Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2092122	02/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Vanguard Medical Specialists, Llc	9348 Grand Cordera Pkwy, Ste 160, Colorado Springs, CO	

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 laboratory's policies and procedures manual, and an interview with the clinical manager (not included on CMS Form 209), the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency of personnel in the positions of Clinical Consultant (CC), Technical Supervisor (TS), General Supervisor (GS), and testing personnel (TP), since the laboratory's last survey was conducted on 3/26/2021. The laboratory conducts approximately 23,000 histopathology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency for the CC, the TS, the GS, or for TP listed on CMS Form-209 since the last survey was conducted on 3/26/2021. 2. Based on an interview with the clinical manager (not on CMS Form 209) on February 8, 2024, at approximately 10:30 AM, confirmed that the laboratory failed to assess the competency of or establish a written policy or procedure for assessing the competency of personnel in the positions of CC, TS, GS, and TP.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 laboratory's policies and procedures manual, and an interview with the clinical manager (not on CMS Form 209), the laboratory director (LD) failed to ensure that the laboratory's policies and procedures manual for quality assurance, histopathology, and dermatopathology had been approved, signed, and dated by the current LD before use since the laboratory's last survey on 3/26/2021. The laboratory conducts approximately 23,000 histopathology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual for quality assurance, histopathology, and dermatopathology revealed that the current LD had not approved, signed, or dated the laboratory's policies and procedures prior to their use in the laboratory. 2. Based on an interview with the clinical manager (not on CMS Form 209), on February 8, 2024, at approximately 10:00 AM, confirmed that the current LD had not reviewed, signed, and dated the laboratory's policies and procedures manual for quality assurance, histopathology, and dermatopathology prior to their use in the laboratory.