Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1091651	09/06/2018
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 at EVMS Dermatology-Andrews Hall on September 6, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 for the twenty-four (24) months reviewed.. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's CMS 209 personnel form revealed that two (2) testing personnel perform 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 six (6) events, revealed the laboratory utilizes PT to verify KOH accuracy twice annually. A review of the API reports revealed the laboratory failed twice annual accuracy verification from September 2016 to the date of the survey 9/6/18 by receiving the following scores: 2016 3rd Event: 50% Unsatisfactory Scoring; failed for KOH--06 2017 1st Event: 50% Unsatisfactory Scoring; failed for KOH--02 2017 3rd Event: No score/Not graded for KOH-05 and KOH-06 2018 2nd Event: 0% Unsatisfactory Scoring; failed for KOH-03 and KOH-04 3. In an interview with the practice manager at approximately 12:00 PM, it was confirmed that the laboratory, by receiving the scores outlined above, failed to successfully verify, twice annually, the accuracy of KOH testing in the twenty-four (24) months reviewed.

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 proficiency testing (PT) records, Corrective Action Forms, and an interview, the laboratory failed to document review and remedial action taken for three (3) unsatisfactory scores out of six (6) mycology PT events in the twenty-four (24) months reviewed. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's American Proficiency Institute (API) mycology PT documentation for the 2016 third event, three (3) events in 2017, and two (2) events in 2018, a total of six (6) events, revealed no evidence of review or remedial action for the following three (3) unsatisfactory proficiency events and analytes: 2016 3rd Event: 50% Unsatisfactory Scoring; failed for KOH--06 2017 3rd Event: No score /Not graded for KOH-05 and KOH-06 2018 2nd Event: 0% Unsatisfactory Scoring; failed for KOH-03 and KOH-04 2. Review of the laboratory's API PT Corrective Action forms revealed no review or corrective/remedial action documentation for the events listed above. 3. In an interview with the practice manager at approximately 12: 00 PM, it was confirmed that the laboratory failed to document review and remedial actions for the three (3) of six (6) mycology PT events listed above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of mycology proficiency testing (PT) records, Corrective Action Forms, and an interview, the laboratory director failed to ensure a corrective action plan was followed and remedial action documented for three (3) unsatisfactory mycology PT scores out of six (6) events in the twenty-four (24) review period. See D6019 (*REPEAT DEFICIENCY).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing (PT) records, Corrective Action Forms, and an interview, the laboratory director (LD) failed to ensure a corrective action plan was followed and remedial action documented for three (3) unsatisfactory

	mycology PT scores out of six (6) event results for the twenty-four (24) months reviewed. **REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's American Proficiency Institute (API) mycology PT documentation for the 2016 third event, the three (3) events in 2017, and two (2) events in 2018, a total of six (6) events, revealed no evidence of LD review or remedial action for the following three (3) unsatisfactory proficiency events and analytes: 2016 3rd Event: 50% Unsatisfactory Scoring; failed for KOH--06 2017 3rd Event: No score/Not graded for KOH-05 and KOH-06 2018 2nd Event: 0% Unsatisfactory Scoring; failed for KOH-03 and KOH-04 2. Review of the laboratory's API Corrective Action forms revealed no LD's corrective or remedial action documentation for the events listed above. 3. In an interview with the practice manager at approximately 12:00 PM, it was confirmed that the laboratory director failed to ensure a corrective action plan was followed and remedial action documented for the three (3) of six (6) mycology PT events listed above.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. 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), laboratory personnel files, histology test logs, and interview, the laboratory director (LD) failed to document training and competency assessments for two (2) of five (5) testing personnel. Findings include: 1. Review of the CMS 209 Laboratory Personnel Report revealed five (5) testing personnel. (See Personnel Code Sheet.) 2. Review of the laboratory personnel files revealed: No documentation of initial training or competency assessment (2016 semi-annual or 2017 annual) records for Testing Personnel D No documentation of education, initial training, or semi-annual competency assessment for Testing Personnel E. The inspector requested to review the documentation. The personnel training and competency assessment records were not available for review on the day of the inspection for TP D or E. 3. Review of the laboratory's test logs revealed that Testing Personnel D was performing high complexity histology grossing of patient tissue samples in 2016 and 2017. Review of the laboratory's test logs revealed that Testing Personnel E was performing high complexity histology grossing of patient tissue samples from March 2016 to the date of the survey on 9/6/18. 4. In an interview with the practice manager at approximately 12:00 PM, it was confirmed that the laboratory director failed to ensure the documentation of training and competency assessments for two (2) of five (5) testing personnel as outlined above.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed.

	This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), laboratory personnel files, and interviews, the laboratory failed to ensure each testing personnel was qualified by retaining evidence of education for one (1) of five (5) testing personnel. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1,

	1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Personnel Report Form (CMS 209), personnel files, histology logs, and interviews, the laboratory failed to ensure testing personnel (TP) qualifications for one (1) of five (5) testing personnel. Findings include: 1. Review of the laboratory's CMS 209 form revealed five (5) TP (see Personnel Code Sheet). 2. Review of the laboratory personnel file for Testing Personnel E revealed that the duties included grossing patient tissue samples. The inspector found no evidence of the required education documentation for high complexity testing. The inspector requested to review additional education documentation for Testing Personnel E. No additional documentation was available. 3. Review of the laboratory histology logs from 3/1/18 to 9/6/18, and an interview with TP E on 9/6/18 at approximately 11:00 AM, revealed that TP E signed the histology logs as performing the grossing of patient tissue specimens. TP E stated "I am currently enrolled in school to add necessary science credits to my transcript. I hope to complete the education requirements in 2019". 4. In an interview with TP E and the Practice Manager at approximately 12:00 PM, it was confirmed that the laboratory did not have documentation of the required education for one (1) of five (5) TP as outlined above.