Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2020808	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Digestive Disease Specialists	3366 Nw Expressway, Bldg D, Suite 350, Oklahoma City, OK	

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 recertification survey was performed 03/12/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the quality improvement/infection control coordinator, interim pathology manager, laboratory manager, and the quality liaison, at the conclusion of the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the quality improvement /infection control coordinator, interim pathology manager, laboratory manager, and quality improvement liaison, the laboratory failed to retain documentation of analytic systems as required, for at least 2 years. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor, the laboratory obtained gastric tissues from biopsies. The tissues were processed, cut, mounted on slides, stained, coverslipped, and then examined microscopically by the pathologist for diagnosis; (2) The surveyor asked the quality improvement/infection control coordinator and laboratory manager where the stains, reagents, and solutions used for the testing were stored. The quality improvement/infection control coordinator and the laboratory manager accompanied the surveyor to the cabinet where the testing materials were stored. The surveror observed the contents of the cabinet and identified the stains, reagents, and solutions that were in use at the time of the survey. Examples included the following: (a) Mayers Modified Hematoxylin stain: Lot #080863, Expiration date 06/01/20 (b) HemaDiff 2 (Xanthene), Lot #089331, Expiration date 04/30/21 (c) HemaDiff 3 (Thiazide), Lot #0745465, Expiration date 07/01/20 (d) Alcian Blue stain,

	pH 2.5, Lot #088899, Expiration date 04/30/21 (e) Periodic Acid stock reagent, Lot #1514115, No Expiration date (f) 0.5% Periodic Acid solution, Prepared date 12/12 /19, Expiration date 03/12/20 (3) The surveyor reviewed testing and QC (Quality Control) records from 03/01/18 through 02/29/20. There was no documentation in the records of the lot numbers, expiration dates, put into use dates, and preparation dates for the stains, reagents, and solutions used to stain the patient tissue slides and QC slides; (4) The surveyor asked the quality improvement/infection control coordinator, laboratory manager, interim pathology manager, and the quality improvement liaison, for the documentation of the lot numbers, expiration dates, put into use dates, and preparation dates for the stains, reagents, and solutions from 03/01/18 through 02/29 /20. The quality improvement/infection control coordinator and interim pathology manager stated to the surveyor, the documentation could not be located; (5) The surveyor explained to the quality improvement/infection control coordinator, interim pathology manager, laboratory manager, and quality liaison that all analytic records of the testing performed in the laboratory, including lot numbers, expiration dates, put into use dates, and preparation dates of stains, reagents, and solutions used for patient testing must be documented and retained for at least 2 years.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure, and interview with the quality improvement/infection control coordinator, interim pathology manager, laboratory manager, and the quality liaison, the laboratory failed to follow its weekly special stain maintenance procedure during 4 of the 24 months reviewed. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor, the laboratory obtained gastric tissues from biopsies. The tissues were processed, cut, mounted on slides, stained, coverslipped, and then examined microscopically by the pathologist for diagnosis; (2) The surveyor reviewed the laboratory's procedure for the AB/PAS (Alcian Blue/Periodic Acid Schiff) special stain which was used on the gastric tissues. The procedure included a protocol to maintain the integrity of the special stain constituents (Alcian Blue stain, 0.5% Periodic Acid, Schiff's Solution, and Mayer's Hematoxylin stain). The procedure did not include the frequency at which the stains and reagents were to be changed or filtered; (3) The interim pathology manager stated to the surveyor the laboratory required weekly special stain maintenace which was documented, along with the date and the procedure performed (i.e. changed or filtered), on the laboratory's "Weekly Special Stain Maintenance" log; (4) The surveyor then reviewed the logs for stain maintenance performed from 03/01 /18 through 02/29/20. The surveyor identified instances during 4 of the 24 months reviewed and patient testing had been performed, when there was no documentation the AB/PAS stain and/or reagents had been changed or filtered, as required on the weekly stain maintenance log. Examples included the following: (a) Between 02/01 /19 and 02/15/19: 0.5% Periodic Acid (i) Patient #1: Testing performed on 02/01/19 (b) Between 02/15/19 and 03/01/19: 0.5% Periodic Acid (i) Patient #2: Testing performed on 02/22/19 (c) Between 02/15/19 and 03/01/19: Schiff's Solution and Mayer's Hematoxylin (i) Patient #3: Testing performed on 03/01/19 (d) Between 03/01

	/19 and 03/29/19: Alcian Blue, 0.5% Periodic Acid, Schiff's Solution and Mayer's Hematoxylin (i) Patient #4: Testing performed on 03/15/19 (ii) Patient #5: Testing performed on 03/28/19 (5) The surveyor reviewed the findings with the quality improvement/infection control coordinator, interim pathology manager, laboratory manager, and the quality liaison. The quality improvement/infection control coordinator stated to the surveyor the laboratory had not followed its written procedure as included on the weekly maintenance log for the AB/PAS special stain.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturers' instructions, and interview with the quality improvement/infection control coordinator, interim pathology manager, laboratory manager, and the quality liaison, the laboratory failed to ensure the manufacturers' environmental specifications had been met for the instruments used to perform patient testing during 24 of the 24 months reviewed. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor, the laboratory obtained gastric tissues from biopsies. The tissues were processed, cut, mounted on slides, stained, coverslipped, and then examined microscopically by the pathologist for diagnosis. The following instruments were used to prepare the samples for the testing: (a) Two ThermoScientific Microm HM 340E Microtomes: Used to cut the paraffin sections; (b) Tissue Tek SCA Automated Coverslipper: Used to coverslip the stained slides. (2) The surveyor reviewed the manufacturers' instructions (operator's manual) and identified the manufacturers' humidity requirements for the instruments: (a) ThermoScientific Microm HM 340E microtomes: Less than/or equal to 60% (b) Tissue Tek SCA Automated Coverslipper: Between 30-70%; (3) The surveyor then reviewed records of 24 months (from 03/01/18 through 02/29/20) and identified during 24 of the 24 months reviewed, the laboratory's acceptable humidity range was 20-80%, which allowed a humidity lower than the 30% required by the manufacturer for the Tissue Tek SCA Automated Coverslipper, and higher than the 60% required by the manufacturer for the ThermoScientific Microm HM 340E microtomes; (4) The surveyor reviewed the findings with the quality improvement /infection control coordinator, interim pathology manager, laboratory manager, and the quality liaison. The quality improvement/infection control coordinator stated to the surveyor, the laboratory failed to ensure the manufacturers' humidity specifications were met for the instruments used to process patient samples for the testing performed.