Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0686950	09/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Specialists Of Coweta County, Llc	710 Newnan Crossing Bypass Suite A, 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 recertification survey was conducted on September 20, 2022. The facility was found to be NOT in compliance with the Clinical Laboratory Improvement Amendments (CLIA) conditions: 42 CFR 493.801 Condition: Enrollment and Testing of Samples 42 CFR 493.803 Condition: Successful Participation 42 CFR 493.1230 Condition: General Laboratory Systems 42 CFR 493.1250 Condition: Analytic Systems 42 CFR 493.1441 Condition: General Laboratory (High Complexity) A cease testing letter was submitted by the laboratory director at the summation discussion.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) logs, review of the procedure manual (SOP), and testing personnel interview, the laboratory failed to follow current SOP instructions for 1 of 1 waived testing performed by the laboratory. The findings include: 1. Review of the SOP revealed QC was required on each shipment/lot number received, and at least once per month. The laboratory failed to perform the required QC documentation since 09/01/2020 for the following waived test: Urine Human Chorionic Gonadotropin (HCG Combo Test cassette). 2. The lab failed to document the dates HCG Combo kits were received and opened. The SOP indicates, "each time a box of urine HCG test is received, an orange label should be placed on the top of the box before it is placed in the closet. If a box is opened, that has an orange sticker on it- check the log and see if the lot# has been tested. If it has, place a green sticker on it with your initials. If it has not been done, it must have external controls done on it. The control results are documented on the log (at each station) and

	a green sticker is placed over the orange sticker with 'OK TO USE' and your initials". 3. Interview with staff #11 (CMS 209), in nursing station B, at approximately 12:30 p. m., on 09/20/22, confirmed the lab failed to document dates the kits were received and opened and the lack of QC documentation since 09/01/2020 for the aforementioned waived test.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the CMS 116 form, lack of proficiency testing (PT) records, and confirmed in testing personnel interview, the laboratory failed to meet the requirements of participating in proficiency testing for the subspecialties of mycology (Dermatophyte Test Medium cultures) DTM or parasitology (presence or absence of parasites) as evidenced by: 1. The lab failed to enroll in PT for the subspecialty of parasitology (presence or absence of parasites) for the year 2021. Review of the CMS 116 form reveals the lab performs 10 parasitology exams per year. 2. The lab failed to enroll in PT for the subspecialty of mycology (DTM cultures) or parasitology (presence or absence of parasites) for the year 2022. 3. Interview with testing personnel # 11 (CMS 209), on 09/20/2022, at 12:29 pm, in nursing station B and phone interview with the CLIA Specialist (administrative office personnel of Epiphany Dermatology, who is based in another city/state, responsible for overseeing the CLIA documents and regulations), on 9/20/22, in the back office, at 2:15 P.M confirmed the laboratory had not enrolled in PT for the aforementioned subspecialties and dates.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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, 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. This CONDITION is not met as evidenced by: Based on review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing (PT) reports and testing personnel interview, the laboratory failed to participate in 2021 PT events 2 and 3, for the subspecialty of Mycology (DTM culture). Refer to: D 2039 and D 2048
D2039	MYCOLOGY CFR(s): 493.827(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing (PT) reports and testing personnel interview, the laboratory failed to participate in 2021 PT events 2 and 3, for the subspecialty of Mycology (DTM culture). The findings include: 1. Review of MLE PT reports of Mycology 2020 event 3 and 2021 events 1, 2, and 3, revealed the laboratory failed to participate in PT events 2 and 3 of 2021 for the subspecialty of mycology. 2. Interview with testing personnel # 11 (CMS 209), on 09/20/2022, at 12:29 pm, in nursing station B and phone interview with the CLIA specialist, on 9/20/22, at 2:15 P.M confirmed the laboratory failed to participate in the aforementioned PT.
