Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0687863	02/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Adarsh A Kumar Md	2040 Timberbrooke Dr, Springfield, IL	

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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: REPEAT DEFICIENCIES: Based on surveyor review of the laboratory records, lack of documentation, the Allegation of Compliance (AOC) submitted 10/11/2018, and interview with the office manager; the laboratory failed to properly manage and evaluate the overall quality of testing. The laboratory must meet the requirements in 493.1231 through 493.1236. Findings include: 1. The laboratory failed to verify the accuracy bi-annually for the Mycology, Parasitology and Histopathology testing performed during 2019 and 2020. See D5217. 2. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. See D5291.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by:

	REPEAT DEFICIENCY Based on record review, lack of documentation, the Allegation of Compliance (AOC) submitted 10/11/2018, and an interview with the office manager, the laboratory failed to verify the accuracy twice annually for Mycology, Parasitology, and histopathology biopsy interpretations performed during the years of 2019 thru 2020. Findings include: 1. The Quality Assessment (QA) Plan, patient test review logs, proficiency testing slide worksheets, the AOC submitted on 10 /11/2018, and test volume worksheets were reviewed. 2. Review of the patients' test review logs and proficiency testing (PT) slide worksheets revealed that twice annual PT for Histopathology, Mycology, and Parasitology were not performed in 2019 and 2020. 3. The laboratory failed to follow the written QA plan submitted as an Allegation of Compliance in 10/11/2018 to perform bi-annual PT for Histopathology, Mycology, and Parasitology.. 4. The tests volume worksheets showed during 01/2020 through 01/2021, the laboratory performed the following patient tests: *Dermatopathology Test Medium (DTM) - 36; *Potassium Oxide (KOH) - 42; and *Histopathology slide interpretations - 532 5. On a Recertification survey conducted on 02/11/2021 at 3:15 PM, the office manager confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on record review, lack of documentation, the Allegation of Compliance (AOC) submitted 10/11/2018, and an interview with the office manager, the laboratory failed to 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, during the years of 2019 thru 2020. Findings include: 1. The Quality Assessment (QA) Plan, patient test review logs, proficiency testing slide worksheets, and the AOC submitted 10/11/2018 were reviewed. 2. The laboratory's QA plan stated the following: *"This laboratory does proficiency testing with a local qualified dermatopathologist on a bi-annual basis for histopathology (10 samples); Mycology (Dermatophyte Test Medium (DTM) - 3 samples, KOH (potassium oxide) - 3 samples), and Parasitology (2 samples). If at any time, there are not enough samples to do Bi-annual testing the lab will order formal test kits from AAB (American Association of Bioanalysts) Proficiency testing Service..." 3. Review of the patients' test review logs and proficiency testing (PT) slide worksheets revealed that PT for Histopathology, Mycology, and Parasitology were not performed in 2019 and 2020. 4. Further review showed the laboratory failed to enroll with AAB PT Service during the above time period. 5. The laboratory failed to follow the written QA plan submitted as an Allegation of Compliance in 10/11/2018. 6. On a Recertification survey conducted on 02/11/2021 at 3:15 PM, the office manager confirmed the above findings.