

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0687863	(X3) Date Survey Completed 04/04/2018
Name of Provider or Supplier Adarsh A Kumar Md	Street Address, City, State 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	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to properly monitor, evaluate, and maintain compliance since the last CLIA inspection of April 13, 2016. The laboratory must meet the requirements in 493.1231 through 493.1236. Findings Include: 1. The laboratory failed to perform bi-annual evaluations of testing for histopathology, mycology, and parasitology. See D5217. Repeat Deficiency. 2. The laboratory failed to monitor and follow the written quality assessment plan. The laboratory failed to ensure continued compliance since the 2016 CLIA survey. See D5291. Repeat Deficiency.</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: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory still fails to perform bi-annual method accuracy evaluations for</p>

mycology, parasitology, and histopathology testing in 2016 through 2018. Findings Include: Repeat Deficiency 1. Review of PT records found no bi-annual verification documents to demonstrate accuracy for dermatophyte test medium (DTM) fungal cultures after previous allegation of compliance response completed in May of 2016. 2. Review of PT records found no bi-annual verification documents to demonstrate accuracy for KOH preparations, scabies examinations, and histopathology were completed in 2016 and 2017. Again, PT was completed for the above mentioned tests in May of 2016 as part of the allegation of compliance to the previous survey and then not completed again till January of 2018. 3. Review of the laboratory's policy and procedure manual identified the policy, "Quality Assessment Plan", on page 3, under the heading of "Proficiency Testing Program" which stated the following: "At least twice annually, the laboratory will verify accuracy of any test performed in each of the specialties. The bi-annual verification of testing will be sent to a qualified individual at another location of verify the accuracy of tests performed." Mycology: 1. Dermatophyte Test Medium Accuracy of DTM interpretation Ten (10) DTM samples inoculated with known samples will be sent to a qualified individual to verify the accuracy of DTM interpretations. 2.KOH Accuracy of KOH interpretations Three (3) KOH preparations with patient samples will be sent to another individual to verify the accuracy of KOH interpretations. Histopathology: Accuracy of slide interpretations Ten (10) slides will be sent to a qualified individual to verify accuracy of histopathology slide interpretations. Parasitology: Scabies Accuracy of slide interpretations Two (2) slides will be sent to another facility to verify accuracy of scabies slide interpretations." 4. PT performed for KOH (potassium hydroxide) and scabies preparations in January of 2018 only had evaluations for 1 slide of each test and not the 3 slides indicated in the PT policy for KOH and 2 slides indicated in the policy for scabies examination. 5. Interview with the LD on 04-04-2018 at 2:30 pm confirmed the laboratory had failed to perform the bi-annual method accuracy evaluations for Dermatophyte fungal cultures with DTM since May of 2016. The LD also confirmed bi-annual method accuracy evaluations failed to be performed as stated in the laboratory PT policy for histopathology, KOH, and scabies preparations after May of 2016 through April 4, 2018.

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:
 Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to follow the written policies for monitoring proficiency testing (PT) and failed to identify problems related to monitoring PT. Findings Include: Repeat Deficiency 1. No records were made available for review when requested by the surveyor. There were no records to demonstrate bi-annual method accuracy evaluations for KOH preparations, scabies examinations, dermatophyte test medium (DTM) fungal cultures, and histopathology testing as directed in the laboratory PT policy. See D5217. 2. Interview with the LD on 04-04-2018 at 2:30 pm confirmed the laboratory had failed to follow the quality assessment plan as described in the document "Quality Assessment Plan" for the twice per year verification of DTM and slide reading testing.

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

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.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283. Findings Include: 1. The current laboratory procedures in use for scabies examinations, potassium hydroxide (KOH) preps, fungal cultures, and histopathology slide examinations failed to include all the required elements of a test procedure. See D5403. 2. The laboratory failed to perform quality control measures for fungal cultures. The laboratory failed to check each batch of dermatophyte test medium (DTM) for sterility, growth, inhibition of growth, and a biochemical response. See D5477. Repeat Deficiency.

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 review of laboratory records and interview with the laboratory director (LD); the laboratory failed to outline all components of test procedures for the specialties of microbiology and pathology. Findings Include: 1. Review of the policy and procedure manual found the laboratory had implemented new procedures in October of 2017 for "Potassium Hydroxide (KOH) examination of skin, hair, or nails", "Ectoparasites", "Fungal Culture/Dermatophyte Test Medium (DTM)", and "Histopathology" testing. 2. The new procedures introduced are generic templates provided by the American Association of Dermatologist and have not been completed

by the laboratory to address the following issues: (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. Requirements for patient preparation. 2. During survey date 04-04-2018, at 2:30 pm, the above findings were confirmed by the LD.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with laboratory personnel; the laboratory failed to check each batch of dermatophyte test medium (DTM) media for sterility, the ability to support growth, inhibit growth, and the ability to produce a biochemical response for mycology testing. Findings Include: Repeat Deficiency. 1. Review of the laboratory's policy and procedure manual identified the procedure, "Fungal Culture/Dermatophyte Test Medium (DTM)" which failed to explain control procedures for DTM. See D5403. 2. Review of the laboratory's "DTM LOG" showed lot # D-1252-1017 was received by the laboratory on 1-12-2018. 3. Review of quality control (QC) records for DTM found no documented quality controls had been performed for lot # D-1252-1017. 4. During tour of the laboratory with the lab director (LD) on 04-04-2018, at 9:45am, the LD stated he was in the process of performing QC for the current lot of DTM in use (D-1252-1017). 5. Interview with the laboratory office manager on 04-04-2018, at 11:30 am, stated patient testing with DTM lot# D-1252-1017 began in February of 2018. 6. A patient testing report generated by the lab office manager found 5 patients had been tested since February of 2018 with DTM lot# D-1252-1017. 7. Interview with the LD on 04-04-2018, at 2: 30 pm, confirmed that the laboratory failed to document quality control testing for DTM before or concurrent with the initial use for lot# D-1252-1017.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the laboratory patient test reports failed to include all the required information. Findings Include: 1. Review of 5 of 5 patient test reports for dermatophyte test medium (DTM) cultures, potassium hydroxide preparations, or scabies wet mounts found the laboratory failed to indicate all the required test report information. Patient Identification Test Test Date Missing information P1 Scabies Prep 01-30-2018 Name and Address, Specimen source P2 Scabies Prep 03-20-2018 Name and Address, Specimen source P3 KOH Prep 02-14-2018 Name and Address P3 DTM Culture Unknown Name and Address, Test Report Date P4 KOH Prep 12-12-2017 Name and Address, Specimen source P4 DTM Culture Unknown Name and Address, Test Report Date P5 KOH Prep 05-26-2017 Name and Address, Specimen source P5 DTM Culture Unknown Name and Address, Specimen source 2. During survey date 04-04-2018, at 2:30 pm, the above findings were confirmed by the LD.