

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0903471	(X3) Date Survey Completed 04/10/2019
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing records and interview with the technical supervisor (TS), the laboratory failed to obtain signatures of testing personnel and the laboratory director on the attestation statement forms in 2017. Findings include: 1. On the day of survey, 04/10/2019, review of CAP proficiency testing attestations forms revealed, in 2017, Flow Cytometry events #1,2 and 3 were not signed by the testing personnel performing testing and by the laboratory director. 2. The TS confirmed the finding above on 04/10/2019 around 9:30 am.</p>
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: A. Based on review of Laboratory procedure manuals and interview with the technical supervisor (TS), the laboratory failed to establish a complete procedure on how to assess the competency of 1 of 1 TS and general supervisor (GS) from 2017 to the date</p>

of survey. Findings include: 1. On the day of survey, 04/10/2019, the laboratory failed to provide a complete written policy that reviews how to assess the competency of 1 of 1 personnel (CMS 209 Laboratory Personnel Report, is listed as the TS and GS) from 2017, 2018 and 2019. 2. The TS confirmed the findings above on 04/10/2019 around 09:15 am. B. Based on review of Laboratory procedure manuals, review of testing personnel competency assessment records and interview with the technical supervisor (TS), the laboratory failed to establish a complete procedure on how to assess the competency of testing personnel performing Flow Cytometry testing from 2017 to the date of survey. Findings include: 1. On the day of survey, review of the laboratory's "Staff Education/Training Plan/ Staff Performance and Competence Assessment Plan", revealed the procedure did not include how to assess the 6 points of personnel competency for TP performing Flow Cytometry testing. 2. In 2017, 2 of 5 (TP # 3 and 4) did not perform in the assessment of test performance through blind testing or proficiency testing. 3. In 2018, 1 of 5 (TP # 2) did not perform in the assessment of test performance through blind testing or proficiency testing. 4. The TS confirmed the findings above on 04/10/2019 around 9:30 am.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the procedure manuals and interview with the technical supervisor, the laboratory director failed to ensure a quality assessment (QA) programs were established and maintained from 2017 to the day of survey. Findings Include: 1. On the day of survey, 04/10/2019, the TS could not provide documentation of QA activities performed to assess the laboratory's pre-analytic, analytic and post analytic phases of testing from September of 2017 to March of 2019. 2. The TS mentioned QA activities were performed but could not provide documentation on 04/10/2019 around 10:45