

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2100099	<b>(X3) Date Survey Completed</b>  04/28/2021
<b>Name of Provider or Supplier</b>  Collins Advanced Dermatology Institute	<b>Street Address, City, State</b>  1750 Red Bud Lane, Round Rock, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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>I. Based on review of the laboratory records, and interview, the laboratory failed to have documentation of performing twice annual accuracy assessments for MOHS histopathology in 2019 and 2020. Findings follow. 1. Review of the MOHS peer to peer reviews emailed after the survey showed they were all performed on March 1, 2021 for the past two years. The cases selected for review were from 2019 (CR19-022, CR19-029, CR19-086) and 2020 (CR20-014). Review of laboratory records found no documentation of on-going twice annual accuracy assessment of results for MOHS histopathology procedures available for review during 2019 and 2020. 2. Interview of the practice manager on April 26, 2021 at 1050 hours in the office confirmed there were no peer reviews for MOHS procedures conducted in 2019, 2020 available for review at the time of the survey. Email correspondence with the Laboratory Director's assistant and the Laboratory Director on April 28, 2021 at 1546 hours about whether there were any reviews performed in 2019 and 2020 to satisfy the twice per year requirement performed in 2019 and 2020 received no reply. II. Based on review of the laboratory's policy and procedure, laboratory records, and interview, the laboratory failed to have documentation of performing twice annual accuracy assessments for KOH (Potassium Hydroxide) preps for fungal elements in 2019 and 2020. Findings follow. 1. Review of the laboratory records found no documentation of accuracy assessment of results for KOH preps for fungal elements available for review for 2019, 2020, or to survey date in 2021. 2. Review of the KOH, Tzanck, Giemsa, Scabies Log showed 54 KOH preps had been performed in 2019, 11 had been performed in 2020, and 1 had been performed to survey date in 2021. 3. Interview with the Practice Manager on April 26, 2021 at 1105 in the office confirmed</p>

there were no twice a year accuracy assessments for KOH. III. Based on review of the laboratory's policy and procedure, laboratory records, and interview, the laboratory failed to have documentation of performing twice annual accuracy assessments for Scabies in 2019 and 2020. Findings follow. 1. Review of the laboratory records found no documentation of accuracy assessment of results for Scabies available for review for 2019, 2020, or to survey date in 2021. 2. Review of the KOH, Tzanck, Giemsa, Scabies Log showed. 3 Scabies had been performed in 2019, 0 scabies had been performed in 2020, and 1 scabies had been performed to survey date in 2021. 3. Interview with the Practice Manager on April 26, 2021 at 1105 in the office confirmed there were no twice a year accuracy assessments for Scabies. The laboratory was not performing testing from 03/23/2020 to 01/11/2021.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:  
Based on review of the quality assurance checklist, laboratory's policy and procedure, laboratory records, and interview, the laboratory failed to accurately assess their quality assurance reviews for 3 of 3 reviews. Findings follow. 1. Review of the Biannual Quality Assurance Checklist from 2019 (6/27/2019 & 12/31/2019) and 2020 (3/31/2020) under "Our proficiency testing policies have been followed" showed Y (Yes) for "all proficiency test results were evaluated," and "Proficiency test failures were investigated and remedial action was taken." 2. Review of laboratory records and interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS histopathology in 2019 and 2020. Refer to D5217 I. 3. Review of the laboratory's policy and procedure, laboratory records, and interview, the laboratory failed to have documentation of performing twice annual accuracy assessment for KOH (Potassium Hydroxide) preps for fungal elements and Scabies in 2019, 2020, and to survey date in 2021. Refer to D5217 II & III. 4. Interview with the Practice Manager on April 26, 2021 at 1455 hours in the office acknowledged the histotech should probably not be completing the quality assurance form because he may not know if things like proficiency testing (accuracy assessments) and competency evaluations were being performed. NOTE: 1. Proficiency testing is another means to achieve accuracy assessments for KOH preps, Scabies, Tzanck preps and Giemsa stains. 2. The laboratory was not performing testing from 03/23/2020 to 01/11/2021.

**D5401**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and interview, the

laboratory failed to have procedures for KOH (Potassium Hydroxide) preps, Scabies prep, Tzanck prep, and Giemsa stain. Findings follow. 1. Review of the CMS-116 showed on page 3 the following PPM (Provider Performed Microscopy) procedures performed by the laboratory listed: KOH preps, Tzanck preps, Giemsa stains, Scabies preps. 2. Review of the laboratory's policies and procedures revealed no test procedures for KOH prep, Scabies prep, Tzanck prep or Giemsa stain. 3. Interview with the Practice Manager on April 26, 2021 at 1210 hours in the office confirmed there were no procedures for the KOH prep, Scabies prep, Tzanck prep, or Geimsa stain.

**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:  
I. Based on review of the test report in the patient chart, and interview, the laboratory failed to ensure the Mohs maps were available in the patient's chart for 1 of 10 Mohs maps reviewed. Findings follow. 1. Review of the Mohs maps in the patient chart showed CR19-040 was missing the Mohs map test report. 2. Interview with the histotechnologist on April 26, 2021 at 1225 hours and the Practice Manager at 1245 hours in the office both confirmed the Mohs map was missing from the patient's chart. II. Based on review of the test report in the patient chart, and interview, the laboratory failed to ensure the laboratory's address was specified on 2 of 10 Mohs maps reviewed. Findings follow. 1. Review of the Mohs maps showed CR21-006 and CR21-001 did not have the location of the testing selected on the Mohs map test report. 2. Interview with the Practice Manager on April 26, 2021 at 1245 in the office confirmed the box for the address of the location of testing was not checked.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures and interview, the laboratory director failed to have procedures for KOH (Potassium Hydroxide) preps, Scabies prep, Tzanck prep, and Giemsa stain (refer to D5401).

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure, competency evaluations and interview, the Technical Consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, for 1 of 1 years reviewed. Findings follow. 1. Review of the laboratory's policy and procedure "Lab Director's Duties" stated, "duties for directing a laboratory include: ... Ensure that policies and procedures have been established for monitoring staff who perform pre-analytic, analytic, and post-analytic steps to assure that they are competent to process, test, and report results of test procedures..." 2. Review of competency evaluations for the previous Physician Assistant who left in Feb or March of 2020, showed one evaluation performed 12/30/2017 in the employee file. 3. Interview with the Practice Manager on April 26, 2021 at 1030 hours in the office confirmed there were no other competency evaluations for the previous employee in the employee file.