Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0920969	09/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermsurgery Associates	6700 West Loop South, Suite 450, Bellaire, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel files, the laboratory's policies, and staff interview, it was revealed the laboratory director failed to have documentation of specifying the responsibilities and duties of the clinical consultant, the general supervisor and the technical supervisor. Findings include: 1. A review of the laboratory's personnel files revealed the records failed to have documentation of the

	responsibilities and duties of the clinical consultant, the general supervisor, and the technical supervisor. 2. A review of the laboratory's policies revealed the laboratory had specified the responsibilities of the laboratory director, but failed to specify these for the clinical consultant, the general supervisor, and the technical supervisor. 3. The laboratory was asked to provide documentation of the job descriptions for the clinical consultant, the general supervisor, and the technical supervisor. No documentation was provided. 4. An interview with the Director of Operations and Human Resources on 9/23/19 at 10:20 a.m. in the laboratory revealed the laboratory director had not defined the duties and responsibilities of the clinical consultant, the general supervisor, and the technical supervisor. This confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel files, and staff interview, it was revealed the technical supervisor failed to perform competency assessments in 2018 on 2 of 4 testing personnel for high complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 9/16/19), revealed the laboratory identified 4 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical supervisor performing competency assessments for 2 of 4 testing personnel for high complexity testing for the speciality Histopathology. The testing personnel with no documentation of competency assessments: A. Testing person #2 B. Testing person #3 3. The laboratory was asked to provide documentation of the required competency assessments. No documentation was provided. 4. An interview with the Director of Operations and Human Resources on 9/23/19 at 10:05 a. m. in the laboratory, after review of the records, confirmed the above findings.