

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2093036	(X3) Date Survey Completed 06/02/2021
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 7385-L Baltimore Annapolis Blvd, Glen Burnie, MD	
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
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on remote record review, phone interview with the Assistant Manager of Quality (AMQ), and email communication with the AMQ, the technical consultant failed to evaluate and document the performance of all testing personnel (TP) annually. Findings: 1. The laboratory listed 12 TP on the Laboratory Personnel Report, form CMS-209. Training and competency records were reviewed for all 12 TP. 2. During the phone interview on 05/19/2021 at 12:30 PM, the AMQ stated that the laboratory's competency assessments consisted of 2 parts, assessment and observation, and were documented as such in the laboratory's electronic database. 3. Database records showed that TP #4 had an initial assessment and observation on 02/05/2018, a 6-month assessment on 10/17/2018, a 6-month observation on 11/02/2018 and an annual assessment and observation on 06/26/2020. There were no records for an annual assessment or observation for 2019. 4. Database records showed that TP #6 had an initial assessment on 01/06/2018, an initial observation on 02/07/2018, a 6-month assessment on 11/08/2018, a 6-month observation on 11/09/2018, an annual assessment on 07/01/2020, and an annual observation on 07/03/2020. There were no records for an annual assessment or observation for 2019. 5. Database records showed that TP #9 had an initial assessment and observation on 02/07/2018, a 6-month assessment on 10/19/2018, a 6-month observation on 01/28/2019, an annual assessment on 07/01/2020, and an annual observation on 07/08/2020. There were no records for an annual assessment or observation for 2019. 6. In an email received on 06/02/2021 at 2:34 PM, the AMQ confirmed that the 2019 annual evaluations could not be located for TP #4, TP #6 and TP #9.</p>