D2048	PARASITOLOGY CFR(s): 493.829(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the laboratory's Medical Laboratory Evaluation (MLE) proficiency testing (PT) reports and testing personnel interview, the laboratory failed to participate in 2021 and 2022 PT for the subspecialty of parasitology. The findings

	include: 1. Review of MLE PT reports revealed the laboratory failed to participate in PT 2021 and 2022 for the subspecialty of parasitology. 2. Interview with testing personnel # 11 (CMS 209), on 09/20/2022, at 12:29 pm, in nursing station B and phone interview with the CLIA specialist, on 9/20/22, at 2:15 P.M confirmed the laboratory failed to participate in the aforementioned PT.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 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. This CONDITION is not met as evidenced by: Based on review of laboratory personnel competency assessment policies, proficiency testing (PT) reports and policy, an interview with testing personnel and the CLIA Specialist, the laboratory failed to have an approved and signed Quality Assurance plan as evidenced by: refer to D 5209
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the Center for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvements Amendments (CLIA) Application for Certification form (CMS 116), lack of laboratory records and testing personnel interview, the laboratory failed to verify the accuracy of qualitative mycology (detecting the presence or absence of fungi) in 2021 and 2022. The findings include: 1. Review of the CMS 116 revealed the laboratory performs approximately 308 qualitative mycology [potassium hydroxide (KOH)] analyses per year. 2. Lack of laboratory records revealed no documentation of peer review or proficiency testing results for qualitative mycology analysis. The lab failed to perform corrective actions to initalize peer reviews or re-enroll in PT after change of ownership, specific to the laboratory testing performed. 3. Interview with testing personnel # 11 (CMS 209) on 9/20/22 at 12:30 P.M in nursing station B confirmed the laboratory has no documentation of peer review or proficiency testing for mycology or parasitology for 2021 and 2022.
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 the review of policy and procedures (SOP), the lack of quality control (QC) records and confirmed by a staff interview, the laboratory failed to meet the requirements of the analytic systems as evidenced by: 1. The laboratory failed to perform the required positive and negative organisms on each batch of media used to perform DTM cultures(refer to D5477). 2. The laboratory failed to have a current, approved SOP for all procedures/examinations performed in the lab. (refer to D5401)
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 testing personnel interview, the laboratory failed to have an approved SOP for all examinations/procedures performed that are specific to the laboratory. Findings include: 1. SOP review revealed the lab failed to have procedures that are specific to the laboratory. The lab changed ownership in October 2021. 2. Interview with testing personnel #11 (CMS 209) in nurse's station B, on 9/20/22 at 12:30 P.M, confirmed the lack of the procedures that are specific to the laboratory.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (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. This STANDARD is not met as evidenced by: Based on review of quality control (QC) log for mycology, QC procedure for Dermatophyte Test Media (DTM) and testing personnel interview, the lab failed to perform the required positive/negative organisms on each batch of media used to perform DTM cultures. The findings include: 1. Review of the DTM QC procedure reveals the laboratory is required to perform a negative control and a positive control organism on each lot number/shipment of DTM culture media prior to use. The results are recorded in the DTM media log located under the "Quality Control" section of the book. 2. Review of QC records reveals the laboratory failed to perform QC on DTM culture media since December 2020. 3. Interview with staff #11 (CMS 209) at 12:29 PM in nursing station - B on 09/20/22 confirms the lab has not performed the QC on DTM cultures since December 2020.

