

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0227250	(X3) Date Survey Completed 08/26/2025
Name of Provider or Supplier Commonwealth Dermatology, Pc	Street Address, City, State 7001 Forest Avenue - Suite 400, Richmond, 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 Commonwealth Dermatology on August 26, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
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:</p> <p>A. Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), lack of documentation and an interview, the laboratory failed to verify the accuracy of the potassium hydroxide (KOH) microscopic examinations twice annually in the calendar year 2024. The findings include: 1. Review of the CMS 116 application and interview with the office manager on August 26, 2025 at 11:20 AM revealed the laboratory performs KOH microscopic examinations. 2. The surveyor requested to review documentation of the verification of accuracy twice annually for the KOH microscopic examinations in the calendar year 2024. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory director and histotechnologist on August 26, 2025, at 1:45 PM, the findings were confirmed. B. Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), lack of documentation and an interview, the laboratory failed to verify the accuracy of the scabies prep microscopic examinations twice annually in the calendar year 2024. The findings include: 1. Review of the CMS 116 application and interview with the office manager on August 26, 2025 at 11:20 AM revealed the laboratory performs scabies prep microscopic examinations. 2. The surveyor requested to review documentation of the verification of accuracy twice annually for the scabies prep</p>

microscopic examinations in the calendar year 2024. The laboratory provided no documentation for review. 3. In an exit interview with the laboratory director and histotechnologist on August 26, 2025, at 1:45 PM, the findings were confirmed.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(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 a review of six randomly selected patient histology slides and Mohs surgical maps, lack of documentation and an interview, the laboratory failed to ensure the laboratory's address was included on six of six selected Mohs surgical maps at the date of the survey on August 26, 2025. The findings include: 1. The surveyor randomly selected six patients for documentation comparison of the histology slides to the Mohs final reports. The laboratory provided the surveyor the patient slides and corresponding Mohs surgical maps for the six patients. 2. During a review of the slides and maps, the surveyor observed that six of six Mohs surgical maps lacked documentation of the laboratory's address (case numbers M24-123, M24-693, M24-1320, M25-416, M25-629, and M25-959). During an interview with the histotechnologist on August 26, 2025 at 1:15 PM, the surveyor inquired what the laboratory considered the final report. The histotechnologist stated the Mohs maps were the final report. 3. In an exit interview with the laboratory director and histotechnologist on August 25, 2025 at 1:45 PM, the findings were confirmed

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Centers for Medicare and Medicaid Services (CMS) 116 form, laboratory policies and procedures, testing log sheets, patient records, lack of documentation, and interviews, the laboratory failed to establish and follow a mechanism to ensure Potassium Hydroxide (KOH) and Scabies prep results were recorded into the electronic health record (EHR) for two (2) of eight (8) patients. The findings include: 1. Review of the laboratory's CMS-116 revealed the laboratory performs KOH and Scabies prep microscopic examinations. 2. An interview with the office manager on August 26, 2025 at 11:30 AM, revealed the providers perform KOH and Scabies prep microscopic examinations, document the results on log sheets and enter the patient's results into the EHR (e-Clinical). 3. Review of 8 randomly chosen EHR records and corresponding KOH/Scabies prep log sheets revealed the

following patient records lacked documentation of the Scabies prep results: # 481229 and 43884. 4. Review of the laboratories policies and procedures revealed a lack of a procedure or mechanism to detect errors for manually entered test results. In an interview with the office manager on August 26, 2025 at 11:35 AM, the office manager stated they did not have a procedure for auditing patient charts. 5. In an exit interview with the laboratory director and histotechnologist on August 26, 2025, at 1:45 PM, the findings were confirmed.