

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0297851	(X3) Date Survey Completed 10/17/2019
Name of Provider or Supplier Myers & Fotopoulos Mds Pa	Street Address, City, State 5534 Gulf Dr Ste 1, New Port Richey, FL	
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 announced CLIA recertification survey was conducted at Myers & Fotopoulos MDs PA on 10/17/19. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 lack of documentation and interview with the Office Manager the laboratory failed to perform competency evaluations on 1 out of 1 Moderately Complex Testing Person for 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of employee competency evaluations revealed no competency evaluations for the Moderately Complex Testing Person. Personnel file review revealed this Testing Person began performing testing on 09/13/16. On 10/17/19 at 11:30 AM, the Office Manager confirmed that no competency evaluations had been completed for the Moderately Complex Testing Person.</p>
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:</p>

	<p>Based on record review and interview with the Office Manager the laboratory failed to verify the accuracy of Scabies testing twice a year for 1 out of 1 year (2018) reviewed. Findings Included: Review of the peer reviews used to verify the accuracy of Scabies testing revealed that it was only performed once in 2018, 05/21/18. Review of policy and procedures revealed that there was no policy in place for peer review. On 10/17/19 at 11:00 AM the Office Manager confirmed that there was no policy in place and that the peer review had only been done once in 2018.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the Medical Assistant the laboratory failed to label the Mineral Oil with the expiration, lot number, and date in use. Findings Included: During a tour of the laboratory on 10/17/19 a bottle labeled Mineral Oil, which was used for Scabies testing was observed. The label contained no lot number, expiration date, or date in which use was started. Interview with the Medical Assistant on 10/17/19 at 9:57 AM, concurrent with the observation, confirmed that only the name was on the bottle of Mineral Oil.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the Medical Assistant the laboratory failed to remove Potassium hydroxide (KOH) from use after the expiration date of 08/01/18. KOH is used for testing in Mycology for yeast and/or fungus. Findings Included: During a tour of the laboratory on 10/17/19 beginning at 9:30 a.m., a bottle of KOH was observed to have an expiration of 08/01/18. Interview on 10/17/19 at 9:57 a.m. with the Medical Assistant confirmed that there was no other KOH available for use. Review of patient records revealed that 205 patients had been tested with the expired KOH.</p>