Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2011382	05/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
David A Colbert Md Pc	119 5th Avenue 4th Fl, New York, NY	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the personnel competency evaluation policy, Standard Operating Procedures (SOPs), lack of training records, as well as interview with the Practice Manager (PM), the laboratory failed to comply with instructions indicated in the current, approved SOP for assessing Testing Personnel (TP) competency. FINDINGS: 1. There was no documentation of TP competency performance for newly hired TP. 2. This is contrary to instructions indicated in the current, approved SOPs. 3. The PM confirmed the findings on May 1, 2025, at approximately 11:30 A.M.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the SOPs as well as interview with the PM, the laboratory failed to document approval and date of approval by the current Laboratory Director (LD) before use. FINDINGS: 1. There was no documentation of LD approval and date of approval for the 2021,2022, 2023, 2024, and 2025 SOPs. 2. The PM confirmed the findings on May 1, 2025, at approximately 11:30 A.M.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 direct observation, review of SOPs, lack of preventative maintenance records, as well as interview with the PM, the laboratory failed to perform and document microscope annual preventative maintenance as per the frequency specified by the manufacturer. FINDINGS: 1. There was no documentation of Leica DM 1000 microscope preventative maintenance performance due in February of 2025. 2. The current, approved SOPs did not include instructions for performing and documenting such activity. 3. The PM confirmed the findings on May 1, 2025, at approximately 11: 30 A.M.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of the personnel competency evaluation policy, SOPs, lack of training records, as well as interview with the Practice Manager (PM), the Laboratory Director (LD) failed to perform and document TP competency and evaluation to ensure that prior to testing patients' specimens, personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. Refer to D5209.