

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2064088	(X3) Date Survey Completed 03/11/2021
Name of Provider or Supplier Collins Advanced Dermatology Institute	Street Address, City, State 311 S Hwy 183, Leander, TX	
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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: D5200 - 42 C.F.R. 493.1230 Condition: General laboratory systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
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 the laboratory's policy and procedure, laboratory records, and interview the laboratory failed to have a system in place to monitor the overall quality of general laboratory systems (see D5217 and D5219).</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:</p>

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 assessment for KOH (Potassium Hydroxide) for fungal elements in 2019 and 2020. Findings follow. 1. Review of the laboratory's General Policy, effective 1/31 /2015, under "Ongoing Assessment" stated, "the programs and methods used for proficiency testing and results of this testing will be evaluated by the laboratory director or an appropriate, designated staff member every 6 months." 2. Review of the laboratory records found no documentation of accuracy assessment of results for KOH for fungal elements available for review for 2019 or 2020. Review of the KOH, Tzanck, Giemsa, Scabies Log showed a line for "co-reader's initials" and showed testing personnel #1 on the line for "co-reader's initials" for a KOH performed on 12 /21/2020. The log showed 10 KOH preps had been performed in 2020. 3. Interview with testing personnel #1 on March 11, 2021 at 1020 hours acknowledged she and the Laboratory Director do not normally work together and don't look at the same specimen. When asked what the "co-reader's initials" meant on the log form, she didn't know and stated she didn't read any KOH preps in Dec. Interview with the Practice Manager on March 11, 2021 at 1025 hours in the breakroom confirmed there were no twice a year accuracy assessments for KOH. 4. Review of the CMS form 116 showed Bacteriology, Mycology, Parasitology, and Virology were checked with an annual test volume of 10 for KOH preps, Tzanck preps, Giemsa stains, and Scabies preps. THIS IS A REPEAT DEFICIENCY CITED IN THE SURVEY CONDUCTED 10/19/2016

D5219

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(c)(2)

At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS histopathology in 2019 and 2020. Findings included: 1. Review of laboratory records found no documentation of accuracy assessment of results for MOHS histopathology procedures available for review for the years 2019 or 2020. 2. Interview of the practice manager conducted on March 11, 2021 at 10: 30 AM confirmed there were no peer reviews for MOHS procedures conducted in 2019 or 2020 available for review.

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 4 of 4 reviews. Findings follow. 1. Review of the

Biannual Quality Assurance Checklist from 2019 (6/27/2019 & 12/31/2019) and 2020 (6/30/2020 & 12/28/2020) 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 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) for fungal elements in 2019 and 2020, refer to D5217. 3. 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 D5219. NOTE: Proficiency testing is another means to achieve accuracy assessments for KOH preps, Scabies, and Tzanck preps.

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 observation, laboratory policies and procedures, stain quality control records, and interview the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems (see D5417 and D5473).

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on observation and interview, the laboratory failed to dispose of stains that had exceeded their expiration dates. Findings follow. 1. Surveyor observed on March 11, 2021 at 1125 hours in the laboratory, the following expired stains located in the cabinet in the stain block holder: a. Delasco Fungal/Tzanck Stain, Toluidine Blue Basic Fuchsin, Lot K137G1, Expired July 2016; b. Delasco Gram 4 Counterstain, Safranin O 0.5%, Lot K059N8, Expiration Sept 2008; c. Delasco Wright-Giemsa Stain, partially obstructed label, Expiration April 2008; d. Delasco Chlorazol Black E, Chlorazol Fungal Stain, Lot K13CA1, Expiration Dec 2014; e. Delasco Gram 1A Crystal Violet, Lot K05C73, Expiration Dec 2008; f. Delasco Triton-X, Methylene Blue Stain, Lot K13AN4, Expiration Oct 2016. 2. Interview with the histotechnologist on March 11, 2021 at 1130 hours in the breakroom confirmed the expired stains were available for use in the laboratory and was not aware of any other stains available for use. Interview with testing personnel #1 on March 11, 2021 at 1200 hours in the laboratory confirmed the stains in the cabinet were currently the reagents in use by the Laboratory Director. 3. Review of the CMS form 116 showed Bacteriology,

Mycology, Parasitology, and Virology were checked with an annual test volume of 10 for KOH preps, Tzanck preps, Giemsa stains, and Scabies preps. THIS IS A REPEAT DEFICIENCY CITED IN THE SURVEY CONDUCTED 11/13/2018 AND 10/19/2016

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, stain quality control records, and confirmed in interview, the laboratory failed to verify the intended negative and positive reactivity for the Hematoxylin and Eosin (H&E) stain at least once each day of use. Findings included: 1. Review of the laboratory's MOHS TEST SLIDES logs found the laboratory used a checkmark in the stain column as documentation of H and E staining acceptability. There was no key to define what the checkmark represented. 2. Additional documentation for H and E stain quality to ensure predictable staining was requested, but not provided. 3. Interview of the histotechnician conducted on March 11, 2021 at 10:50 AM confirmed that the laboratory did not have any records to document negative and positive reactivity of H and E stains used each day of patient testing. THIS IS A REPEAT DEFICIENCY CITED IN THE SURVEY CONDUCTED 10/19/2016

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 8 Mohs maps reviewed. Findings follow. 1. Review of the Mohs maps in the patient chart showed CL20-121 was missing the Mohs map test report. 2. Interview with the histotechnologist on March 11, 2021 at 1135 hours in the breakroom confirmed the Mohs map was not scanned into the patient's chart. II. Based on review of the testing logs, patient chart, and interview, the laboratory failed to ensure the test result was recorded into the patient's chart for 2 of 3 KOH (Potassium Hydroxide) test reports reviewed. Findings follow. 1. Review of the KOH, Tzanck, Giemsa, and Scabies testing log showed: a. MRN 019927 was tested on 04/30/2020 and was negative for

	<p>fungal elements. Review of the Visit Note in the patient's chart showed the test was not reported; b. MRN 019413 was tested on 02/21/2020 and was negative for fungal elements. Review of the Visit Note in the patient's chart showed the test was not reported. 2. Interview with the Practice Manager on March 11, 2021 at 1145 hours in the breakroom confirmed the KOH result was not recorded in the patient's chart. KEY: MRN = Medical Record Number</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation and interview the laboratory director failed to provide overall management and direction of the laboratory (see D6014).</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview the laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results (see D5417).</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>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 semiannually during the first year of performing testing. Findings follow. 1. Review of the laboratory's General Policy, effective 1/31/2015, under "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 testing</p>

	<p>personnel #1 who began employment August 31, 2020 showed no semiannual evaluation was performed. 3. Interview with the Practice Manager on March 11, 2021 at 1010 hours in the breakroom confirmed they didn't have a semiannual competency evaluation for testing personnel #1.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>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. Findings follow. 1. Review of the laboratory's General Policy, effective 1/31 /2015, under "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 2020, showed one evaluation performed in 2017 in the employee file. 3. Interview with the Practice Manager on March 11, 2021 at 1045 hours in the breakroom confirmed there were no other competency evaluations for the previous employee in the employee file. THIS IS A REPEAT DEFICIENCY CITED IN THE SURVEY CONDUCTED 10/19/2016</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, stain quality control records, test report, and interview the laboratory director failed to provide overall management and direction (see D6079).</p>
<p>D6079</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are</p>

properly performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, stain quality control records, test report, and interview the laboratory director failed to provide overall direction and technical oversight of the laboratory (see D5219, D5473 and D5805).