

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1051598	(X3) Date Survey Completed 06/18/2019
Name of Provider or Supplier Emmanuel R Loucas Md Pc	Street Address, City, State 69 East 76th Street, New York, NY	
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
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 a lack of twice annual verification record for KOH and Scabies slides, and an interview with the medical assistant, the laboratory failed to verify the accuracy of the interpretation of KOH and scabies slides at least twice per year. Findings Include: The medical assistant confirmed on June 18, 2019, at approximately 11:15 AM, that the laboratory failed to verify the accuracy of KOH and Scabies slides for 2018. Approximately 100 patients' slides KOH and Scabies were interpreted and reported during that time.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the medical assistant, it was confirmed with the medical assistant on June 18, 2019, at approximately 10:45 AM that the director failed to approve, sign and date the laboratory procedure manual for Fungal culture, KOH, and Scabies testing.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a lack of twice annual verification records, and an interview with the medical assistant, the director failed to ensure that the laboratory's QA program for mycology and parasitology were maintained for all phases of laboratory testing. Refer to D5217

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's policy and procedure manuals and an interview with the medical assistant, the laboratory director failed to approve (sign and date) the laboratory's manual for Fungal culture testing, KOH and Scabies slides. Refer to: D5407