Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1016329	05/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aw Dermatopathology Service	3715 Prytania St, Suite 306, New Orleans, 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 conducted on May 29, 2018 at AW Dermatopathology Service-CLIA ID # 19D1016329. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard 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 ensure written policies and procedures to address competency for the Clinical Consultant, Technical Supervisor, and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 1 and Personnel 2 serve as the laboratory's Clinical Consultants, Technical Supervisors, and General Supervisors. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Clinical Consultant, Technical Supervisor, and General Supervisor. 3. Review of personnel records for Personnel 2 revealed competency assessments for the duties of Clinical Consultant, Technical Supervisor, and General Supervisor were not performed. 4. In interview on May 29, 2018 at 10:07 am, Personnel 3 stated the laboratory did not perform competency assessments for Personnel 2's duties as Clinical Consultant, Technical Supervisor and General Supervisor.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or

	procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of the performance of molecular testing at least twice annually. Findings: 1. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs molecular testing for T-cell and B-cell rearrangements in skin specimens. 2. In interview on May 29, 2018 at 11:00 am, Personnel 3 stated the laboratory uses College of American Pathologists (CAP) to verify the accuracy of molecular testing twice a year. 3. Review of the laboratory's proficiency testing (PT) records for 2017 revealed the laboratory had enrolled in "Molecular Hematologic Oncology" with the College of American Pathologists (CAP). 4. Further review of the laboratory's 2017 College of American Pathologists (CAP) records revealed the laboratory performed one event for "Molecular Hematologic Oncology." 5. In interview on May 29, 2018 at 11:00 am, Personnel 3 further stated the laboratory performed one CAP survey in 2017. Personnel 3 confirmed the laboratory did not verify the accuracy of molecular testing at least twice annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey date November 22, 2016*** Based on observation, record review and interview with personnel, the laboratory failed to ensure reagents were stored per manufacturer requirements. Findings: 1. Review of the manufacturer's instructions for reagents utilized in molecular testing revealed the following storage requirements: a) Applied Biosystems AmpliTaq Gold DNA Polymerase with Gold Buffer and MgCl2: Store -15 to -25 degrees Celsius b) Invivoscribe IGK Gene Clonality Assay Gel Detection: Store -65 to -85 degrees Celsius c) Invivoscribe TCRB and TCRG T-Cell Clonality Assay Gel Detection: Store -65 to -85 degrees Celsius d) Invivoscribe IGH Gene Clonality Assay Gel Detection: Store -65 to -85 degrees Celsius 2. Review of the "TCRG Gene Clonal Assay" procedure under "Storage Conditions" revealed "PCR master mixes are sensitive to freeze/thaw cycles. Therefore, for any duration other than immediate use, our master mixes and assay kits should be stored at -65 degrees Celsius to -85 degrees Celsius." 3. Review of the laboratory's "DNA and reagent storage conditions" policy revealed the following: a) "If there is a short term malfunction of the freezer identified (the content of the freezer is not melted), the condition of the DNA sample and reagents will be checked and documented. The reagents will be checked to make sure their activity is adequate. Otherwise the content of the freezer will be disposed." b) "The specimens may be transferred to Tulane University for storage if a predicted long term power outage or malfunction of the freezer will occur." 4. Observation during the laboratory tour on May 29, 2018 at 9:19 am revealed the following

	reagents were stored in the So-Low Ultra Low Freezer at -38 degrees Celsius: a) Applied Biosystems AmpliTaq Gold DNA Polymerase with Gold Buffer and MgCl2 b) Invivoscribe IGK Gene Clonality Assay Gel Detection c) Invivoscribe TCRB and TCRG T-Cell Clonality Assay Gel Detection d) Invivoscribe IGH Gene Clonality Assay Gel Detection 5. In interview on May 29, 2018 at 9:28 am, Personnel 3 stated the -80 degrees Celsius freezer has been down for about a month. 6. Further observation during the laboratory tour on May 29, 2018 revealed no reagents were stored in the VIP Plus -80 degrees Celisus freezer. 7. In further interview on May 29, 2018 at 11:50 am, Personnel 3 stated the master mixes and quality controls for molecular testing are stored in the So-Low Ultra Low Freezer since the -80 degrees freezer has been broken. 8. Review of the 2018 temperature log for the VIP Plus -80 degrees Celsuis freezer revealed the laboratory documented the freezer as "at repair shop" as of March 15, 2018 through May 24, 2018. Further review of the temperature log revealed temperatures of -79 degrees Celsius documented as of May 25, 2018. 9. Review of the 2018 temperature log for the So-Low Ultra Low Freezer revealed the freezer had documented temperatures between -37 to -42 degrees Celsius since March 15, 2018.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey date November 22, 2016*** Based on observation and interview with personnel, the laboratory failed to ensure reagents have not exceeded their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on May 29, 2018 revealed the following expired item: Stored in Slo-Low Ultra freezer: a) Invivoscribe IGK Gene Clonality Assay Gel Detection, Lot # G0001134, Expiration Date: 2018-04, Quantity: one (1) box 2. In interview on May 29, 2018 at 9:31 am, Personnel 3 confirmed the identified item was expired. Personnel 3 stated the IGK kit was not used and unaware it was expired.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: ***REPEAT DEFICIENCY from survey date November 22, 2016*** Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of the performance of molecular testing at least twice annually. Refer to D5217. 2. The laboratory failed to ensure reagents were stored per manufacturer requirements. Refer to D5413. 3. The laboratory failed to ensure reagents have not exceeded their expiration dates. Refer to D5417.
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 established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to ensure the procedures to assess personnel competency were complete. Findings: 1. Review of the laboratory CMS-209 (Laboratory Personnel Report) revealed the following testing personnel: Personnel 1 Personnel 2 Personnel 3 Personnel 4 2. Review of the laboratory's personnel records revealed the laboratory utilizes an "Assessment of competency" form to assess competency for molecular diagnostics and gross technique for Histopathology; however, this form did not 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 or 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 May 29, 2018 at 10:00 am, Personnel 3 stated the laboratory utilizes the "Assessment of competency" form. Personnel 3 confirmed the form did not include at a minimum the required six (6) procedures.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the General Supervisors failed to ensure competency assessments for testing personnel were performed annually. Findings: 1. Review of the laboratory CMS-209 (Laboratory Personnel Report) revealed the following testing personnel: Personnel 1 Personnel 2 Personnel 3 Personnel 4 2. Review of the laboratory's personnel records revealed the laboratory did not document competency assessments for 2017 for the following personnel: Personnel 1 Personnel 2 Personnel 3 Personnel 4 3. In interview on May 29, 2018 at 10:00 am , Personnel 3 stated the laboratory did not document competency assessments in 2017.