Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0689775	07/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Clear Lake Dermatology	13938 Hwy 3 Unit 100, Webster, 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.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the laboratory's Quality Assurance Manual, a review of the laboratory's quality assurance records from 10/2017 to 6/2019, and staff interview, it was revealed the laboratory director failed to follow the quality assessment (QA) program to assure the quality of laboratory services provided. Findings include: 1. A review of the laboratory's Quality Assurance Manual revealed the laboratory director is responsible for the following: A. The Laboratory Director reviews all quality control charts and

	logs on at least a monthly basis. All out of control situations not resolved by a simple repeat analysis will be reviewed by the Laboratory Director as soon as practical after the event. The Laboratory Director will review the corrective action to ensure that appropriate action is taken and proper procedures were followed. B. The Laboratory Director will ensure that appropriate laboratory personnel monitor test requisitions for appropriateness to patient's age, sex, and diagnosis. The results will also be compared to other readily available laboratory data on the patient. If any requisitions or results appear inappropriate, proper consultation will be obtained from the Laboratory Director. C. If the laboratory has employees, the Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance. D. The Laboratory Director will monitor the requisitioning and results of testing performed in the laboratory to ensure that any communication problems are corrected as soon as possible. 2. The laboratory was asked to provide documentation of the laboratory director's assessments for the quality assessment program from 10/2017 to 6/2019. No documentation was provided. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/9/19) on 7/8/19 at 10:15 in the office revealed there was no documentation of the laboratory director's assessments for the QA program.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure that testing personnel had documentation of the appropriate training to perform moderate complexity testing (refer to D6066).
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 the laboratory's submitted CMS 209 form, review of the laboratory's personnel files, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 2 of 5 testing personnel for moderately complex testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 7/9/19), revealed the laboratory identified 5 testing personnel. 2. A review of the laboratory's personnel

	records revealed that there was no documentation of the technical consultant performing competency assessments for 2 of 5 testing personnel for moderately complex testing for the specialities Mycology and Parasitology. The testing personnel with no documentation of competency assessments: A. Testing person #2 B. Testing person #3 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 7/8/19 at 0940 in the office revealed there was no documentation of competency assessments for the 2 testing personnel. This confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. 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 records, and staff interview, it was revealed the laboratory failed to have documentation of training for 1 of 5 testing personnel to perform moderately complex testing. Findings include: 1. A review of the laboratory's CMS 209 form (signed by the laboratory director on 7/9/19) revealed the laboratory identified 5 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for testing person #4 (as indicated on the CMS 209 form) for moderately complex testing for the specialties Mycology and Parasitology: 3. The laboratory was asked to provide documentation of the training of the testing person #4. No documentation was provided. 4. An interview with testing person number #1 (as indicated on the CMS 209 form) on 7/8/19 at 09:30 in the office revealed there was no documentation of training for testing person #4. This confirmed the above findings.
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: Based on the laboratory's Quality Assurance Manual, a review of the laboratory's quality assurance records from 10/2017 to 6/2019, and staff interview, it was revealed the laboratory director failed to follow the quality assessment (QA) program to assure the quality of laboratory services provided. Findings include: 1. A review of the laboratory's Quality Assurance Manual revealed the laboratory director is responsible for the following: A. The Laboratory Director reviews all quality control charts and logs on at least a monthly basis. All out of control situations not resolved by a simple repeat analysis will be reviewed by the Laboratory Director as soon as practical after the event. The Laboratory Director will review the corrective action to ensure that appropriate action is taken and proper procedures were followed. B. The Laboratory Director will ensure that appropriate laboratory personnel monitor test requisitions for appropriateness to patient's age, sex, and diagnosis. The results will also be compared to other readily available laboratory data on the patient. If any requisitions or results appear inappropriate, proper consultation will be obtained from the Laboratory

	Director. C. If the laboratory has employees, the Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance. D. The Laboratory Director will monitor the requisitioning and results of testing performed in the laboratory to ensure that any communication problems are corrected as soon as possible. 2. The laboratory was asked to provide documentation of the laboratory director's assessments for the quality assessment program from 10/2017 to 6/2019. No documentation was provided. 3. An interview with testing person #1 (as indicated on the CMS 209 form, signed by the laboratory director on 7/9/19) on 7/8/19 at 10:15 in the office revealed there was no documentation of the laboratory director's assessments for the QA program.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview revealed the laboratory director failed to ensure 1 of 5 testing personnel had documentation of training to perform high complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 7/9/19) revealed the laboratory identified 5 testing personnel performing high complexity testing. 1. A review of the laboratory's personnel records revealed testing person #4 (as indicated on the CMS 209 form) failed to had documentation of training for performing high complexity testing in the specialty of Histopathology. 3. An interview with testing person# 1 (as indicated on the CMS 209 form) on 7/8/19 at 09:30 in the office revealed there was no documentation of training for testing person #4. 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 on 2 of 5 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 7/9/19), revealed the laboratory identified 5 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 5 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 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 7/8/19 at 0940 in the office revealed there was no documentation of competency assessments for the 2 testing personnel. This confirmed the above findings.