Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0982056	05/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Oaks Medical Group	557 West 2600 South, Bountiful, UT	

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 record review and interview, the laboratory failed to establish and follow written policies and procedures to assess the competency of its consultant personnel. The laboratory lacked any written policy or procedure requiring a competency assessment for 1 of 1 technical consultant (TC). . The findings include: 1. A review of the laboratory's personnel manual on 05-27-26, revealed that the laboratory failed to establish any written competency assessment policies or procedures for consultant-level personnel. 2. A review of the personnel records on 05-27-206 confirmed that no competency assessment had been performed or documented for the technical consultant since the laboratory began testing. 3. During an interview on 05-27-206, at 4:25 PM, the technical consultant confirmed that the laboratory did not have a written policy requiring a competency assessment for their position, and verified that no evaluation of their regulatory responsibilities had been conducted or documented. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of

	results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on review of the laboratory's written procedure manual and an interview with the technical consultant, the laboratory failed to include reference intervals (normal values) in the written procedure for Complete Blood Count (CBC) testing. . The findings include: 1. Review of the laboratory's written procedure manual on 05/27 /2026 revealed that the procedure for CBC testing lacked the required reference intervals. 2. During an interview on 05/27/2026 at 3:54 PM, the technical consultant confirmed that the laboratory's CBC written test procedure did not contain reference intervals. 3. The laboratory performs 18,000 hematology tests annually.