Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2273158	04/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Oncology Consultants	27700 Northwest Freeway, Suite 400, Cypress, TX	

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 announced survey of the laboratory was conducted on 04/11/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
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 laboratory's submitted form CMS 209 (Laboratory Personnel Report), personnel records. policies/procedures and staff interview, the laboratory failed to establish and document competency assessment for one of one clinical consultant employed by the facility. Findings included: 1. Review of laboratory's submitted form CMS 209 revealed the laboratory employed one clinical consultant. 2. Review of laboratory's personnel records revealed the laboratory did not have competency assessment documented for its clinical consultant. 3. Review of laboratory's policies/procedures revealed there were no protocols in place addressing competency assessment for the clinical consultant position. 4. In an interview on 04/11/2024 at 1030 hours in the breakroom, the facility's Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 laboratory's personnel records and staff interview, the laboratory director failed to ensure testing personnel's training was documented for this facility prior to starting patient sample testing for one of three testing personnel employed in 2023 and 2024, Testing Person number 1 (TP1). Findings included: 1. In an interview on 04/11/2024 at 1005 hours during a tour of the laboratory, the facility's Laboratory Director stated that patient testing started at this facility in July of 2023. 2. Review of laboratory's personnel records revealed TP1, had training documented as completed in August of 2021 at a sister facility. There was no documentation of training or evaluation of competency for TP1 at this facility prior to starting patient testing in July 2023. 3. In an interview on 04/11/2024 at 1030 hours in the breakroom, the facility's Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted form CMS 209 (Laboratory Personnel Report), personnel records and staff interview the laboratory director failed to ensure responsibilities and duties were specified in writing for two of five personnel employed by the facility, the Laboratory Director and Clinical Consultant. Findings included: 1. Review of laboratory's submitted form CMS 209 revealed the facility employed a Laboratory Director, who also performed the duties of the laboratory's Technical Consultant, and one Clinical Consultant. 2. Review of laboratory's personnel records revealed the file for the person holding the title of Laboratory Director contained only delineation of responsibilities/duties for a Laboratory Manager /Technical Consultant position. There was no documentation of written specifications for the duties and responsibilities for the role of Laboratory Director. 3. Further review of laboratory's personnel records revealed the file for the person holding the title of Clinical Consultant did not have documentation of written specifications for the duties and responsibilities for that role. 4. In an interview on 04/11/2024 at 1030 hours in the breakroom, the facility's Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.