Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0975745	05/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Utah Digestive Health Institute	6028 Ridgeline Dr Ste 201, Ogden, 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
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on patient test reports review, lack of documentation, and interview with staff, the laboratory failed to retain 2 of 3 immunohistochemical (IHC) special stain slides referenced in the laboratory report for 3 of 5 special stain histopathology cases reviewed. Findings include: 1. Patient test reports reviewed for patient case number EA9818688 collected on 02/18/2019, stated, "There is no intraepithelial lymphocytosis as confirmed by CD3 immunohistochemical staining." Test report for patient number EA9828723 collected on 03/15/2019 stated, " H. pylori micro organisms were not identified as confirmed by IHC stain." Test report reviewed for case number EA9837877 collected on 04/08/2019 stated, "No intraepithelial lymphocytosis as confirmed by IHC stain of CD3" 2. The laboratory lacked CD3 stained slides for cases EA9818688, EA9828723 and EA9837877. 3. In an interview conducted with staff on 05/17/2019 at approximately 4:00 P.M. staff stated CD3 stained slides could not be located for the requested case slides. Staff was asked to look for the CD3 stained slides in the next batch of slides received and was not able to locate the slides in the subsequent slide batch.
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 lack of documentation and confirmation by staff, the laboratory failed to document twice annual accuracy verification of histopathology in 2017 and 2018. Findings include: 1. The laboratory failed to document twice annual histopathology verification of histopathology diagnoses for colonoscopy and upper gastrointestinal specimens in 2017. 2. The laboratory failed to document twice annual histopathology verification of histopathology diagnoses for colonoscopy and upper gastrointestinal specimens for 1 of 2 events in 2018. 3. In an interview conducted on 05/17/2019 at approximately 4 :00 P.M. staff confirmed they lacked documentation of twice annual verification of histopathology diagnoses in 2017 and 2018.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on patient test reports review, lack of documentation, and interview with staff, the laboratory failed to ensure they received quality control (QC) slides that were stained with each patient slide or group of patient slides for 2 of 9 special stain cases reviewed, (H. pylori QC for case EA866639 collected on 07/02/2018 and HAV and CD3 QC slides for Case EA9818688 collected on 02/18/2019.) Findings include: 1. Patient test reports reviewed for case number EA866639 stated there were no H. pylori present. Patient H. pylori slides were present but staff were unable to locate H. Pylori QC slides for comparison. Patient test reports reviewed for case number EA9828723 stated No H. Pylori present. Patient H. pylori slides were present but staff were unable to locate H. pylori QC slides for the batch sent with the patient's case. 2. In an interview conducted on 05/17/2019 at approximately 4:00 P.M. staff stated control slides were filed for each day of slides received and that QC slides for the days selected could not be located.
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: Based on patient test records review and interview with staff, the laboratory pathology test reports failed to include the laboratory location where tests were performed for 3 of 14 reports reviewed. Findings include: 1. Patient test reports review included the location testing was reported included Valley Dermatology, West Jordan, UT. for Case number EA7853704 collected on 05/22/2017 and for case number EA7894267 collected on 09/06/2017. Patient test reports review included the location testing was reported was Summit Urology Group for case number EA9837877 collected on 04/06 /2019. 2. In an interview with staff on 05/17/2019 at approximately 1:30 P.M., staff stated slides were shipped to the pathologist for reading. He brings the slides to the laboratory location in Ogden for reading and reporting at least once per week. Staff stated slides are read and reported at the Ogden location. THIS IS A REPEAT DEFICIENCY.