

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1070827	(X3) Date Survey Completed 01/10/2022
Name of Provider or Supplier Cutaneous Immunopathology Laboratory	Street Address, City, State 6000 Harry Hines, Dallas, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 review of laboratory policy, review of laboratory documents, and confirmed in interview the laboratory failed to follow its own written policy for the semi-annual competency assessments for one of two clinical consultants (CC-2). The findings include: 1. Review of the laboratory policy titled "Employee Competency Evaluation Policy" stated: "Competency assessment of Laboratory Personnel who serve as Clinical Consultants (CC) and/or Technical Consultants (TC) will be performed by the Director twice a year using the following methods: ..." 2. Review of laboratory semi-annual QC reports for 2020 and 2021 had a single checkmark next to the word "personnel". 3. Surveyor queried on 1/10/2022 at 11:30 hours in the laboratory director's (LD) office, for individual competency assessments documentation for 2020 and 2021 for the following personnel listed on the Center for Medicare and Medicaid Services (CMS) form 209: CC-2 No documentation was provided for the semi-annual competency assessments for the clinical consultant as</p>

outlined in the laboratories written policy. 4. In an interview on 1/10/2022 at 11:35 hours in the LD's office, the LD confirmed that there was no individual competency assessments for CC-2 for 2020 and 2021. .

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:

. Based on surveyor observation and confirmed in interview, the laboratory failed to ensure reagents did not exceed their expiration dates for one of four reagents observed. The findings include: 1. During a tour of the laboratory on 1/10/2022 at 09:10 hours, the surveyor observed the following expired reagent on a shelf above the testing persons workbench: Tris-HCL, Molecular Biology Grade - Ref H5121 Lot 000175167 Expiration: 2020-11-29 2. In an interview on 1/10/2022 at 10:40 hours in the laboratory, testing person-3 (TP-3) stated that the reagent was used for the Skin Splitting procedure, and that there was no additional Tris-HCL available for use in the laboratory. 3. In an interview on 1/10/2022 at 12:02 hours in the conference room, TP-3 confirmed that the reagent had exceeded its expiration date and was available for use. .

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

. Based on review of laboratory policy, review of laboratory documents, and confirmed in interview the technical supervisor (TS) failed to document the semi-annual competency assessments for one of three testing personnel, (TP-2). The findings include: 1. Review of the laboratory policy titled "Employee Competency Evaluation Policy" stated: "Competency assessments will be performed by the Director of the Cutaneous Immunopathology Laboratory (who in this instance also serves as the Technical Supervisor [TS] of the laboratory). ... Competency assessment of Laboratory Personnel who perform laboratory testing (i.e., Testing Personnel [TP]) will be performed twice each year by the Director using the following methods and assessments:" 2. Review of laboratory semi-annual QC reports for 2020 and 2021 had a single checkmark next to the word "personnel". 3. Surveyor queried on 1/10/2022 at 11:30 hours in the laboratory director's (LD) office, for individual competency assessments documentation for 2020 and 2021 for the following personnel listed on the Center for Medicare and Medicaid Services (CMS) form 209: TP-2 No documentation was provided for the semi-annual competency assessments for TP-2 as

outlined in the laboratory's written policy. 4. In an interview on 1/10/2022 at 11:35 hours in the LD's office, the LD confirmed that there was no individual competency assessments for TP-2 for 2020 and 2021. .