Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1091651	01/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Evms Dermatology- Andrews Hall	721 Fairfax Avenue - Suite 200, Norfolk, VA	

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 for EVMS Dermatology-Andrews Hall on January 21, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview and virtual record review conducted on 1/14/2021. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D5200 - 42 CFR. 493.1230 Condition: General Laboratory Systems. Specific deficiencies cited are as follows.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) documentation, and an interview, the laboratory failed to retain attestation statements signed by the laboratory director (LD) and testing personnel (TP) for seven (7) of 7 mycology microscopy PT events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) mycology PT documentation, a total of 7 events, revealed no LD or TP signed attestations for the following: 2018 3rd Event; 2019 Events 1-3; 2020 Events 1-3. The inspector requested to review the LD and TP

	attestation documentation for the 7 PT events outlined above. No documentation was available for review. 2. In an interview with the practice manager on 1/21/21, at approximately 2:30 PM, the above findings were confirmed.
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: Based on a review of the laboratory's Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report Form, mycology proficiency testing (PT) records, available PT Corrective Action Forms, CMS 2018 CLIA Survey Statement of Deficiencies and Plan of Correction Form 2567, and interviews, the laboratory failed to monitor and evaluate their PT protocols to produce remedial action documentation and adherence to their approved 2018 CMS 2567 corrective action plan during the twenty-eight months reviewed (September 2018 to the date of the survey on January 21, 2021). See D5217 and D5221 (*REPEAT DEFICIENCIES).
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: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), mycology proficiency testing (PT) records, and an interview, the laboratory failed to verify the accuracy of Potassium Hydroxide (KOH) mycology testing twice annually from September 2018 to July 2020. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed that four (4) testing personnel performed patient KOH microscopy examination. (See Testing Personnel Code Sheet.) 2. Review of the laboratory's American Proficiency Institute (API) mycology PT documentation, a total of seven (7) events, revealed the laboratory utilizes PT to verify KOH mycology accuracy. A review of the API reports revealed the laboratory failed twice annual accuracy verification by receiving the following unsatisfactory scores from September 2018 and up to July 2020: 2018 3rd Event: 0% Unsatisfactory Scoring; failed for KOH-05 and KOH--06; 2019 1st Event: 50% Unsatisfactory Scoring; failed for KOH--01; 2019 3rd Event: 0% No score/Not graded for KOH-05 and KOH-06 due to failure to participate; 2020 1st Event: 50% Unsatisfactory Scoring; failed for KOH-01; 3. In an interview with the practice manager on 1/21/21, at approximately 2:30 PM, the above findings were confirmed.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's mycology proficiency testing (PT) records, PT Corrective Action Forms, Centers for Medicare and Medicaid Services 2019 Statement of Deficiencies and Plan of Correction Form (CMS 2567), and interviews, the laboratory failed to document reviews and remedial actions taken for four (4) unsatisfactory out of seven (7) PT events in the twenty-eight (28) months reviewed. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT documentation for the 2018 3rd Event, 2019 Events 1-3, 2020 Events 1-3, a total of 7 events, revealed no evidence of review or remedial action for the following unsatisfactory mycology challenges samples: 2018 3rd Event: 0% Unsatisfactory Scoring; failed for KOH-05 and KOH--06; 2019 1st Event: 50% Unsatisfactory Scoring; failed for KOH--01 (Unsuccessful long term performance); 2019 3rd Event: 0% No score for KOH-05 and KOH-06 due to failure to participate (Unsuccessful long term performance); 2020 1st Event: 50% Unsatisfactory Scoring; failed for KOH-01(Unsuccessful long term performance). 2. Review of the available API Corrective Action forms revealed no review or corrective/remedial action documentation for the events listed above. The inspector requested to review corrective action for the failed challenges during the timeframe outlined. No records were found. The practice manager stated on 1/21/20 at approximately 2:00 PM: "We have not been able to locate any of the PT records that you have requested. We were able to reprint the results from the API website. I will try to locate the corrective action forms". 3. Review of the laboratory's 2018 CMS 2567 CLIA Plan of Correction revealed a lab director approved plan dated 09/21/2018 that stated: "Effectively immediately, the lab director will develop and document a corrective action plan for all proficiency test failures. The practice manager will maintain signed reports and monitor implementation of corrective plans when indicated." 4. In an interview with the practice manager on 1/21/21, at approximately 2:30 PM, the above findings were confirmed.