

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2112402	<b>(X3) Date Survey Completed</b>  03/10/2020
<b>Name of Provider or Supplier</b>  Sean M Kaufman Md Pa	<b>Street Address, City, State</b>  10625 Sw 68 Ave, Miami, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted on 03/10/2020 found that Sean M Kaufman MD PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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: Based on record review and owner interview, the laboratory failed to have the annual competency assessment for 1 out of 1 Clinical Consultant (CC), 1 Technical Supervisor (TS), 1 General Supervisor (GS), and 1 Testing personnel (TP) signed by the laboratory director for 2 out of 2 years reviewed (2018-2019). Findings include: 1) Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 02/17/2020 revealed that: -The CC, TS, GS and TP was the same person. 2) Record review revealed no annual competencies for the personnel that has the previous listed CLIA positions for the years 2018 and 2019. During an interview on 03/10/202 at 9:00 AM, with owner (also CC, TS, GS and TP), he confirmed that there was not written competencies for the years of reference for the above listed CLIA positions.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:  
Based on record review and interview with owner, the current laboratory director failed to review and sign the procedure manual. Findings include: Review of the laboratory's procedure manual revealed that the new laboratory director who started since 09/2019 failed to sign and date the procedure manual. During an interview on 3/10/20 at 9:15 AM, the owner acknowledged that the procedure manual was not reviewed, signed and dated by the new Laboratory Director.

**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 and interview with owner, the laboratory failed to perform annual preventive maintenance to microscope for 2 out of 2 (2019, 2020) years reviewed. Findings include: Observations taken during the survey on 3/10/2020 at 9:00 AM revealed that for the Microscope Olympus BH2 the last maintenance performed was in february of 2018, no records of annual preventive maintenance for microscope after that one. During an interview on 3/10/2020 at 9:15 AM, with the laboratory owner, he confirmed the laboratory failed to have to do the annual preventive maintenance for microscope for the years of reference.