| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 11D1100651 | 04/09/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dermatology Associates Of Georgia | 2665 N Decatur Road Suite 650, Decatur, 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 |
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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on April 9, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited: |
| **D2005** | ENROLLMENT<br>CFR(s): 493.801(a)(4)<br><br>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview the facility failed to authorize the PT program to release all PT data to CMS as required. Findings include: 1, American Academy of Family Physicians (AAFP) PT document review revealed the facility's PT results were not reported to CMS in 2017, 2018, and 2019 thus far. 2. An interview with the credentialing coordinator on 4/9/2019 in a medical office at approximately 2:30 p.m. confirmed the PT results were not released for the aforementioned dates. |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, |

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| | subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on American Academy of Family Physicians (AAFP) proficiency test (PT) document review and staff interview, the laboratory failed to successfully participate in a PT program approved by CMS. Findings include: Refer to D2046 |
| **D2046** | MYCOLOGY<br>CFR(s): 493.827(e)<br><br>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory failed to achieve an overall testing event score of satisfactory performance for two consecutive testing events is unsuccessful PT performance. Findings include: 1. American Academy of Family Physicians (AAFP) PT report review revealed the laboratory failed the following Mycology (Dermatophyte Screening) PT events: 2018 -- Event B (60 percent); Event C (40 percent). 2. An interview with the credentialing coordinator in a medical office on 4/9/2019 at approximately 2:30 p.m. confirmed the aforementioned PT event failures in 2018. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency. Findings include: 1. SOP review revealed the laboratory did not establish and follow a six-procedure policy and procedure for evaluating TP competency. 2. An interview with the credentialing coordinator in a medical office on 4/9/2019 at approximately 2:30 p.m. confirmed the SOP did not contain a competency policy and procedure. |
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| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) document review and staff interview, the laboratory failed to document PT corrective action as required. Findings include: 1. American Academy of Family Physicians (AAFP) document review revealed corrective action was not documented for the following Mycology (Dermatophyte) PT events: 2018 -B (score of 60 percent; 2018-C (score of 40 percent). 2. An interview with the credentialing coordinator in a medical office on 4/9/2019 at approximately 2:30 p.m. confirmed the lack of corrective action for the aforementioned failed PT scores. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory policy and procedure manual (SOP) and staff interview the laboratory failed to include required policies and procedures. Findings include: 1. SOP review revealed there not a venipuncture policy and procedure included in this manual. 2. An interview with the credentialing coordinator in a medical office on 4/9/2019 at approximately 2:30 p.m. confirmed there was not a venipuncture policy and procedure in the SOP. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. |

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| | (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on laboratory maintenance document review and staff interview, the laboratory failed to monitor and document the laboratory refrigerator temperature as required. Findings include: 1. Laboratory maintenance document review revealed the laboratory failed to monitor and document the laboratory refrigerator temperature for 2017 and 2018. 2. An interview with the credentialing coordinator in a medical office on 2/9 /2019 at approximately 2:30 p.m. confirmed the laboratory refrigerator temperature was not monitored and documented for the aforementioned dates. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and staff interview, the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacture. Findings include: 1. Observation during the laboratory tour at approximately 1:00 p.m. revealed the Accuscope microscope was due for calibration in January, 2018. 2. Observation during the clinical laboratory tour at approximately 1:00 p.m. revealed the Path Group centrifuge was last calibrated on June 4, 2013. 3. An interview with the credentialing coordinator in the clinical laboratory on 4/9/2019 at approximately 1:00 p.m. confirmed the aforementioned overdue calibrations. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on maintenance log document review and staff interview, the laboratory failed to perform and document function checks as defined by the manufacturer and with the frequency specified by the manufacturer. Findings include: 1. Maintenance log document review revealed the laboratory failed to provide a microscope maintenance log for 2018 at the time of the survey. 2. An interview with the credentialing coordinator on 4/9/2019 at approximately 2:30 p.m. in a medical office confirmed there was not a 2018 microscope maintenance log available at the time of the survey. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g) |

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| | (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory quality control (QC) documents and staff interview the laboratory failed to perform mycology media quality control (QC) as required. Findings include: 1. QC document review revealed the laboratory failed to check each batch of DTM media for sterility in 2017, 2018, and 2019 thus far. 2. QC document review revealed the laboratory failed to check each batch of DTM media for its ability to support or inhibit growth of specific organisms or produce a biochemical response in 2017, 2018, and 2019 thus far. 3. An interview with the credentialing coordinator in a medical office on 4/9/2019 at approximately 2:30 p.m. confirmed the aforementioned QC was not performed for the DTM media in 2017, 2018, and 2019 thus far. |
| **D5789** | TEST RECORDS<br>CFR(s): 493.1283(b)<br><br>Records of patient testing including, if applicable, instrument printouts, must be retained.<br><br>This STANDARD is not met as evidenced by:<br>Based on patient log sheet review, patient test report review, and staff interview, the laboratory failed to retain patient test records as required. Findings include: 1. Review of patient log sheets and patient test reports revealed the laboratory failed to retain DTM patient test reports and DTM log sheets for 2017, 2018, and 2019 thus far. 2. An interview with the credentialing coordinator in a medical office on 4/9/2019 at approximately 2:30 p.m. confirmed there were no DTM patient test reports or DTM log sheets available at the time of the survey. for the aforementioned dates. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency test (PT) report review and staff interview, the laboratory director (LD) failed to ensure all PT reports were reviewed by the appropriate staff as required. Findings include: 1. American Academy of Family Physicians (AAFP) PT |

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| | report review revealed the LD failed to review the following Mycology (Dermatophyte) PT events: 2017-C and 2018-C. 2. An interview with the credentialing coordinator in a medical office on 4/9/2019 at approximately 2:30 p.m. confirmed the aforementioned PT reports were not reviewed. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) document review and staff interview the laboratory director (LD) failed to ensure that, prior to testing patients' specimens, all TP receive the appropriate training for the type and complexity of the services offered. Findings include: 1. TP document review revealed an initial training competency for moderate complexity testing (dermatophyte) was not performed for Staff #4 (CMS 209) in 2018. 2. An interview in a medical office with the credentialing coordinator on 4/9 /2019 at approximately 2:30 p.m. confirmed an initial training competency for moderate complexity testing (dermatophyte) was not performed for Staff #4 (CMS 209) in 2018. |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on testing personnel (TP) document review and staff interview the technical supervisor (TS) failed to evaluate the competency of all TP and assuring the staff maintain their competency to perform test procedures as required. Findings include: 1.1. TP document review revealed the TS failed to perform a six-month competency for Staff #3 in 2018. 2. TP document review revealed the TS failed to perform an annual competency for Staff #3 (CMS 209) in 2018 and 2019 thus far and for Staff #4 (CMS 209) in 2019. 3. An interview on 4/9/2019 in a medical office at approximately 2:30 p.m. confirmed competencies were not performed in 2018 and 2019, thus far, for the aforementioned TP. |