

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2128320	<b>(X3) Date Survey Completed</b>  10/15/2024
<b>Name of Provider or Supplier</b>  Akro Gastro, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An initial certification survey was conducted on October 3, 2024 to October 15, 2024. Akro Gastro Llc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to have positive reactivity control slides for fungus Giemsa stain, periodic-acid Schiff and Alcian Blue stain for 1 out 1 patient reviewed. Findings Included: Review of patient records revealed patient 1 was reported for fungus Giemsa stain, periodic-acid Schiff and Alcian Blue stain on 1/22/2024. Review of controls slides revealed no labeled control slides for 1 /22/2024. Review of Quality Control Staining signed by the Laboratory Director on 4 /14/2023 read, "For all other deferral stain or special stains, a control slide of known reactivity is stained with each patient or group of patient slides." The policy did not include labeling of dates for when controls were done. On 10/3/2024 at 3:10 PM, the Laboratory Coordinator confirmed no labeled control slides for Giemsa stain, periodic-acid Schiff and Alcian Blue on 1/22/2024.</p>
<b>D5787</b>	<p><b>TEST RECORDS</b> CFR(s): 493.1283(a)</p>

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, the laboratory failed to record professional component specimens received date and time instead of technical components specimen received date and time on final reports for 3 out of 3 patients reviewed. Findings included: Review of professional component patient reports revealed the following : A. Patient 1's specimen was collected on 1/17/2024 and received on 1/18/2024 at 1:51 AM for Haematoxylin & Eosin(H&E) , periodic acid-Schiff (PAS) , Alcain Blue (AB) ,and Giemsa stain. B. Patient 2's specimen was collected on 1/10/2024 and received on 1/11/2024 at 12:08 AM for H&E stain. C. Patient 3's specimen was collected on 2/14/2024 and received on 2/15/2024 at 1:51 AM for H&E ,PAS AB and Giemsa stain. Review of Quality control slides revealed: a. Patient 1 had no control slides b. Patient 2's H&E control slides were labeled for 1/12/2024. c. Patient 3's H&E, PAS AB and Giemsa stain control slides were labeled for 2/16/2024. Review of Transportation of Slides, Specimens and Other Materials signed by the Laboratory Director on 4/14/2023 revealed no policy for professional component (lab performing the slide reading) on receiving specimens slides or blocks with date and time from technical component(lab performing the grossing). On 10/3/2024 at 2:55 PM, the Laboratory Manager and owner stated they were recording the received dates and times on the final report for the technical component instead of the professional component.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

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

(7) The technical supervisor is responsible for 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; (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 record review, and interview, the Technical Supervisor failed to evaluate initial and 6 month competency assessments for 1 out 1 Testing Personnel, (A). Finding included: A review of Competency Assessments revealed Testing Personnel A had an initial competency performed on 10/20/2023 and 6 month competency performed 9/9/2024 without the signature of the Technical Supervisor. Review of Pathologist Professional Competency signed by the Laboratory Director on 4/5/2023 revealed no statement on Technical Supervisor or Laboratory Director performing competency assessments. On 10/3/2024 at 3:10 PM , the Laboratory Coordinator confirmed competency assessments were not signed or performed by the Technical Supervisor.