D5523	PARASITOLOGY CFR(s): 493.1264(a)(d) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the Center for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvements Amendments (CLIA) Application for Certification form (CMS 116), quality control (QC) document review and testing personnel interview, the laboratory failed to perform and document QC on potassium hydroxide (KOH) and parasitology slides. The findings include: 1. No QC documents were available to review on KOH or parasitology slides at the time of survey. 2. Review of the CMS 116 form reveals the lab performs approximately 10 parasitology and approximately 308 KOH exams per year. 3. Interview with testing personnel #11 (CMS 209) on 9/20 /22 at 12:30 PM in nursing station B, confirmed controls were not performed on KOH or parasitology slides.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) assessement documents, policy review of the General Quality Assessment review policy (section 4) and interview with the CLIA Specialist, the lab failed to document and follow policies to assess TP competency. The findings include: 1. Review of TP documents revealed the lack of competency records for 7 of 7 personnel performing procedures in mycology (potassium hydroxide-KOH and DTM culture) and parasitology (presence or absence). 2. Review of the General QA policy reveals the lab is to : a)" Assess employee competency (documentation of an evaluation every six months during the first year of employment and annually thereafter." b) "Assess consultant competency, if applicable" 3. Review of the competency assessment documents reveals the assessment fails to evaluate: a) Direct observation of test performance b) Monitoring recording and reporting of results c) Review intermediate test results,worksheets, Quality Control, Proficiency Test, and maintenance records d) Assessment of test performance thru previously analyzed specimens, internal blind testing samples or external PT e) Assessment of problem solving skills f) Direct observation of instrument maintenance/function checks 4. Phone interview with the CLIA Specialist, in the back office , on 9/20/22 at 2:11 P.M, confirmed the lack of documented competency assessment for the aforementioned TP.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	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. This CONDITION is not met as evidenced by: Based on review of laboratory documents including: competency evaluations, Proficiency Testing (PT), quality control (QC), Quality Assurance (QA) plan and interviews with testing personnel and CLIA Specialist, the laboratory director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed to conduct competency evaluations on testing personnel (refer to D6103). 2. The Laboratory Director failed to ensure the laboratory enrolled in Proficiency Testing (PT) (refer to D6088). 3. The Laboratory Director failed to ensure the lab performed and documented quality control (QC) (refer to D6093). 4. The Laboratory Director failed to establish a Quality Assurance (QA) plan specific to the current ownership (refer to D6094).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of laboratory Proficiency Testing (PT) records and interviews with testing personnel and the CLIA Specialist, the laboratory director failed to ensure the lab enrolled in Proficiency Testing (PT) in the subspecialties of mycology & parasitology. The findings include: 1. Review of laboratory records revealed the lab director failed to ensure the lab enrolled in PT for 2022 to include subspecialty of mycology (DTM cultures) and parasitology (presence or absence of parasites). 3. Interview with testing personnel # 11 (CMS 209) on 09/20/2022 at 12:29 pm, in nursing station B and phone interview with the CLIA specialist, on 9/20/22, at 2:15 P. M., confirmed the laboratory director failed to ensure the lab enrolled in PT for 2022.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the CMS 116, patient result log sheets, quality controls (QC) log sheets, and testing personnel interview, the lab director failed to ensure the lab follows the QC procedures and documents the parasitology and mycology QC. The findings include: 1. Review of the CMS 116 revealed the lab performed : -approximately 15 DTM mycology cultures annually - approximately 308 Potassium Hydroxide (KOH) slides annually -approximately 10 parasitology slides annually 2. Review of patient result log sheets and Mycology/KOH/Parasitology QC log sheets, revealed the lack of

	QC documentation. 3. Interview with testing personnel # 11 (CMS 209), on 09/20 /2022 , at 12:29 pm , in nursing station B, confirmed the laboratory director failed to ensure the lab documents QC in the subspecialties of parasitology and mycology.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Review of the the laboratory manuals revealed the lab director failed to have an approved and signed Quality Assessment (QA) plan. The findings include: 1. No approved laboratory QA manual was available which reflected the ownership change of the laboratory, as of October 2021. No QA plan specific to the laboratory. 2. Interview with testing personnel # 11 (CMS 209), on 09/20/2022 , at 12:29 pm , in nursing station B, confirmed the laboratory director failed to ensure the lab has an approved and signed Quality Assessment plan.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records, interview with the CLIA Specialist, the laboratory director failed to conduct competency evaluations on testing personnel. The findings include: 1. Review of TP documents revealed the lack of competency records for 7 of 7 personnel performing procedures in mycology and parasitology. 2. Laboratory Director failed to ensure the Competency evaluation included the six competency assessment criteria: a) Direct observation of test performance b) Monitor recording and reporting of results c) Review Intermediate test results, worksheets,QC, PTand PM records d) Direct observation of instrument maintenance/function checks e)Assessment of test performance thru testing previously analyzed specimens, Internal blind testing samples or external PT f)Assessment of problem solving skills 3. Phone interview with the CLIA Specialist, in the back office, on 9/20/22, at 2:11 P.M, confirmed the lab director failed to conduct and document competency for the aforementioned TP.