Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0689175	03/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Duke Neal Medical, Llc	12 Professional Dr, Houma, 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 13, 2019 at SLMA Dermatology, CLIA ID # 19D0689175. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to follow their established competency assessment policy. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the Laboratory Director and Personnel 2 serve as testing personnel for KOH testing. 2. In interview on March 13, 2019 at 1:30 pm, Personnel 3 stated Personnel 2 was hired September 2017. 3. Review of the laboratory's "Quality Assurance Manual" under the"Personnel Assessment" section revealed "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." 4. Review of the laboratory's "Risk Assessment Worksheet" for KOH under "Testing Personnel" section revealed "Must meet 6 CLIA elements of competency assessment." 5. Review of the laboratory's "Quality Control Plan Worksheet" for KOH under "Training Competency Assessment" section revealed "annually successfully meet all six CLIA Elements for Competency Assessment." 6. Review of personnel records for Personnel 2 revealed the laboratory did not have documentation of performance of a competency assessment at least semi-annually during the first year (due March 2018). 7. In interview on March 13, 2019 at approximately 2:00 pm, Personnel 3 stated the Laboratory Director did not perform a competency assessment for Personnel 2.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 interview with personnel, the laboratory failed to establish a written policy for verification of the accuracy of histopathology test performance. Findings: 1. In interview on March 13, 2019 at approximately 3:00 pm, Personnel 3 stated quarterly Quality Assurance (QA) is performed, where another dermatologist reviews the Laboratory Director's cases. 2. Review of the laboratory's policy and procedure manual and QA records revealed the laboratory did not have a written policy/procedure for verification of the accuracy of histopathology, including acceptability criteria and a corrective action plan. 3. In further interview on March 13, 2019, Personnel 3 stated she could not find the written policy for the histopathology quarterly case review.
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.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.