

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2150723	(X3) Date Survey Completed 10/21/2021
Name of Provider or Supplier Cardiovascular Association, PLLC	Street Address, City, State 18450 Hwy 59 N, Humble, 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
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: An unannounced revisit was performed on 10/21/21. Based on review of the laboratory plans of correction with a completion date of 8/10/21, review of laboratory and patient test records, and confirmed in interview, the laboratory director failed to ensure the laboratory quality assessment programs were established and maintained to assure quality of lab services in hematology. Refer to D5405, D5411</p>