personnel for testing personnel performing qualitative post-vasectomy semen analysis at the laboratory (refer to D5989).
D5983	PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359 The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must-- This STANDARD is not met as evidenced by: . A. Based on a lack of documentation and interview with the Director of Practices, the laboratory director failed to ensure verification of accuracy was performed at least twice annually for its qualitative post-vasectomy semen analysis testing. Refer to D5217. B. Based on record review and interview with the Director of Practices, the laboratory failed to ensure test results were accurately documented. Refer to D5801.
D5987	PPM LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1359(b) The laboratory director must-- (b) Ensure that any procedure listed under 493.19(c)-- (b)(1) is personally performed by an individual who meets the qualification requirements in 493.1363; and (b)(2) Is performed in accordance with applicable requirements in subparts H, J, and K of this part. This STANDARD is not met as evidenced by: . Based on record review and interview with the Director of Practices, the laboratory director failed to ensure personnel performing specimen processing for qualitative post-vasectomy semen analysis were qualified as testing personnel. Refer to D5991.
D5988	PPM LABORATORY DIRECTOR RESPONSIBILITIES (c) Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to- (c)(1) Direct observations of routine patient test performance, including, if applicable, specimen handling, processing, and testing; (c)(2) Monitoring the recording and reporting of test results; (c)(3) Review of test results or worksheets; (c)(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and (c)(5) Assessment of problem-solving skills; and

	This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Director of Practices, the laboratory director failed to evaluate the competency of testing personnel for testing personnel performing qualitative post-vasectomy semen analysis at the laboratory for two (May 2024 to May 2026) of two years requested. Findings include: 1. The surveyor requested testing personnel competency assessments performed between May 2024 and May 2026 on 5/19/26 at 9:27 am and was provided with a blank copy of the "Competency Checklist: Qualitative Semen Analysis" at 10:59 am. 2. An interview on 5/19/26 at 12:02 pm with the Director of Practices confirmed no documentation of testing personnel competency assessments was present for the two testing personnel that had performed qualitative post-vasectomy semen analysis between May 2024 and May 2026.
D5989	PPM LABORATORY DIRECTOR RESPONSIBILITIES (d) Evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the Director of Practices, the laboratory director failed to establish a competency assessment policy to assess testing personnel performing qualitative post-vasectomy. Refer to D5209.
D5990	PPM TESTING PERSONNEL CFR(s): 493.1361 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1363 to perform the functions specified in 493.1365 for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview with the Director of Practices, the laboratory failed to ensure personnel performing specimen processing for qualitative post-vasectomy semen analysis were qualified as testing personnel (refer to D5991) and the laboratory failed to ensure staff performing semen specimen processing were qualified as testing personnel (refer to D5993).
D5991	PPM TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1363 Each individual performing PPM procedures must-- (a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and (b) Meet one of the following requirements: (b)(1) Be a physician, as defined in 493.2. (b)(2) Be a midlevel practitioner, as defined in 493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located. (b)(3) Be a dentist as defined in 493.2 of this part.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Director of Practices, the laboratory failed to ensure personnel performing specimen processing for qualitative post-vasectomy semen analysis were qualified as testing personnel for one (medical assistant #3) of one testing personnel listed in patient test reports as performing specimen processing. Findings include: 1. A review of five patient test reports revealed the following: a. Patient #1 had testing performed on 7/16/25 with a note stating, "Specimen was plated by [medical assistant #3], and [testing personnel #1] was informed that slide is ready to be assessed [sic]." b. Patient #2 had testing performed on 4/25/25 with a note stating, "Specimen was plated by [medical assistant #3], and [testing personnel #1] was informed that slide is ready to be assessed [sic]." 2. A review of the laboratory's "Qualitative Semen Analysis" test procedure revealed a section titled, "Qualitative Semen Analysis Slide Preparation" stating, "Label a clean microscope slide with specimen identification. Using a sterile transfer pipette or dropper, gently mix the specimen with the pipette. Remove a specimen from the tube and place one drop (10 uL) on the labeled microscope slide. Immediately put a coverslip over the specimen for examination. Examine the slide to verify it is not overfilled and leaking once the cover slip is in place." 3. An interview on 5/19/26 at 12:08 pm with the Director of Practices clarified "plated" means the specimen was dispensed on the slide and covered with a coverslip. The surveyor requested medical assistant #3's state physician or midlevel provider license and it was not made available.

D5993

PPM TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1365(a)

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be-- (a) Personally performed by one of the following practitioners: (a)(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee. (a)(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee. (a)(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Director of Practices, the laboratory failed to ensure staff performing semen specimen processing were qualified as testing personnel. Refer to D5991.