Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0946415	02/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Four Corners Ambulatory Surgery Center, Llc	2300 East 30th Street, Building A, Farmington, 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	The following deficiencies were cited as the result of a recertification survey on 02/10 /2021 for 42 CFR part 493 Laboratory Requirements.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the review of 8 (PT #1 - PT #8) of 8 (PT #1 - PT #8) patient medical records, Cryostat (a machine used to freeze and cut patient samples or biopsies into sections for mounting onto a glass slide) Log, labeling information on patient slides, laboratory policies and interview with the Facility Director, the laboratory failed to use a patient identification system that ensured positive patient identification throughout the collection, processing, and reporting of tests. The laboratory reported performing 30 frozen sections (A frozen section is a laboratory technique used for rapid microscopic analysis usually used with cancer surgery. Rapid diagnosis can guide the surgical team with patient care management during the surgery.) Findings are: A. Review of the final patient reports issued by the surgery center laboratory's affiliated hospital laboratory for 8 (PT #1 - PT #8) of 8 (PT #1 - PT #8) patients revealed no documentation of the laboratory's internal medical record number on the final report for each patient which could be used to confirm the identity of the patient and corresponding sample. B. Review of the Cryostat Log revealed the laboratory had no documentation of the hospital laboratory's accession number. The Cryostat Log used a labeling system that included the patient name, date of birth, date of service (surgery), and internal medical record number to identify the patient undergoing surgery but not the corresponding hospital accession number which could be used to

	confirm the identity of the patient and corresponding sample. C. Review of the laboratory policies (Cryostat Frozen Section Protocol dated 12/17/2014 and Medical Quality Improvement Program dated 09/25/2018) revealed no written policy for patient identification on the Cryostat Log, patient slides, or on the final patient report. D. Review of the slide labeling information for 8 (PT #1 - PT #8) of 8 (PT #1 - PT #8) patients revealed no documentation of the laboratory's internal medical record identification number on the paper label or on the handwritten label underneath. 1. One patient, PT #1, had a different last name on the final report than in the Cryostat Log and the slide label (handwritten and paper). 2. During interview on 02/10/2021 at 2:10 pm, the Facility Director stated that the patient's last name had changed but the laboratory is not able to update the name in the hospital laboratory's electronic record. When asked, the Facility Director stated that the laboratory used the date of service documented in the Cryostat Log to confirm the identity of the patient.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of the Medical Quality Improvement Program Policy, the Pathology Peer Review documents for 2019 and 2020, and the interviews with the Facility Director, the laboratory failed to verify the accuracy of the gross examination and microscopic evaluation of frozen tissue sections twice a year. The laboratory reported performing 30 frozen sections (A frozen section is a laboratory technique used for rapid microscopic analysis usually used with cancer surgery) per year. Findings are: A. The Peer Review Documents from 2019 and 2020 revealed the laboratory failed to perform the twice a year verification of the gross examination (the process by which tissue is measured, dyed, cut, and mounted on glass slides) and microscopic evaluation (used to diagnose or determine the effectiveness of the surgery) of frozen tissue sections. 1. Peer review documents for 2019, for both Pathologist #1 (also the Laboratory Director) and for Pathologist #2, indicated that four different slide samples identified with four different dates of service (DOS) in 2019, were selected for review. The signatures on the form indicated the review form was signed by the Physician Reviewing on 8/24/2020 and 8/25/2020 and by the Medical Director on 8/28/2020. The Peer review form did not have any indication that the peer review occurred in 2019. 2. Peer review documents for 2020, for both Pathologist #1 (also the Laboratory Director) and for Pathologist #2, indicated that four different slide samples, identified with four different dates of service (DOS) in 2020, were selected for review. The signatures on both forms indicated the review forms were signed by the Physician Reviewing on 8/25/2020 and by the Medical Director of 8/28/2020. The Peer Review forms did not have any indication that the peer review occurred twice a year, on different, distinct dates. B. Review of the established Quality Improvement policy, last revision date of 09/25/2018, stated "CLIA Pathologist Peer Review will be conducted every 6 months due to the low volume of cases." and "All peer review will be discussed at MEC (Medical Executive Committee) and Board of Managers Meetings" revealed that the laboratory failed to follow the written policy. C. During interview with the Facility Director on 02/10 /2021 at 11:45 am, when asked if she was performing the twice a year verification of test system/processes, she stated that she was only doing it once a year and was using four sample slides. She also stated that there was not a written policy regarding the

	"twice a year" checks. The Facility Director also stated that she thought it might fall under the facility's "reappointment" policy. D. During interview with the Facility Director, on 02/10/2021 at 2:20 pm, she provided the written Medical Quality Improvement Program Policy which included the twice a year peer review. She stated that they had just not been doing it. When asked about the 2019 peer review signature dates, she stated that the peer review was done 2019 but that the physician did not sign it until 2020.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of 8 (PT #1 - PT #8) of 8 (PT #1 - PT #8) patient medical records, the Cryostat (a machine used to freeze and cut patient samples or biopsies into sections for mounting onto a glass slide) Log, laboratory policies, and interview with the Facility Director, the laboratory failed to perform and document the quality of the Hematoxylin and Eosin stain (one of the principal and widely used tissue stains used in histology that aids in identifying nuclear details in cells) used for staining frozen sections. The laboratory reported performing 30 frozen sections (A frozen section is a laboratory technique used for rapid microscopic analysis usually used with cancer surgery) per year. Findings are: A. Review of the Cryostat Log revealed no documentation of stain quality assessment by the laboratory. B. Review of 8 (PT #1 - PT #8) of 8 (PT #1 - PT #8) patient medical records revealed no documentation of stain quality assessment by the laboratory. C. Review of the laboratory policies (Cryostat Frozen Section Protocol dated 12/17/2014 and Medical Quality Improvement Program dated 09/25/2018) revealed no written policy to document the stain quality each day of use. D. During interview on 02/10/2021 at 3:30 pm, the Facility Director stated the Laboratory Director had told her that he documented the stain quality each day of use at the hospital laboratory and agreed that he should have done that at the surgical center laboratory.