

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0673541	(X3) Date Survey Completed 06/27/2024
Name of Provider or Supplier East Texas Family Medicine Pa	Street Address, City, State 4201 South Loop 256, Palestine, TX	
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 onsite survey conducted 06/27/2024 found the laboratory out of compliance with 42 CFR Part 493, Requirements for Laboratories for the following conditions: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documents, and confirmed in interview, the laboratory failed to perform twice annual accuracy evaluation for direct wet mount procedures being performed for records reviewed in 2023. The findings included: 1. During a tour of the facility space on 6/27/2024 at 11:30 hours the surveyor observed a microscope next to a box of slides, slide covers, saline, and pipettes. Surveyor asked what the microscope was utilized for and testing personnel (TP) 3 stated, on 6/27/2024 at 11:34 in the nursing area, that the laboratory director and TP11 performed vaginal wet preps on patients. 2. Review of the laboratory policy titled "Quality Assurance Policies and Procedures" did not include instructions for a twice annual accuracy evaluation for non-regulated analytes. 3. Review of laboratory Current Procedural Terminology (CPT) code billing summary with for "Wet mount for infection agents" for 2023 and January 2024 - June 27, 2024 included 27 patients that had a direct wet mount procedure performed and billed for. 4. In an interview on 6/27/2024 at 12:00 hours, in the office, the practice manager confirmed that the laboratory did not perform twice annual accuracy evaluations for direct wet mount procedures.</p>

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(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 surveyor observation, review of laboratory documents, billing records, and confirmed in interview, the laboratory failed to have a written policy for the direct wet mount procedures being performed on patient specimens for records reviewed in 2023 and January to June 27, 2024. The findings included: 1. During a tour of the facility space on 6/27/2024 at 11:30 hours the surveyor observed a microscope next to a box of slides, slide covers, saline, and pipettes. Surveyor asked what the microscope was utilized for and testing personnel (TP) 3 stated, on 6/27/2024 at 11:34 in the nursing area, that the laboratory director and TP11 performed vaginal wet preps on patients. 2. Surveyor asked for the laboratory policy for the direct wet mount procedures being performed and none was provided. 3. Review of laboratory Current Procedural Terminology (CPT) code billing summary with for "Wet mount for infection agents" for 2023 and January 2024 - June 27, 2024 included 27 patients that had a direct wet mount procedure performed and billed for. 4. In an interview on 6/27/2024 at 11:45, in the office, the practice manager confirmed that the laboratory did not have a written policy in place for direct wet mount procedures being performed.

D5787

TEST RECORDS

CFR(s): 493.1283(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 surveyor observation, review of laboratory documents, and confirmed in interview, the laboratory failed to maintain information or record for the positive identification of specimens, date and time the specimen was received and tested, and the identity of the personnel performing the test for direct wet mount procedures being performed in 2023 and 2024. The findings included: 1. During a tour of the facility space on 6/27/2024 at 11:30 hours the surveyor observed a microscope next to a box of slides, slide covers, saline, and pipettes. Surveyor asked what the microscope was utilized for and testing personnel (TP) 3 stated, on 6/27/2024 at 11:34 in the nursing area, that the laboratory director and TP11 performed vaginal wet preps on patients. 2. Surveyor asked how the laboratory tracked specimens being tested to ensure proper patient identification, test performance, results, and personnel performing the test. The practice manager stated, on 6/27/2024 at 11:36 hours in the nursing pod, they didn't even know the test was being performed. 3. Review of laboratory Current Procedural Terminology (CPT) code billing summary with for "Wet mount for infection agents" for 2023 and January 2024 - June 27, 2024 included 27 patients that had a direct wet

mount procedure performed and billed for. 2023: 13 patients Patient 1, Patient 2, Patient 3, Patient 4, Patient 5, Patient 6, Patient 7, Patient 8, Patient 9, Patient 10, Patient 11, Patient 12, Patient 13 (See Crosswalk) January 1, 2024 - June 27, 2024: 14 patients Patient 14, Patient 15, Patient 16, Patient 17, Patient 18, Patient 19, Patient 20, Patient 21, Patient 22, Patient 23, Patient 24, Patient 25, Patient 26, Patient 27 (See Crosswalk) 4. In an interview on 6/27/2024 at 11:55 hours, in the office, the practice manager confirmed that the laboratory did not have record for the positive identification of specimens, date and time the specimen was received and tested, and the identity of the personnel performing the test for direct wet mount procedures being performed in 2023 and 2024.

