

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0989207	<b>(X3) Date Survey Completed</b>  08/07/2018
<b>Name of Provider or Supplier</b>  Affiliated Dermatologists Green Hills Pc	<b>Street Address, City, State</b>  4301 Hillsboro Road Suite 200, Nashville, TN	
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: Based on review of the Quality Assurance Proficiency Testing Request Forms, previous Centers for Medicare and Medicaid Services(CMS)-2567 statements of deficiencies, and interview with the Practice Manager determined the laboratory failed to verify the accuracy of the Moh's Testing at least twice annually in 2017. The findings include: 1, Review of the Quality Assurance Proficiency Testing Request Forms revealed the last accuracy verification of the Moh's testing was performed July 21, 2016. 2. Review of previous CMS-2567 statements of deficiencies for surveys performed December 2, 2011 and April 4, 2014, revealed the same citation for failure to verify the accuracy of the Moh's testing at least twice annually. 3. Interview with the Practice Manager on August 7, 2018, at 10:30 AM confirmed no Quality Assurance Proficiency Testing Request Forms had been sent out to verify the accuracy of the Moh's Testing in 2017.</p>
<b>D5400</b>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p>

This CONDITION is not met as evidenced by:  
 The Laboratory failed to follow the Laboratory Procedure Manual for labeling and staining the H&E slides (Refer D5401), failed to ensure all reagents used in patient testing are labeled with the date opened and expiration dates(Refer D5415), failed to document performance of Cryostat maintenance and temperatures when patient testing is performed(Refer D5433), failed to maintain QC records that include reagent lot numbers(Refer D5609).

**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:  
 Statement 1. Based on review of patient slides, Laboratory Procedure Manual and interview with the Tech determined the laboratory failed to label the Hematoxylin and Eosin(H&E) slides according to the Procedure Manual in 2017 and 2018. The findings include: 1. Review of the H&E slides for the chart audit of ten patients (numbers 16-043, 16-056, 16-071, 17-001, 17-018, 17-079, 18-001, 18-012, 18-018, and 18-036) on August 7, 2018, at 11:35 AM revealed the slides failed to be labeled with the date performed. 2. Review of the Laboratory Procedure Manual stated the labeling of the H&E slides is to include the date performed. 3. Interview with the Tech on August 7, 2018, at 11:50 AM confirmed the laboratory failed to include the testing date when labeling the H&E slides in 2017 and 2018. Statement 2 Based on observation of the posted H&E Stain procedure, review of the Laboratory Procedure Manual, review of the H & E procedure posted on the stain line, and interview with the Tech determined the laboratory failed to follow their written Laboratory Procedure for performing the H&E staining in 2017 and 2018. The findings include: 1. Observation of the Laboratory Area on August 7, 2018, at 9:05 AM revealed a Procedure for performance of H&E staining posted on the hood. The procedure includes steps: 1) Hematoxylin(1 minute), 2)Tap Water(rinse), 3)Acid Alcohol(1 Quick Dip), 4)Tap Water(rinse), 5)Ammonia Water(30 seconds), 6)Tap Water(rinse), 7)Eosin(15 seconds), 8)95% Alcohol diluted with Tap Water(10 dips), 9)100% Alcohol(10 dips), 10)100% Alcohol(10 dips), 11)Sub-X(1 minute), 12)Sub-X(1 minute). 2. Review of the Laboratory Procedure Manual revealed the procedure to be used for hand staining H&E slides matches the posted procedure with the exception of these steps: 1)100% Alcohol(30 to 60 seconds) 2) ( H2O 10 dips), 3)Hematoxylin(30 to 60 seconds), 5)Wash in Water(15 seconds), 6)Ammonia Water(15 seconds), 7) Wash in Water(30 seconds, 8)Eosin(30 to 60 seconds), 9)90% Alcohol(10 dips) 10) 95% Alcohol(30 seconds), 11)100% Alcohol(15 seconds), 12)100% Alcohol(30 seconds)13)Sub-X(30 seconds). 3. Review of the H&E procedure posted on the stain line revealed the steps matched the procedure posted on the hood with the exception of these steps: 2) Tap Water(2dips), 3) Acid Alcohol(2 dips), 4) Tap Water (10 dips), 6) TapWater(10 dips), 4. Interview with the Tech on August 7, 2018, at 9:40 AM confirmed that he currently stains the H&E slides using the procedure that is documented on the stain line in 2017 and 2018.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory area and interview with the Tech confirmed the laboratory failed to ensure all reagents are labeled with the date opened and expiration dates in 2017 and 2018. The findings include: 1. Observation of the laboratory area on August 7, 2018 at 10:20AM revealed a biohazard cabinet containing Hematoxlyn, Eosin, Safe Clear, 95% Reagent Alcohol, Acid Alcohol, 100% Reagent Alcohol and Ammonia Water. None of the reagents were labeled with opened and expiration dates. 2. Interview with the Tech on August 7, 2018, at 10:25 AM confirmed the laboratory failed to label the reagents with opened and expiration dates in 2017 and 2018.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

This Standard is not met as evidenced by: Based on review of the Cryostat Maintenance Logs and interviews with the Tech and Practice Manager determined the laboratory failed to document performance of the Cryostat Maintenance Logs for 2016, 2017, and 2018. The findings include: 1. Review of the Cryostat Maintenance Logs revealed no documentation of Daily Maintenance(including temperature, clean inside, clean outside, and oil Gibs) performed for August 4, 2016, September 1, 2016, February 16, 2017, May 18, 2017, and August 1 - 7, 2018. 2. Interview with the Tech on August 7, 2018, at 11:00 AM confirmed the he failed to document the Cryostat Daily Maintenance for August 1 and August 2, 2018. The Tech stated two patients (numbers 0-46, and 0-47) were tested on August 1, 2018 and one patient (number 0-48) was tested on August 2, 2018. 3. Interview with the Practice Manager on August 7, 2018, at 11:45 AM confirmed the laboratory had no documentation of Cryostat Daily Maintenance being performed for August 4, 2016, September 1, 2016, February 16, 2017, May 18, 2017, and August 1 - 7, 2018.

**D5609**

**HISTOPATHOLOGY**

CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control

procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

This Standard is not met as evidenced by: Based on lack of Quality Control (QC) records, and interview with the Tech confirmed the laboratory failed to maintain QC records that include reagent lot numbers in 2017 and 2018. The findings include: 1. No QC Records were available for review for tracking reagent lot numbers for H&E stains in 2017 and 2018. 2. Interview with the Tech on August 7, 2018, at 9:45 AM, confirmed the laboratory failed to maintain QC logs of lot numbers of the reagents for H&E Stains in 2017 and 2018.

**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:

This Standard is not met as evidenced by: Based on review of ten patient operative notes (test reports), CM-116 form, and interview with the Practice Manager determined the test reports failed to contain the name and address of the laboratory location where the testing was performed in 2016, 2017, and 2018. The findings include: 1. Review of ten patient operative notes(test reports) (numbers 16-043, 16-056, 16-071, 17-001, 17-018, 17-079, 18-001, 18-012, 18-018, and 18-036) revealed the name and address of the laboratory where the testing was performed was missing on all ten reports. 2. Review of the CMS-116 form revealed the laboratory name and address is Retief Skin Center at 4301 Hillsboro Pike, Suite 200, Nashville, TN 37215. 3. Interview with the Practice Manager on August 7, 2018, at 11:30 AM confirmed the laboratory name and address do not appear on the patient operative report which serves as the patient final report in 2016, 2017, and 2018.