

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0903471	(X3) Date Survey Completed 09/26/2023
Name of Provider or Supplier Clinical Lab - Cellular Therapy	Street Address, City, State 1100 Walnut Street Mob, Suite 801, Philadelphia, PA	
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
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 the laboratory's competency assessment records and interview with the Technical Supervisor (TS) (CMS 209), the laboratory failed to establish a procedure to assess the competency of 1 of 1 TS, 1 of 1 General Supervisor (GS) and 1 of 4 Testing Personnel (TP) #1 (CMS 209) for their supervisory and testing responsibilities in flow cytometry in 2022 and 2023. Findings include: 1. On the day of survey, 09/26/2023 at 12:58 PM, the laboratory could not provide competency assessment records for the following personnel for their supervisory and testing responsibilities in flow cytometry laboratory 2022 and 2023: - 1 of 1 TS -1 of 1 GS - 1 of 4 TP 2. The TS confirmed the findings above on 09/26/2023 at 14:30 PM.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Proficiency Testing (PT) Performance Evaluation records and interview with Technical Supervisor (TS) (CMS-209) the laboratory failed to document a corrective action taken to evaluate 1 of 1 unacceptable PT results in Flow Cytometry in 2022. Findings include: 1. On the day</p>

of survey 09/26/2023 at 13:01 PM, review of CAP PT performance evaluation records revealed the laboratory obtained Unacceptable score for the FL B event in 2022 for Abs CD19+ B Lymph FL-09. 2. The laboratory failed to document a corrective action taken to evaluate the unacceptable result. 3. Interview with the TS on 09/26/2023 at 14:30 PM confirmed the above findings.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the Laboratory's Proficiency Testing (PT) record review and interview with the Technical Supervisor (TS) (CMS 209), the Laboratory Director (LD) failed to delegate responsibilities to the TS based on their qualifications. Findings Include: 1. The CLIA Laboratory Personnel Report (CMS-209) signed by the Laboratory Director on 09/26/2023, states the LD holds the positions of the director (D) and CC. Personnel #2 holds the positions of TS and GS. 2. On the day of survey, 09/26/2023, a review of the laboratory's Flow Cytometry College of American Pathologist (CAP) PT records and laboratory personnel records revealed, the TS (CMS 209 Personnel #2) performed roles of an LD and signed the PT Attestation statements for 3 of 3 events in 2023. 3. The laboratory was unable to provide evidence of delegation of duties for the TS. 4. The TS confirmed the findings above on 09/26/2023 at 14:30 PM.