

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0929550	(X3) Date Survey Completed 10/04/2018
Name of Provider or Supplier Dallas Associated Dermatologists	Street Address, City, State 6750 N Macarthur Blvd, Suite 260, Irving, 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	The Clinic Manager and Histology Manager were at the entrance conference conducted 10/04/2018. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Clinic Manager and Histology Manager on 10/04/2018. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Department of State Health Services, Health Facility Compliance Arlington Group.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory procedure manual, and confirmed in interview the laboratory failed to follow their own written policy ensuring annual maintenance was performed on the microscope in the years 2016, 2017 and 2018. Findings: 1. During a tour of the laboratory on 10/04/2018 at 10:45 am the microscope was observed to be stored on the counter and not have a maintenance tag. 2. Review of laboratory policy "Equipment Quality Control" stated: "Microscope Use Protocol Indicate frequency of activity in appropriate space, e.g., every six months. 1. Microscope stage and ocular eyepieces are to be cleaned every month or as needed. 2. Grounding check is monitored every year. 3. The ocular micrometer is calibrated every year. 5. Every action is documented on the Task List." No "Task List" or any</p>

documentation of yearly maintenance for the microscope was provided. 3. On 10/04/2018 at 10:49 am, the clinic manager stated the required maintenance had not been performed confirming the above findings.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant 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 policy manual, CMS 209 form, personnel records and confirmed in interview the laboratory director failed to specify, in writing, the responsibilities and duties of each person engaged in all phases of testing, which examinations and procedures each individual is authorized to perform, whether supervision is required, or whether consultant or director review is required prior to reporting patient test results for 5 of 5 Testing Persons records. Findings: 1. Review of the CMS 209 form listed 5 Testing Persons who perform moderate complexity testing, which included microscopic procedures. 2. Review of their personnel records for the 5 Testing Persons revealed the laboratory director did not specify in writing their duties and responsibilities. 3. On 10/04/2018 at 10:43 a.m., the clinic manager was unable to provide written duties and responsibilities for Testing Persons as written by the laboratory director. This confirmed the above findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of CMS 209 form, personnel records, annual competencies and confirmed in interview, the technical consultant (who is also the laboratory director) failed to evaluate and document the performance of 3 of 5 Testing Persons (TP-2, TP-3, TP-5) who perform moderate complexity testing, at least semiannually during the first year the Testing Person tested patient specimens in 2016 and 2017. Findings: 1. Review of the CMS 209 form revealed TP-2, TP-3, and TP-5 listed as individuals who perform moderate complexity testing, which included microscopic procedures. 2. Review of personnel records for Testing Persons in 2016 and 2017 revealed the following: TP-2: Hire date 06/27/2017; semi-annual competency should have occurred on 12/2017. There was no record of competency evaluation. TP-3: Hire date 03/01/2016; semi-annual competency should have occurred on 09/2016. There was no

record of competency evaluation. TP-5: Hire date 03/01/2016; semiannual competencies should have occurred on 09/2016 and 03/2017. There was no record of competency evaluations. Note: There were no competency records available for TP-5. The technical consultant did not ensure semi-annual competency assessments were evaluated and documented for the above TP's. 3. On 10/04/2018 at 10:43 a.m., the clinic manager was unable to provide semi-annual competencies for the mentioned above TP's. This confirmed the above findings.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of CMS 209 form, personnel records, and confirmed in interview, the technical consultant (who is also the laboratory director) failed to evaluate and document the competencies of 3 of 5 testing personnel (TP-3, TP-4, TP-5) annually in 2017 and 2018. Findings: 1. Review of CMS 209 form listed TP-3, TP-4, and TP-5 who perform moderately complexity testing, which included microscopic procedures. 2. Review of personnel records revealed the Technical Consultant (TC) failed to perform and document annual competency for TP-3 2018. (last documented training was 03/28/2017) The TC failed to perform and document annual competency for TP-4 in 2017 and 2018. (last documented competency was 02/2016 and 09/2016) The TC failed to perform and document annual competency for TP-5 in 2017 and 2018. (no records of training/competency; hired 03/01/2016) 3. During an interview on 10/04/2018 at 10:43 am, the clinic manager confirmed the above findings.