Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2054255	02/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Digestive Health Associates Pa	7558 Sw 61st Ave, Ocala, FL	

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	At the time of the announced, onsite recertification survey, Digestive Health Associates was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
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 record review and interview, the laboratory failed to retain histopathology specimen blocks for at least 2 years for 5 months reviewed in 2022. Findings include: Review of specimen logs showed patient testing was performed between 8/16/22 and 12/23/22. The laboratory was unable to locate the pathology specimen blocks for case numbers DH22-262 through DH22-392. The interview with the Quality Coordinator on 2/27/23 at 11:45am confirmed the blocks were unable to be located.
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 record review and staff interview, the laboratory failed to document laboratory humidity for two months in 2023. Findings include: The laboratory was unable to provide documentation indicating the laboratory room temperature and humidity was being monitored in 2023. During an interview on 2/27/23 at 11:45 AM the Quality Coordinator confirmed the documentation could not be located.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview, the laboratory had expired staining reagents stored in the flammable cabinet, under the sink in the laboratory, and in a laboratory overhead cabinet. Findings include: 1. During the laboratory walk thru, the following stains and solutions were found stored in the flammable cabinet. - (1 gallon) Mercedes Scientific Eosin Y Stain Solution, 1% w/v in Alcohol lot#1924210 expiration date 9/21 - (1 gallon) Mercedes Scientific Eosin Y Stain Solution, 1% w/v in Alcohol lot#2021707 expiration date 8/22 - (1 gallon) Fisherfinest Clarifier 2 lot#500789 expiration date 7/21 - (3 gallons) Mercedes Scientific Xylenes lot#2021101 expiration date 2/1/23 - (1 gallon) Eki Acetic Acid Solution, 3% v,v lot#1932510 expiration date 11/21 2. The following expired stains and solutions were found under the laboratory sink: - (1 gallon) Fisherfinest Clarifier 2 lot#500780 expiration date 7/21 - (1 gallon) Mercedes Scientific Eosin Y Stain Solution, 1% w/v in Alcohol lot#2021707 expiration date 8/22 - (1 gallon) Mercedes Scientific Quik-Dip Stain 3 lot#1924209 expiration date 9/21 - (2 gallons) Eki Acetic Acid Solution, 3% v,v lot#1932510 expiration date 11/21 - (2 gallons) Mercedes Scientific Scott's Tap Water Substitute lot#2003108 expiration date 2/21 3. The following expired stains were found in a laboratory overhead cabinet: -(2 500ml) Mercedes Scientific Alcian Blue, pH 2.5 lot#86842 expiration date 8/20 4. The record review of the laboratory form titled "Alcian Blue/Pas Modified Giemsa (Diff Quick Stain) QC Sheet" dated September 2021, April 2022, May 2022, June 2022, and July 2022 showed the "Diff Quick #3" lot #1924209 expiration 9/22 used for 25 testing days. Based on photographic evidence obtained during survey, the container of Quik-Dip Stain 3 lot #1924209 had an expiration of 9/21. 5. The record review of the laboratory forms titled "Alcian Blue/Pas Modified Giemsa (Diff Quick Stain) QC Sheet" dated October 2021, November 2021, December 2021, January 2022, February 2022, and March 2022 showed the "Diff Quick #3" lot #1924209 expiration 9/23 used for 45 testing days. Based on photographic evidence obtained during survey, the container of Quik-Dip Stain 3 lot #1924209 had an expiration of 9/21. 6. The record review of the laboratory form titled "Alcian Blue/Pas Modified Giemsa (Diff Quick Stain) QC Sheet" dated August 2022, September 2022, October 2022, November 2022, and December 2022 showed Alcian Blue lot #86842 expired 8/23. Based on photographic

	evidence obtained during survey, the Alcian Blue with lot #86842 expired 8/20. The interview with the Quality Coordinator on 2/27/23 at 11:45am confirmed the stains were expired and the documentation was incorrect.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain complete Histopathology quality control documentation for 2 of 2 months reviewed in 2023. Findings include: The laboratory was unable to provide quality control documentation of what stains were used on patient histopathology slides during processing in 2023. There was no documentation that showed a quality control slide was made at the time of staining. The interview with the Quality Coordinator on 2/27/23 at 11:45 AM confirmed no documentation could be located.