

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0683024	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Concierge Medical Associates Pllc	Street Address, City, State 475 Biltmore Way, Ste 201, Coral Gables, 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	A validation survey conducted on 12/17/2019 found that Coral Gables Cardiology Associates clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on missing records and interview with testing personnel (TP) A, the laboratory failed to maintain the records for the Complete Blood Cell (CBC) analyzer Cell Dyn for 2018. Findings include: Record review revealed the following: -The laboratory used two different CBC analyzers for the years 2018-2019. -In 2018, the laboratory used the Cell Dyn 1800. -In 2019 the laboratory used the Horiba ABX Micro 60 -No records of the quality control, daily maintenance and calibration for the CBC Cell Dyn analyzer for 2018 were available to review. During an interview on 12/17/2019 at 11: 30 am, TP A revealed that after their accreditation survey, the laboratory produced the recods and during this process, they have misplaced the Cell Dyn 1800 binder were all the records of reference were kept.</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>

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the laboratory failed to perform the annual competency assessment for 1 (TP A) out of 4 Testing Personnel (TP A, TP B, TP C and TP D) for 1 out of 2 years reviewed (2018 and 2019) Findings include: - Review of personnel files revealed that there was no documentation of the annual competency assessment for TP A for year 2018. During an interview on 12/17 /2019 at 11:30 AM, with Office Manager, she confirmed that there was no documentation of the competency assessment for the TP A for the period of reference.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on observation, missing documentation and interview with office manager, the laboratory failed to perform annual preventive maintenance to the microscope for 2 out of 2 years reviewed. Findings include: During laboratory tour, it was noted that that the microscope in the laboratory had a service sticker with date 1/2016. The laboratory could not provide documentation of microscope maintenance for the years 2018 and 2019. During an interview on 12/17/2019 at 11:30 AM, with office manager, she confirmed that there were no records of the annual preventive maintenance for the microscope for 2018 and 2019.