Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2282705	06/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology And Skin Care Associates	7249 Liberty Way, West Chester, OH	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 record review and an interview with Testing Personnel (TP) #2, the laboratory failed to follow their "Lab Director Signature Page" policy and procedure. This deficient practice had the potential to affect 220 out of 220 patients tested in the subspecialty of Histopathology from 01/01/2024 through 06/10/2025. Findings Include: 1. Review of the policy and procedure titled "Lab Director Signature Page" found the following statements: "Procedure: The lab director will review the procedures to be utilized in the clinic. The director will sign the cover of the signature page annually to authorize the listed procedures in the clinic labs." 2. Review of the cover of the signature page found the most recent Laboratory Director signature dated 01/09/2023. 3. The inspector requested the 2024 Laboratory Director signature page from TP #2. TP #2 confirmed the Laboratory Director did not sign the signature page for 2024. The interview occurred on 06/10/2025 at 2:00 PM.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the laboratory failed to establish and follow written policies and procedures, and document all assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. This deficient practice had the potential to affect 220 out of 220 patients tested in the subspecialty of Histopathology from 01/10/2024 through 06/10/2025. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Lab Manual", approved via signature and date by the Laboratory Director on 01/09/2023, found no mention of an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems. 2. The inspector requested detailed documentation of post analytic assessment activities from TP #2. TP #2 stated the laboratory did not perform and document post analytic activities and was unable to provide the requested information. The interview occurred on 06/10/2025 at 1:45 PM.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 record review and an interview with Testing Personnel (TP) #2, the Laboratory Director failed to ensure policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and post analytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform tissue biopsy grossing procedures, and report test results promptly and proficiently. This deficient practice had the potential to affect 220 out of 220 patients tested in the subspecialty of Histopathology from 01/10/2023 through 06 /10/2025. Findings Include: 1. Review of the laboratory's policy and procedure manual titled, "Lab Manual", approved via signature and date on 01/09/2023 and provided on the date of the inspection, did not find a competency assessment policy and procedure. 2. The Inspector requested the laboratory's competency assessment policy and procedure from TP #2. TP #2 confirmed the laboratory did not establish a competency assessment policy and procedure and was unable to provide the requested documentation. The interview occurred on 06/10/2025 at 1:30 PM.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the Technical Supervisor (TS) failed to include direct observations of routine patient test

	performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation of the competency for two out of three testing personnel (TP) who conducted high complexity tissue biopsy grossing procedures. This deficient practice had the potential to affect 220 out of 220 patients tested in the subspecialty of Histopathology from 01/10/2024 through 06/10/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 05/07/2025, revealed three out of four individuals listed as TP to perform high complexity tissue biopsy grossing procedures. 2. Review of the 2024 and 2025 "Employee Evaluations" forms found no direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation for TP #2 and TP #3. 3. Review of the laboratory's policy and procedure manual titled, "Lab Manual" approved via signature and date by the Laboratory Director on 01/09/2023, and provided on the date of the inspection, did not find any mention of competency assessment procedures. 4. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation of the competency for TP #2 and TP #3 from TP #2. TP #2 confirmed the laboratory did not establish a competency assessment policy and procedure, and did not include direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation of TP #2 and TP #3 competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 06 /10/2025 at 1:30 PM.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the Technical Supervisor (TS) failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency for two out of three testing personnel (TP) who conducted high complexity tissue biopsy grossing procedures. This deficient practice had the potential to affect 220 out of 220 patients tested in the subspecialty of Histopatholgy from 01/10/2024 through 06/10/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 05/07/2025, revealed three out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing procedures. 2. Review of the 2024 and 2025 "Employee Evaluations" forms found no assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation for TP #2 and TP #3. 3. Review of the laboratory's policy and procedure manual titled, "Lab Manual" approved via signature and date by the Laboratory Director on 01/09/2023 and provided on the date of the inspection did not find any mention of competency assessment procedures. 4. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of competency for

	TP #2 and TP #3 from TP #2. TP #2 confirmed the laboratory did not establish a competency assessment policy and procedure, and did not include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of TP #2 and TP #3 competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 06/10/2025 at 1:30 PM.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) (b)(8)(vi) Assessment of problem-solving skills; and This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #2, the Technical Supervisor (TS) failed to include the assessment of problem solving skills in the evaluation of the competency for two out of three testing personnel (TP) who conducted high complexity tissue biopsy grossing procedures. This deficient practice had the potential to affect 220 out of 220 patients tested in the subspecialty of Histopathology from 01/10/2024 through 06/10/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 05/07/2025, revealed three out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing procedures. 2. Review of the 2024 and 2025 "Employee Evaluations" forms found no assessment of problem solving skills in the evaluation for TP #2 and TP #3. 3. Review of the laboratory's policy and procedure manual titled, "Lab Manual" approved via signature and date by the Laboratory Director on 01/09/2023 and provided on the date of the inspection did not find any mention of competency assessment procedures. 4. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included problem solving skills in the evaluation of the competency for TP #2 and TP #3 from TP #2. TP #2 confirmed the laboratory did not establish a competency assessment policy and procedure, and did not include problem solving skills in the evaluation of TP #2 and TP #3 competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 06/10/2025 at 1:30 PM.