

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2022272	(X3) Date Survey Completed 06/04/2021
Name of Provider or Supplier Digestive Disease Consultants	Street Address, City, State 4381 East Lohman Ave Ste B, Las Cruces, NM	
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 following deficiencies were cited as the result of a recertification survey on June 4, 2021 for 42 CFR part 493 Laboratory Requirements.
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 the review of temperature log, Storage Policy for the paraffin (soft colorless, solid wax in which human tissue is embedded) blocks, observation, and interview with the laboratory staff, the laboratory failed to document and define the room temperature range to ensure preservation of the paraffin blocks for 5 of 5 months in 2021(January through May). Findings are; A. Review of the temperature log "Humidity Chart 2021 (Storage)" revealed the laboratory did not define a temperature range to ensure proper preservation of the paraffin blocks (January through May 2021). The temperature log included the following, " Temperature range --10% - 90% ". The log included documentation of a single numerical entry daily. The laboratory had not defined a temperature gradient (Celsius or Fahrenheit) for monitoring and documenting the paraffin block storage room. A1. During an interview on 06/04/2021 at 11:10 am, testing person (TP#1) confirmed that the single numerical entry was a record of the daily humidity being monitored and documented on the log. She stated that she was not told to monitor and/or record the room temperature. B. Review of the Storage Policy states the following; "All paraffin blocks which have generated a report will be filed and stored for a minimum of 10 years. Block will be stored in a cool and dry area to prevent melting. Blocks are filed numerically with numbers on the outside of each filing drawer listing the number or the first block and the last block in the file cabinet drawer located in the storage room with a temperature range of 10% - 90%. Note: All specimen blocks are stored in cool,</p>

dry storage room and protected against damage." The laboratory had not included a defined temperature gradient (Celsius or Fahrenheit) in their written policy for monitoring and documenting storage of paraffin blocks. B1. Review of the Storage Policy did not identify "10% to 90%" as humidity but as temperature. The policy did not include defined ranges for both humidity (%) and temperature (Celsius or Fahrenheit) to ensure preservation of paraffin blocks. C. Observation of the Storage room on 06/04/21 at 11:10 am, revealed that the laboratory failed to define, monitor and document the daily temperature of the storage room to ensure long-term preservation of the blocks.

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 the review of 1 of 1 temperature log (June 2021), observation, and interview with laboratory staff, the laboratory failed to define and document temperature range /criteria for the room in which reagents/stains were stored, according to the manufacturer's storage requirements. Findings are; A. Review of the temperature log "Tissue Processor Temperature and Maintenance" for June 2021, revealed that the laboratory failed to define the room temperature, consistent with the manufacturer's instruction, for all reagents onboard the Leica ASP300S tissue processor and onboard the DRS-601 Sakura Diversified Stainer. A1. The temperature log for June 2021 revealed the word "Ambient" (the laboratory had not defined "ambient") instead of a defined numerical temperature range (Celsius or Fahrenheit), consistent with the required temperature for all reagents utilized in the laboratory. B. Observation on 06 /04/2021 at 9:15 am, revealed a cabinet, storing the following reagents/stains: Formalin (used for the Leica ASP300S tissue processor), Buffer, Define, Eosin, Hematoxylin, and Xylene (used for the DRS-601Stainer). The above reagents/stains included manufacturer's storage requirement of "15C-30C". C. Interview on 06/04 /2021 at 8:59 am, testing person (TP#1) stated that she was told to only focus on taking the humidity in the laboratory and not the room temperature. She stated that by placing an "A" (Ambient) on the temperature log was sufficient to notate that the reagents were being kept at room temperature.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on the review of the maintenance records, the maintenance policy, and an interview with testing person (TP#1), the laboratory failed to ensure preventative maintenance was performed on the Leica ASP300S tissue processor and on the DRS-601 Sakura Diversified Stainer for 2018. Findings are; A. Review of the periodic maintenance records for 2018, revealed that the tissue processor and slide stainer were last serviced on 11/07/2018. B. Review of the maintenance policy titled "Quality Control-Equipment", reference #3024, under the slide stainer section states: "Preventative maintenance [PM] is done by Bio-medical Specialists. Record in maintenance log." Preventative maintenance on the slide stainer is done by Clinical Equipment Services LLC (CES), as per service inspection records, not by Biomedical Specialists as stated in the policy reference #3024. B1. Review of Service Inspection invoice/record dated 11/07/2018 states; "Notes: CES (Clinical Equipment Services LLC) will only perform a basic operational check and an electrical safety inspection. Actual PM will have to be done by OEM." Invoice of inspection states that PM was not performed by CES and "will have to be done by OEM", indicating that preventative maintenance will need to be scheduled with OEM. C. During an interview on 06/04/21 at 9:20 am, TP#1 stated she was not aware of what "OEM" stood for and did not know that the service report stated that the preventative maintenance will need to be scheduled separately from the operational check and the electrical safety inspection.