

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0254636	<b>(X3) Date Survey Completed</b>  02/25/2020
<b>Name of Provider or Supplier</b>  Snapfinger Woods Family Practice Group	<b>Street Address, City, State</b>  5040 Snapfinger Woods Dr Ste 108, Decatur, GA	
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>D0000</b>	An offsite PPM survey was conducted on May 21, 2020, for all previous deficiencies cited on February 25, 2020. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with all regulations surveyed.
<b>D3011</b>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation and an interview with the laboratory director and office manager, the laboratory failed to implement and established safety procedure to ensure protection from physical, biochemical, and biohazardous materials. Findings include: 1. During the laboratory tour it was observed there was not a maintenance log or eyewash equipment in the phlebotomy or the testing laboratory area. 2. An interview with the laboratory director and office manager, during the laboratory tour on 02/25/2020 at approximately 01:30 p.m., confirmed the absence of eyewash equipment and maintenance log.</p>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by:  A review of the procedure manual and an interview with the laboratory director, the laboratory failed to have an adequate Quality Assurance (QA) policy specific to the specialty of Provider Performed Microscopy (PPM) in 2018, 2019 and 2020. Findings include: 1.) Procedure manual review revealed that the clinic does not have an adequate (QA) policy specific to PPM testing. 2.) An interview with the laboratory director at approximately at 03:35 pm, on 02/25/2020 in the break room, confirmed that the clinic did not have an adequate written QA policy specific to PPM testing.</p>
<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b>  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 493.1289 for each specialty and subspecialty of testing performed.</p> <p>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, interviews with the laboratory director and office manager, 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, D5291, D5435, and D5449</p>
<p><b>D5403</b></p>	<p><b>PROCEDURE MANUAL</b>  CFR(s): 493.1251(b)</p> <p>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.</p> <p>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</p>

following written procedures for Quality Control (QC) of some waived tests, wet prep procedures and equipment maintenance protocol. 2. An interview with the lab director on 2/25/2020 at approximately 03:45 p.m. in the break room confirmed the lack of following the laboratory SOP for the aforementioned procedures.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

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.

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 2/25/2020 at approximately 1:45 p.m. revealed the Bausch & Lomb Microscope has never been serviced. 2. No room temperature checks in the laboratory from January 2018 to February 2020. 3. No maintenance logs for the microscope from January 2018 to February 2020. 4. An interview with the lab director and office manager on 2/25/2020 at approximately 3:50 p.m. in the break room confirmed the microscope has no logs and never been serviced, no room temperature checks from January 2018 to February 2020.

**D5449**

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

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.

This STANDARD is not met as evidenced by:  
Based on quality control (QC) documents review and interview with the laboratory director, 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 02/25 /2020 at 03:40 PM in the break room confirmed controls were not performed on saline wet prep samples.