

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2006073	(X3) Date Survey Completed 02/26/2025
Name of Provider or Supplier North Valley Gi Medical Group	Street Address, City, State 870 Shasta St Ste 200, Yuba City, CA	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's specimen labeling discrepancy records, and interview with the laboratory testing person on February 26, 2025, at 12:00 pm, the laboratory failed to label specimen correctly during the collection and subsequent processing. The findings include: 1. The laboratory received GI biopsy specimen from its surgery center next door. In many instances, the laboratory switched the specimen labeling due to possible mislabel during collection. For example, on 11/19/2024, the laboratory switched the labeling bottle 1 to 2; on 11/25/2024, the laboratory switched the labeling bottle 4 to 5; on 11/27/2024, the laboratory switched the labeling bottle 1 to 2. The testing person said that the reason for switching the bottle label was mismatch of writing on the bottle cap and the body, and the switching was done after discussion with the specimen collection staff. Although, sometime mislabeled specimen can be correctly identified by a pathologist at microscopic observation due to the tissue architecture, tissue taken from proximity would be difficult. Therefore, the accuracy of the specimen labeling and patients' test results rendered by the laboratory cannot be assured and may have harmed patient. 2. The laboratory testing person on February 26, 2025, at 12:00 pm, affirmed that the laboratory switched the specimen labeling on many occasions. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/3/2025, stated that the laboratory performed approximately 9,000 tests, annually.</p>

D5393

PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(b)(c)

(b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's quality assessment records, and interview with the laboratory testing person on February 26, 2025, at 12:00 pm, the laboratory failed to review the effectiveness of the corrective action taken to prevent recurrence of the sample labeling problems. The findings include: 1. The laboratory had a mechanism to monitor the ongoing problem in sample labeling and correction of the error. However, it did not have any records documenting the effectiveness of the corrective action taken to resolve the problems, and revision of the policy and procedures. See D5311. 2. The laboratory testing person on February 26, 2025, at 12:00 pm, affirmed that the laboratory did not review and made any revisions of the sample collection and labeling procedures. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/3/2025, stated that the laboratory performed approximately 9,000 tests, annually.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's specimen labeling discrepancy records, and interview with the laboratory testing person on February 26, 2025, at 12:00 pm, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: The laboratory director failed to ensure the maintenance of an acceptable levels of quality laboratory services in the preanalytical system. See D5311.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's quality assessment records, and interview

with the laboratory testing person on February 26, 2025, at 12:00 pm, the laboratory director failed to assure the quality of the laboratory services provided. The findings include: See D5311 and D5393.