

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2020808	(X3) Date Survey Completed 02/05/2026
Name of Provider or Supplier Digestive Disease Specialists	Street Address, City, State 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 on 02/05/2026. Standard-level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with testing person #1 and the laboratory director, the laboratory failed to ensure the laboratory temperature was maintained as required by the manufacturer for the Boekel Scientific illuminated tissue floatation bath for 21 of 40 days of patient testing from December 1, 2025 to the January 31, 2026. Findings include: (1) On 02/05/2026 at 2: 00 pm, testing person #1 stated that the laboratory used a Boekel Scientific Illuminated tissue floatation bath for processing patient specimens; (2) A review of the operating instructions for the Boekel Scientific Illuminated tissue floatation bath stated, "This equipment is intended for indoor use and will meet it's performance figures within the ambient temperature range of 20 degrees Celsius to 30 degrees Celsius"; (3) A review of temperature records identified the temperature readings were less than 20 degrees Celsius for 21 of 40 days of patient testing from December 1, 2025 to January 31, 2026; (4) The records were reviewed with the laboratory</p>

director who stated on 02/05/2026 at 2:00 pm, the laboratory temperature had not been maintained as required by the manufacturer.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(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 a review of records and interview with the laboratory director and testing person #1, the laboratory failed to ensure test reports reflected accurate laboratory information where the testing was performed for two of two reports reviewed.

Findings include: (1) On 02/05/2026 at 02:15 pm, the laboratory director and testing person #1 stated the laboratory performed grossing of digestive tissues; (2) A review of patient reports identified the address of the laboratory on the reports (3366 NW Expressway, Building D, Suite 350) did not match the address on the CLIA certificate (10029 N Oklahoma Ave, STE 200, Oklahoma City, OK 73114) for the following: (a) Patient sample # OKC25-12169 testing performed on 01/06/2026 (b) Patient sample # OKC25-00400 testing performed on 01/23/2025 (3) The findings were reviewed with the laboratory director and testing person #1 who stated on 02/05/2026 at 02:15 pm, the correct laboratory address had not been included in the patient test reports.