

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2167478	(X3) Date Survey Completed 11/04/2019
Name of Provider or Supplier Gift Of Life Marrow Registry	Street Address, City, State 5901 Broken Sound Parkway Nw Suite 100, Boca Raton, FL	
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	An initial certification survey conducted at Gift of Life Marrow Registry on 11/04 /2019, found the laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review of College American Pathologists (CAP) proficiency testing records and interview with Technical Consultant (TC), the laboratory received an unsatisfactory score for 1 (3rd event of 2019) out of 1 event for Hematology specialty reviewed. Findings include: Review of CAP proficiency records for 2019 3rd event, revealed that the laboratory received a 0 % score for Cell Identification test and 40 % for Hematocrit test resulting in an overall score of 73 % for the Hematology specialty. During an interview on 11/04/2019 at 1:30 PM, the TC confirmed that the laboratory failed the event of reference.</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:</p>

Based on record review and interview with laboratory personnel, the laboratory did not have job descriptions for the Technical Supervisor (TS) and Technical Consultant (TC) positions; in the procedure manual and failed to perform the initial competency assessment for 1 out of 1 TC and 1 (TS B) out of 2 TS (TS A and TS B). Findings include: -Review of procedure manual on 11/1/2019, revealed that there was not job description for TC and TS. - Review of personnel files revealed that, there was no documentation of the initial competency assessment for TC and TS B, who is the same person. During an interview on 11/04/2019 at 12:00 PM, with TC (TS B), she confirmed that there was no job description for TC and TS in the procedure manual and that there was no documentation of her competency assessment listed above for the period of reference.