Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0992485	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Msu Health Care Family Medicine	804 Service Rd Suite A225, 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 Health Care Family Medicine for complaint intake number MI00155669. The State of Michigan Licensing and Regulatory Affairs Department has evaluated this facility and determined that it is out of compliance with CLIA regulations (42 CFR Part 493, Laboratory Requirements) for the following condition-level deficiencies: 493.1230 Condition: General laboratory systems. 493.1250 Condition: Analytic systems. 493. 1290 Condition: Postanalytic Systems. 493.1355 Condition: Laboratories performing PPM procedures; laboratory director.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to establish a competency assessment policy (refer to D5209), failed to verify the accuracy of its wet mount preparation testing at least twice annually (refer to D5217), and failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in general laboratory systems (refer to D5291).
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 record review and interview with the practice manager, the laboratory failed to establish a competency assessment policy for two (May 2024 to May 2026) of two years reviewed. Findings include: 1. A review of the laboratory's Form CMS-116 showed the laboratory listed it performed non-waived wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous. 2. The surveyor requested the laboratory's competency assessment policy on 5/19/26 at 2:06 pm and it was not made available. 3. An interview on 5/19/26 at 3:52 pm with the practice manager confirmed the laboratory's competency assessment policy was not available.
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 interviews with the practice manager, the laboratory failed to verify the accuracy of its wet mount preparation testing at least twice annually for two (May 2024 to May 2026) of two years reviewed. Findings include: 1. A review of the laboratory's Form CMS-116 showed the laboratory listed it performed non-waived wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous. 2. The surveyor requested the laboratory's verification of accuracy records for its wet mount preparation testing records between May 2024 and May 2026 on 5/19/26 at 2:06 pm. Documentation was not made available. 3. An interview on 5/19/26 at 4:16 pm with the practice manager confirmed the laboratory had not been enrolled in proficiency testing. 4. An interview on 5/19/26 at 4:52 pm with the practice manager confirmed the laboratory had not verified the accuracy of its wet mount preparation testing at least twice annually between May 2024 and May 2026.
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 practice manager, 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 2:06 pm and the records were not made available. 2. An interview on 5/19 /26 at 5:11 pm with the practice manager 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 practice manager, 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 2: 06 pm and the records were not made available. 2. An interview on 5/19/26 at 5:11 pm with the practice manager confirmed quality assessment records from May 2024 to May 2026 were not present.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to have written procedures for its wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous (refer to D5401), failed to ensure its Potassium Hydroxide 10% solution, used in wet mount preparation testing, had not been used when it had exceeded its expiration date (refer to D5417) and failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in analytic systems (refer to D5791).
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 practice manager, the laboratory failed to have written procedures for its wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous for two (May 2024 to May 2026) of two years reviewed. Findings include: 1. A review of the laboratory's Form CMS-116 showed the laboratory listed it performed non-waived wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous. 2. The surveyor requested the laboratory's test procedures for its non-waived testing on 5/19/26 at 2:06 pm and 3:52 pm. The procedures were not made available. 3. An interview on 5/19/26 at 4:16 pm with the practice manager confirmed the test procedures for wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous testing were not available.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the clinic coordinator, the laboratory failed to ensure its Potassium Hydroxide 10% solution, used in wet mount preparation testing, had not been used when it had exceeded its expiration date for one of two bottles observed. Findings include: 1. The surveyor observed two bottles of Potassium Hydroxide 10% solution next to the laboratory's microscope on 5/19/26 at 2:43 pm. One bottle included the expiration date of 3/31/24. 2. An interview on 5/19/26 at 2:44 pm with the Clinic Coordinator confirmed the above finding.
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 practice manager, 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 2:06 pm and the records were not made available. 2. An interview on 5/19/26 at 5:11 pm with the practice manager confirmed quality assessment records from May 2024 to May 2026 were not present.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290

	Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on a lack of documentation and interviews, the laboratory failed to provide test report information maintained as part of patients' charts upon request (refer to D5803) and failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in postanalytic systems (refer to D5891).
D5803	TEST REPORT CFR(s): 493.1291(b) (b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on a lack of documentation and interview with the practice manager, the laboratory failed to provide test report information maintained as part of patients' charts upon request for four (Patients #2-#5) of five patient test reports requested. Findings include: 1. The surveyor requested the test reports for five patients most recently receiving wet mount preparation testing at the laboratory on 5/19/26 at 2:54 pm. Four of the five test reports were not made available. 2. An interview on 5/19/26 at 5:14 pm with the practice manager confirmed the four patient test reports would not be available.
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 practice manager, the laboratory failed to establish quality assessment policies and procedures to monitor, assess, and correct identified problems in postanalytic 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 2: 06 pm and the records were not made available. 2. An interview on 5/19/26 at 5:11 pm with the practice manager 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 observations, record review, and interviews, the laboratory director failed to ensure verification of accuracy testing was performed for its wet mount preparation testing at least twice annually (refer to D5983 A), failed to establish written procedures for its wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous (refer to D5983 B), failed to ensure its Potassium Hydroxide 10% solution, used in wet mount preparation testing, had not been used when it had exceeded its expiration date (refer to D5983 C), failed to ensure test report information maintained as part of patients' charts were available upon request (refer to D5983 D), failed to evaluate the competency of testing personnel performing wet mount preparations at the laboratory (refer to D5988), and failed to establish a competency assessment policy (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 record review and interviews with the practice manager, the laboratory director failed to ensure verification of accuracy testing was performed for its wet mount preparation testing at least twice annually. Refer to D5217. B. Based on record review and interview with the practice manager, the laboratory director failed to establish written procedures for its wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements and post-coital direct, qualitative examinations of vaginal or cervical mucous. Refer to D5401. C. Based on observation and interview with the clinic coordinator, the laboratory director failed to ensure its Potassium Hydroxide 10% solution, used in wet mount preparation testing, had not been used when it had exceeded its expiration date. Refer to D5417. D. Based on a lack of documentation and interview with the practice manager, the laboratory director failed to ensure test report information maintained as part of patients' charts were available upon request. Refer to D5803.
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 record review and interviews, the laboratory director failed to evaluate the competency of testing personnel performing wet mount preparations 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 2:06 pm and documentation was not made available. 2. A review of the laboratory's Form CMS-209 revealed a total of seven testing personnel were performing wet mount preparation testing at the laboratory. 3. An interview on 5/19/26 at 4:34 pm with testing personnel #2 revealed they had not had a competency assessment performed at this laboratory and they were employed at this practice for about three years. 4. An interview on 5/19/26 at 5:14 pm with the practice manager confirmed the above findings.
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 record review and interview with the practice manager, the laboratory director failed to establish a competency assessment policy. Refer to D5209.