

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2126901	(X3) Date Survey Completed 03/20/2019
Name of Provider or Supplier Sanova Dermatology Metairie	Street Address, City, State 701 Metairie Rd, Suite 2a-205, Metairie, LA	
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 Certification Survey was performed on March 20, 2019 at Sanova Dermatology-Metairie, CLIA ID # 19D2126901. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following two (2) testing personnel: Personnel 1 Personnel 2 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on March 20, 2019 at 1:48 pm,</p>

Personnel 1 stated a personnel competency policy was not included in the policy and procedure manual. Personnel 1 further stated she was unaware a competency assessment was required for physicians performing testing.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) 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 interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.

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 record review and interview with personnel, the Laboratory Director failed to provide a written job description for Testing Personnel. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory did not have a written job description for Testing Personnel. 2. In interview on March 20, 2019 at 3:23 pm, Personnel 1 stated the laboratory did not have a written job description for Testing Personnel.