

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1091184	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier Miles Family Medicine Llc	Street Address, City, State 1605 Highway 34 E Suite A2, Newnan, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Provider Performed Microscopy (PPM) Clinical Laboratory Improvement Amendments (CLIA) survey was completed on February 11, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to follow a policy and procedure to assess (TP) competency as required. Findings include: 1. Lack of TP competency documents revealed there was no annual competencies performed for the following TP(CMS 209) for 2018, 2019, and 2020 thus far: Staff #2, Staff #3. 3. An interview with the lab director in the staff breakroom on 2/11/2020 at approximately 12:40 p.m. confirmed there were no competency documents available at the time of survey for the aforementioned staff for 2018, 2019, and 2020 thus far.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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</p>

493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory policy and procedure manual (SOP), lack of microscopic qualitative quality control (QC) documents, lack of maintenance records, and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required. Findings include: For details refer to D5403, D5433, D5435, and D5449

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 (SOP) review and staff interview, the laboratory failed to follow the SOP as written and approved. Findings include: 1. SOP review reveals the laboratory is not following written procedures for testing personnel competency, Quality Control (QC) of wet preparations, and equipment maintenance protocol. 2. An interview with the lab director on 2/11/2020 at approximately 12:20 p.m. confirmed the lack of following the laboratory SOP for the aforementioned procedures.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

	<p>Based on lack of equipment maintenance documents and subsequent staff interview, the laboratory failed to perform and document equipment maintenance activities as required. Findings include: 1. Laboratory document review revealed there were no routine maintenance documents available at the time of survey for the LW Scientific Revelation III microscope or the Horizon miniE centrifuge for 2018, 2019, and 2020 thus far. 2. An interview with the office manager and laboratory director on 2/11/2020 in the staff breakroom at 09:55 a.m. confirmed the lack of routine maintenance for the laboratory microscope and centrifuge for the aforementioned dates..</p>
<p>D5435</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to perform and document equipment function checks as required. Findings include: 1. Observation during the laboratory tour on 2/11/2020 at approximately 10:47 a.m. revealed the LabCorp centrifuge was last calibrated on 08/25/08. 2. An interview with the lab director on 2/11/2020 at approximately 12:20 p.m. in the laboratory confirmed the lack of annual calibration for LabCorp centrifuge.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on saline wet preparation slides. Findings include: 1. No QC documents were available to review on saline wet preparation slides at the time of survey. 2. An interview with the lab director on 02/11/2020 at 12:20 PM in the laboratory confirmed controls were not performed on saline wet preparation slides .</p>
<p>D5787</p>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>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</p>

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 review of patient reports and an interview with the lab director (LD), the laboratory failed to include all required components on the facility's result reports. Findings include: 1. Review of in-house patient report (KB) performed on 8/21/19 reveals the lack of testing personnel identification. The same report also lacked the reference range, units of measurement of the analytes, a unique patient identifier, and the laboratory address. 2. An interview with the lab director on 02/11/2020 at approximately 12:40 PM in the staff breakroom, confirmed the aforementioned patient report lacked all required components.