

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2180140	(X3) Date Survey Completed 07/07/2021
Name of Provider or Supplier Digestive Care Specialists, Llc	Street Address, City, State 19851 Observation Drive #245, Germantown, MD	
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
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview with the assistant from the laboratory that provides the stained slides and the laboratory director (LD), the laboratory performing the interpretation failed to maintain quality control (QC) slides from each day that slides were received for interpretation. Findings: 1. The "Digestive Care Specialists Quality Control Histology" worksheets from 10/22/2020 and 10/27/2020 were reviewed. The worksheets documented the acceptability of the five different types of stains received by the laboratory. The worksheets listed the abbreviation of the five different types of stain QC slides provided by the staining laboratory. 2. A patient slide and the QC slides were pulled from each worksheet for review. The assistant from the staining laboratory stated that the QC slides from 10/22/2020 were missing. The assistant from the staining laboratory explained that the LD reads slides at two different CLIA laboratory locations. When the QC slides are prepared for both locations the staining lab only prepares one set of QC slides for both labs. 3. The QC slides for 10/22/2020 were being stored at another laboratory. The worksheet indicated that the QC slides were reviewed and found acceptable at the laboratory being surveyed along with the patient slides. 4. During the survey on 07/07/21 at 10:30 AM, the assistant from the laboratory that provides the stained slides and the LD confirmed that the QC slides from 10/20/2020 were not being reviewed and stored along with the patients slides at the laboratory being surveyed.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of the quality control (QC) slides, interview with the assistant from the laboratory that provides the stained slides and the laboratory director (LD), the laboratory receiving the stained patient and QC slides failed to ensure that the QC slides received from the staining laboratory included the date of preparation. Findings: 1. The staining laboratory provided the laboratory with the stained patient slides and the QC slides in protective cardboard slide folders. 2. On the day of the survey all of the slides that were in the cardboard slide folders included the date of staining except the QC slides. The QC slides were only labeled with name of the staining laboratory, "CONTROL", and the abbreviation of the type of stain QC provided, e.g. PAS for Periodic Acid-Schiff stain. There was no way to verify if the QC slides had actually been prepared on the same date along with the patient slides. 3. During the survey on 07/07/2021 at 10:30 AM, the assistant from the laboratory that provides the stained slides and LD confirmed that the QC slides provided failed to include the date of preparation to ensure that the patient slides being interpreted were stained in the same batch as the QC slides.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on record review and interview with the assistant from the laboratory that provides the stained slides, the laboratory failed to ensure that the slides, are part of the laboratory records, included the dates of all specimen testing. Findings: 1. The laboratory records showed that a stained slide was received on 05/20/2021 and reviewed. A special stain was requested on 05/23/2021. The slide that was received with the special stain was dated 05/20/2021. 2. During the survey on 07/07/2021 at 10:30 AM, the assistant from the laboratory that provides the stained slides confirmed that slide with the special stain did not include the date that the slide was prepared.

D5819

TEST REPORT
CFR(s): 493.1291(j)

All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

This STANDARD is not met as evidenced by:

Based on record review, interview with the assistant from the laboratory that provides the stained slides and the laboratory director (LD), the laboratory failed to ensure that records with the patients information were maintained in the appropriate laboratory. Findings: 1. During the survey a folder with a second opinion consultation form for a patient was reviewed. The first two identifiers on the patient specimen listed on the worksheet began with the letters "MD." The assistant from the laboratory that provides the stained slides stated the the first two identifiers of the patients at the laboratory being surveyed should begin with the letters "CH". 2. After review of the documentation it was determined that the second opinion consultation form belonged to another laboratory and should not be maintained in this office. During the discussion the LD stated that a second opinion consultation form for one of his patient was being stored at the LD's home and not at the office where the testing was being performed. 3. During the survey on 07/07/2021 at 10:30 AM, the assistant from the laboratory that provides the stained slides and the LD, confirmed that the second opinion consultation forms were not being maintained at the appropriate location and in a manner that permits timely retrieval and accessibility.

D6090

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the proficiency testing (PT)/split samples worksheets, interview with the assistant from the laboratory that provides the stained slides and the laboratory director (LD), the LD failed to ensure that the PT worksheets included the correct date of review. Findings: 1. The PT/split sample worksheets for 2020 and 2021 were reviewed. The worksheets consisted of two pages. The first two thirds of page one listed the identity of the slides sent for review in 2020 and the bottom third of page listed the slides sent in 2021 for review. The identity of the slides listed on page two were sent in 2021. 2. The bottom of each page required a review signature and date. Page one did not have a signature and date. Page two was signed and dated in June of 2021. 3. The assistant from the laboratory that provides the stained slides stated that the split sample slides were sent out in 2020 and 2021 but the worksheet did not identify the two different events. 4. During the survey on 07/07/2021 at 10:30 AM, the assistant from the laboratory that provides the stained slides and LD confirmed that the PT/split sample worksheets failed to identify when each set of slides were sent for comparison to show that the PT/split samples were performed during each annual timeframe as required.