

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2164484	(X3) Date Survey Completed 04/26/2021
Name of Provider or Supplier Circulogene Theranostics, Inc	Street Address, City, State 1555 Palm Beach Lakes Blvd Ste 830, West Palm Beach, 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 unannounced complaint survey #2020003971 was completed on 4/26/21 at Circulogene Theranostics, a Clinical Laboratory in West Palm Beach, Florida. The complaint was completed in conjunction with the initial certification. The complaint allegations were not substantiated.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview with the Laboratory Director, the laboratory failed to verify the accuracy of the result interpretation of Genomic Sequencing and Molecular Pathology PCR at least twice a year since testing began 8/29/19. The findings included: Review of quality assurance documents revealed that there was no twice a year review to verify the accuracy of testing. There was no policy for the twice a year review. Interview on 4/26/21 at 1:00 p.m., the Laboratory Director confirmed that the twice a year verification of accuracy was not performed.</p>