

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2059065	(X3) Date Survey Completed 01/19/2021
Name of Provider or Supplier Surgical & Cosmetic Dermatology	Street Address, City, State 1615 Highway 34 East, Suite B, Newnan, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 19, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interview, the laboratory failed to maintain copies of all PT documents. Findings include: 1. Review of PT records revealed the lack of documents for 2019 event #3 and 2020 event #2. 2. An interview with lead histotechnologist in the breakroom on 1/19/2021 at approximately 10:30 a.m confirmed the lack of documents for the aforementioned events.</p>
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or</p>

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 testing personnel (TP) document review and staff interview, the laboratory failed to verify at least twice annually the accuracy of any test or procedure performed. Findings include: 1. TP document review revealed there were no twice annually peer reviews performed for Histopathology (MOHS) testing in 2020. 2. An interview with lead histotechnologist in the breakroom on 1/19/2021 at approximately 09:15 a.m. confirmed the lack of Pathology peer reviews for the aforementioned year.

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 Procedure Manual (SOP) review and staff interview, the laboratory director (LD) failed to ensure an approved Potassium Hydroxide (KOH) Quality Control (QC) procedure was available as required. Findings include: 1. SOP review revealed the LD did not ensure an approved KOH QC procedure was available in the SOP for mycology slides. 2. An interview with the lead histotechnologist at the facility on 01/19/2021 at 10:00 AM in the breakroom, confirmed the control procedure is not available for KOH slides.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on potassium hydroxide (KOH) slides. Findings include: 1. No QC documents were available to review on KOH slides at the time of survey for 2019 or 2020. 2. An interview with the lead histotechnologist at the facility on 01/19/2021 at 10:00 AM in the breakroom, confirmed controls were not performed on KOH slides .

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results were returned to the PT agency by the event due date. Findings include: 1. Review of PT records for 2019 and 2020 revealed the laboratory received a score of 0% or "no results received" on 2019 Events 2 and 3; and Events 1,2, and 3 of 2020. 2. Interview with the lead histotechnologist on 1/19/2021 at 11:00 am in the breakroom confirmed results were not reported to the PT agency in time to be evaluated which resulted in a score of 0% or "no results received".

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure PT results are reviewed upon receipt from the PT agency. Findings include: 1. Review of PT records for 2019 events 2 & 3 and 2020 events 1,2, & 3 revealed no review of results upon receipt from the PT agency. 2. An interview with lead histotechnologist in the breakroom on 1/19 /2021 at approximately 10:30 a.m confirmed the lack of review.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) 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 review of the laboratory personnel files and staff interview, the laboratory director (LD) failed to ensure testing personnel (TP) receive the appropriate training for the testing performed of potassium hydroxide (KOH) preps. Findings include: 1.

	<p>Review of the laboratory personnel files reveals the lack of training documentation for staff #7 (CMS 209 form). 2. Interview with lead histotechnologist in the breakroom on 1/19/2021 at approximately 09:45 a.m confirmed the lack of training documentation.</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 testing personnel(TP) documents and staff interview, the technical consultant failed to perform semiannual competency on all testing personnel. Findings include: 1. Review of the laboratory personnel files reveals the lack of semiannual competency documentation for staff #7 (CMS 209 form). 2. Interview with lead histotechnologist in the breakroom on 1/19/2021 at approximately 09:45 a.m confirmed the lack of semiannual competency documentation.</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 testing personnel(TP) documents and staff interview , the technical consultant failed to perform annual competency on all testing personnel. Findings include: 1. Review of the laboratory personnel files reveals the lack of 2019 and 2020 annual competency documentation for staff #6 (CMS 209 form). 2. Interview with lead histotechnologist in the breakroom on 1/19/2021 at approximately 09:45 a.m confirmed the lack of 2019 and 2020 annual competency documentation.</p>