

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2128320	(X3) Date Survey Completed 09/04/2026
Name of Provider or Supplier Akro Gastro, Llc	Street Address, City, State 201 Sw 16th St, Okeechobee, 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	An announced CLIA recertification survey was conducted at Akro Gastro Llc from September 1, 2026, to September 4, 2026. The laboratory was surveyed under 42 CFR, Part 493, CLIA requirements. Standard deficiencies cited are as follows:
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on interview, and record review, the laboratory failed to follow policy and perform annual competency assessments for two (B and C) out of three testing personnel in 2025. Findings Included: 1. Review of Pathologist Competency Assessment showed the following: A. Testing personnel B had an initial competency assessment done on 4/23/24 and six month competency done on 10/28/25. There was no annual competency assessment performed in 2025. B. Testing personnel C had an initial competency assessment done on 4/23/24 and six month competency done on 10/28/25. There was no annual competency assessment performed in 2025. 2. Review of Pathologist Professional Competency signed by the Laboratory Director on 8/04/26 read, "Initial Training: must be completed and competency verified before testing personnel report patient results. First year (New Hires): Assessments are required at 6 months and 12 months after starting. Competency evaluation is performed by the Laboratory Director of the CLIA location." {copied as written} 3. On 9/01/26 at 1:58 PM, the Laboratory Compliance Officer confirmed the annual competency was not done for testing personnel B and C in 2025.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on interview, and record review, the Technical Supervisor failed to perform annual competency assessments for two (B and C) out of three testing personnel in 2025. Findings Included: 1. Review of Pathologist Competency Assessment showed the following: A. Testing personnel B had an initial competency assessment done on 4/23/24 and six month competency done on 10/28/25. There was no annual competency assessment performed in 2025. B. Testing personnel C had an initial competency assessment done on 4/23/24 and six month competency done on 10/28/25. There was no annual competency assessment performed in 2025. 2. Review of the Pathologist Professional Competency signed by the Laboratory Director on 8/04/26 read, "Initial Training: must be completed and competency verified before testing personnel report patient results. First year (New Hires): Assessments are required at 6 months and 12 months after starting. Competency evaluation is performed by the laboratory director of the CLIA location." {copied as written} 3. On 9/01/26 at 1:58 PM, the Laboratory Compliance Officer confirmed the annual competency was not done for testing personnel B and C in 2025.