Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2169878	05/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
West Texas Digestive Disease Center Pa	5115-80th Street, Lubbock, 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
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for gross analysis of tissue specimens in 2020 . Findings included: 1. Review of laboratory records found no documentation of accuracy assessment of results for gross analysis of tissue specimens available for review for 2020. 2. Review of the policy titled Quality Improvement Review Method Accuracy Verification (implemented February 2, 2020) found on page one under the heading Purpose: "Each technical employee is Histology will be evaluated by the Medical Director to ensure that each employee understands and follows all procedures for grossing and slide preparation. Every biannual the laboratory staff will pick 5 random cases to review all aspects of grossing, processing, staining and microtomy." Method Accuracy Verification_ Biannual assessments were requested but not provided. 3. Interview of the histotechnician conducted on May 10, 2021 at 3:25 PM confirmed there were Method Accuracy Verification_ Biannual assessments available for review.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Review of the laboratory's own Quality Assessment procedure, and interview of facility personnel found that the laboratory failed to follow it's own procedure for identifying, monitoring and correction of problems in analytic systems. The findings included: 1. Review of the policy titled Quality Assurance for Quality Improvement (Implemented February 2, 202) found under the heading Procedure : "1. All procedures in the Histology laboratory will be reviewed at least annually by the laboratory director or his/her designee. If there is a change in directorship, the new director will promptly review and approve all procedures and policies." 2. Interview of the Histotechnician conducted on May 10, 2021 at 3:25 PM confirmed that the laboratory did not have a quality assurance manual and did not have documentation of annual review of policies and procedures. In addition he confirmed that the new laboratory director (effective 05/01/2021) had not yet approved the policies and procedures since the change in directorship.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Review of pathology reports and interview of facility personnel found that the laboratory failed to ensure the name and address of the laboratory performing the gross analysis of tissue specimens appeared on eight of ten reports reviewed. The findings included: 1. Review of 10 pathology reports found no documentation of the name and address of the laboratory performing gross analysis (performed by this laboratory) for eight of 10 reports: a. Accession DP20-164732 reported 14 SEP 2020 b. Accession DP20-161013 reported 22 JUL 2020 c. Accession DP21-121153 reported 20 JAN 2021 d. Accession DP20-158756 reported 25 JUN 2020 e. Accession DP20-156876 reported 29 MAY 2020 f. Accession DP20-159465 reported 02 JUL 2020 g. Accession DP21-120712 reported 13 JAN 2021 h. Accession DP21-122137 reported 03 FEB 2021 2. Interview of the testing personnel conducted on May 10, 2021 at 1:25 PM confirmed that the name and address of the laboratory performing the microscopic tissue examination did not appear on the final report. He stated he was performing gross analysis of tissue specimens at this address as well as the technical component (slide preparation and staining).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least semiannually during the first year the individual tests patient specimens for one testing person performing gross analysis of tissue specimens. The findings included: 1. Review of personnel files found one competency assessment dated 01/10/2021. no other documentation of competency assessment was available for review. Competency assessments performed in 2020 were requested but not provided. 2. Review of the procedure titled Competency Assessment for Non-Technical Personnel (implemented January 28, 2020) found on page 1 under the heading Procedure: "1. After an employee has been with the laboratory for 6 months, they will be observed by the laboratory supervisor to determine their competency level. 2. After the employee's 6 month evaluation, they will have an annual competency evaluation on or about the anniversary date of their hire date." 3. Interview of the histotechnician conducted on May 10, 2021 at 3:05 PM confirmed that competency assessments had not been performed and documented at the frequency defined in their own procedure for testing person one.