Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2060139	(X3) Date Survey Completed 05/08/2019
Name of Provider or Supplier Skin Surgery Centre Llc	**Street Address, City, State** 1615 Metairie Rd, Suite 101, 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 May 8, 2019 at Skin Surgery Centre-Metairie, CLIA ID # 19D2060139. 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: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Clinical Consultants, Technical Supervisors, and General Supervisors were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 and Personnel 3 serve as the laboratory's Clinical Consultants, Technical Supervisors, and General Supervisors. 2. Review of the laboratory's "PROFICIENCY TESTING Competency and CLIA competency assessment" policy revealed "Documented competency is required for individuals Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to comply with the procedures in their competency assessment in addition to a competency based on their federal regulatory responsibilities. Results of each Competency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent record." 3. Further review of the laboratory's "PROFICIENCY TESTING Competency and CLIA competency assessment" policy revealed frequency of performance of the assessment was not included. 3. Review of personnel records revealed competency assessments for the duties of Clinical Consultant, Technical Supervisor, and General Supervisor were not

	performed. 4. In interview on May 8, 2019 at 1:54 pm, Personnel 4 stated the Laboratory Director did not perform competency assessments for the identified personnel for their duties as Clinical Consultant, Technical Supervisor, and General Supervisor. II. Based on record review and interview with personnel, the laboratory failed to follow their established policy to assess competency of Testing Personnel. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following testing personnel: Personnel 1 Personnel 2 Personnel 3: hire date August 2018 2. Review of the laboratory's "PROFICIENCY TESTING Competency and CLIA competency assessment" policy revealed "Evaluation and documenting competency of personnel responsible for testing is required at least semi annually during the first year the individual sees patient specimens. After the first year, competency assessment must be performed at least annually." 3. Further review of the laboratory's "PROFICIENCY TESTING Competency and CLIA competency assessment" policy revealed "The following procedures are requirements for assessment of competency for all personnel performing laboratory testing. 1. Direct observation of routine patient test performance, including preparation, if applicable specimen handling, processing and testing. 2. Monitoring the recording and reporting test results 3. Review of intermediate results, and preventative maintenance records 4. Direct observation of performance of instrument maintenance procedures and function checks 5. Assessment of test performance through testing previously testing samples 6. Assessment of problem solving skills Competency assessment, which includes the procedures, must be performed for testing personnel for each test that the individual is approved by the laboratory director to perform." 4. Review of personnel records revealed the laboratory did not have documentation of performance of competency assessments for the identified testing personnel: Personnel 1: 2017 and 2018 Personnel 2: 2017 and 2018 Personnel 3: initial and semi-annual: due February 2019 5. In interview on May 8, 2019 at 1:53 pm, Personnel 4 stated the laboratory did not have documentation of competency assessments for the identified testing personnel.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform annual maintenance for the fume hood per laboratory policy. Findings: 1. Review of the laboratory's "AIR VENT/FUME HOOD POLICY' revealed "Grounding to be checked and documented annually." 2. Review of the laboratory's fume hood maintenance logs and service records for 2017 and 2018 revealed the laboratory did not have documentation that grounding check was performed. 3. In interview on May 8, 2019 at 1:57 pm, Personnel 4 stated she did not have documentation of the grounding check for the fume hood.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)

	The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure required maintenance was performed to ensure acceptable levels of performance. Refer to D5433.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 followed for assessing personnel competency. Refer to D5209 I and D5209 II.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 record review and interview with laboratory personnel, the Technical Supervisors failed to document the evaluation of competency for testing personnel performing Histopathology. Refer to D5209 II.