Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2291614	06/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Unm Comprehensive Cancer Center	1201 Camino De Salud Ne, Albuquerque, NM	

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 onsite intial survey conducted on June 14, 2024, at UNM Comprehensive Cancer Center found the laboratory to be in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with standard deficiencies cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 FNA (fine needle aspirate) H&E (Hematoxylin and Eosin) Stain Quality Control Form, the Non-Gyn Quick Stain Procedure, Non-Gyn Diff-Quick Stain Procedure, and interview with testing personnel 5, the laboratory failed to have a written policy or procedure that lists the criteria required for specimen

	adequacy during slide review for 6 of 6 days from May 2024 through June 2024 Findings included: 1. Review of the FNA H&E Stain Quality Control Form revealed the following dates where FNAs were collected, and quality control slides were documented as either "good or bad". 1. 05/3/2024 = Good 2. 05/10/2024 = Good 3. 05 /24/2024 = Good 4. 05/24/2024 = Good 5. 06/7/2024 = Good 6. 06/14/2024 = Good No criteria listed to indicate what a good or bad slide is. 2. Review of the Non-Gyn Quick Stain Procedure and Non-Gyn Diff-Quick Stain Procedure revealed instructions for making and staining slides but no criteria for how adequacy is assessed for the quality control slides. 3. Laboratory was asked to provide documentation of a policy to assess the adequacy of the quality control slides. None was provided. 4. Interview on 06/14/2024 at 11:50am with testing personnel 5 confirmed the above findings. 5. The laboratory reports performing 300 fine needle aspirates annually
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 Non-Gyn Quick Stain Procedure, Non-Gyn Diff-Quick Stain Procedure and interview with the critical care nurse manager, the laboratory failed to have the laboratory director approve and sign off on 2 of 2 procedures since 2023 through June of 2024 Findings included: 1. Review of the Non-Gyn Quick Stain Procedure and Non-Gyn Diff-Quick Stain Procedure revealed no sign off from the laboratory director. 2. Facility was asked to provide polices signed off by the laboratory director. The laboratory failed to provide polices that were approved by the laboratory director. 3. Interview on 06/14/2024 at 11:00am with the critical care nurse manager confirmed the above findings. 4. The laboratory reports performing 300 fine needle aspirates annually
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 the CMS-209 form, lack of documentation, and interview with the critical care nurse manager, the laboratory director failed to ensure initial training and competencies were performed for 4 of 5 testing personnel (TP) in 2023. Findings included: 1. Review of the CMS -209 laboratory personnel report form revealed 5 testing personnel. 2. Based on lack of documentation the laboratory director failed to ensure initial trainings were completed for the following testing personnel, TP1, TP2, TP3, and TP4 3. Based on lack of documentation the laboratory director failed to

	ensure 6-month competencies were completed for the following testing personnel, TP1, TP2, TP3, and TP4 4. Based on lack of documentation the laboratory director failed to ensure annual competencies were completed for the following testing personnel, TP1, TP2, TP3, and TP4 5. Interview on 06/14/2024 at 11:30am with the critical care nurse manager confirmed the above findings. 6. The laboratory reports performing 300 fine needle aspirates annually