D5805

TEST REPORT
CFR(s): 493.1291(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 surveyor observation, review of laboratory documents, and confirmed in interview, the laboratory failed to ensure that the patient final report included the test results for direct wet mount procedures being performed for records reviewed in 2023 and 2024. The findings included: 1. During a tour of the facility space on 6/27/2024 at 11:30 hours the surveyor observed a microscope next to a box of slides, slide covers, saline, and pipettes. Surveyor asked what the microscope was utilized for and testing personnel (TP) 3 stated, on 6/27/2024 at 11:34 in the nursing area, that the laboratory director and TP11 performed vaginal wet preps on patients. 2. Review of laboratory Current Procedural Terminology (CPT) code billing summary with for "Wet mount for infection agents" for 2023 and January 2024 - June 27, 2024 included 27 patients that had a direct wet mount procedure performed and billed for. Review of patient final reports did not include the results of the direct wet mount procedure. 3. In an interview on 6/27/2024 at 12:10 hours, in the office, the practice manager confirmed that the patient final reports did not include the test results for the direct wet mount procedures being performed.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on surveyor observation, review of laboratory personnel records, laboratory documents, patient charts, and confirmed in interview the laboratory director failed to ensure proper management and direction for personnel performing direct wet mount

procedures, from preanalytical phases of testing through the analytical and postanalytical phases of testing (D6007), and ensuring testing personnel had the appropriate training and continued competencies to ensure accurate and reliable testing (D6029) for records reviewed from January 2023 to June 27, 2024.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on surveyor observation, review of laboratory documents, and confirmed in interview, the laboratory director failed to ensure that all aspects of the direct wet mount procedures, performed by providers and mid-level practitioners, were met for records reviewed in from January 2023 to June 27, 2024. The findings included: 1. During a tour of the facility space on 6/27/2024 at 11:30 hours the surveyor observed a microscope next to a box of slides, slide covers, saline, and pipettes. Surveyor asked what the microscope was utilized for and testing personnel (TP) 3 stated that the laboratory director and TP11 performed vaginal wet preps on patients. 2. Review of laboratory documents did not include a written policy for the direct wet mount procedures being performed on patient specimens for records reviewed in 2023 and January to June 2024. Refer to D5401. 3. Review of laboratory documents did not include record for the positive identification of specimens, date and time the specimen was received and tested, and the identity of the personnel performing the test for direct wet mount procedures being performed in 2023 and 2024. Refer to D5787. 4. Review of laboratory documents failed to ensure that the patient final report included the test results for direct wet mount procedures being performed for records reviewed in 2023 and 2024. Refer to D5805.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory personnel files and confirmed in interview, the laboratory director failed to ensure that all personnel had the appropriate training

(refer to D6066) and continued competency to ensure accurate and reliable test results (refer to D6053 and D6054) for records reviewed in 2023.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of personnel records, laboratory policy, and confirmed in interview, the technical consultant failed to ensure two of two new testing personnel received two competency assessments in the first year of testing, for records reviewed in 2023 and 2024. The findings included: 1. Review of laboratory personnel records included the following two testing personnel who began testing in 2023: TP Hire Date 1st Competency TP8 3/12/2023 3/28/2023 TP9 4/12/2023 4/29/2023 Surveyor asked for the above testing personnel had their second annual competency assessment and none was provided. 2. Review of the laboratory policy titled "Quality Assurance Policies and Procedures", section 6. "Personnel Assessment" did not include instructions for semiannual competency assessments in the first year of testing for new testing personnel. 3. In an interview on 6/27/2024 at 09:20 hours, in the break room, the practice manager confirmed that the technical consultant did not perform a second competency assessment for the above two testing personnel during the first year of testing.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, personnel records, and confirmed in interview, the technical consultant failed to ensure annual competency evaluations were performed in 2023 for seven of seven testing personnel performing moderate complexity testing. The findings included: 1. Review of the laboratory policy titled "Quality Assurance Policies and Procedures", section 6. "Personnel Assessment" stated the following: "The laboratory director will use the results of Proficiency testing and direct observation to perform an annual evaluation of all testing personnel to ensure competency in job performance." 2. Review of personnel records included the following six testing personnel, performing testing on the Sysmex XN-330 hematology analyzer, who did not have a 2023 competency assessment performed: TP1, TP2, TP3, TP4, TP5, TP6, TP7 Review of personnel records included the following one personnel, performing direct wet mount preparations, who did not have a 2023 competency assessment performed: TP11 3. In an interview on 6/27/2024 at 09:20 hours, in the breakroom, the practice manager confirmed that the technical consultant failed to perform annual competency assessments in 2023.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory personnel records, manufacturers' instructions for use, and confirmed in interview, the laboratory failed to ensure three of three new testing personnel met the qualification requirements at 493.1423 (b)(4)(ii) for records reviewed in 2023 and 2024. Refer to D6066.

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records, manufacturers' instructions for use, and confirmed in interview, the laboratory failed to ensure three of three new testing personnel had documentation of training on the Sysmex XN-330 hematology analyzer before being patient testing. The findings included: 1. Review of laboratory personnel records included the following three testing personnel (TP) who were qualified under 493.1423(b)(4)(i) without documentation of training for the testing performed on the Sysmex XN-330 hematology analyzer: TP8, hire date 3/12/2023 TP9, hire date 4/12/2023 TP10, hire date 4/23/2023 2. Review of the "Sysmex XN-330 General Information" instructions for use, chapter 2 "Safety Information", subsection 2.9 "Operators" had the following statement: "Caution! The instrument must only be used by properly trained personnel." 3. In an interview on 6/27/2024 at 09:15 hours, in the breakroom, the practice manager confirmed that training for the new employees had not been documented.