

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2072678	(X3) Date Survey Completed 04/17/2018
Name of Provider or Supplier Akrivis Laboratories, Llc	Street Address, City, State 1402 South Magnolia Street, Suite H, Hammond, LA	
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	A Certification Survey was conducted on April 17, 2018 at Akrivis Laboratories, LLC, CLIA ID # 19D2072678. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure monthly maintenance for the Indiko was performed and documented for one (1) of nine (9) months reviewed. Findings: 1. Review of the Indiko "Maintenance Checklist" indicated the laboratory was to perform and document the following tasks: *Monthly - Perform End of Day procedure -Clean water containers and tubing -Exit Software and Power Down Workstation and Instrument -Clean incubator cuvette positions -Power Up the Instrument and Workstation 2. Further review of the Indiko "Maintenance Checklist" revealed the laboratory did not document maintenance for the following month: January 2018 3. In interview on April 17, 2018 at 2:56 pm, Personnel 2 stated the Indiko's monthly maintenance for January was not documented.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that</p>

perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to take corrective action when the laboratory's room humidity did not meet acceptable requirements per laboratory policy. Findings: 1. Review of the laboratory's "Room Temperature and Humidity Record" logs revealed the laboratory's acceptable humidity range is 40% to 70%. 2. Review of the laboratory's temperature and humidity logs for January 2017 through April 17, 2018 revealed the following dates with unacceptable humidity: January 3, 2017 recorded humidity 33% January 4, 2017 recorded humidity 35% January 5, 2017 recorded humidity 32% January 6, 2017 recorded humidity 35% January 9, 2017 recorded humidity 33% January 10, 2017 recorded humidity 33% January 11, 2017 recorded humidity 35% January 12, 2017 recorded humidity 33% January 13, 2017 recorded humidity 33% January 16, 2017 recorded humidity 35% January 17, 2017 recorded humidity 37% January 18, 2017 recorded humidity 39% January 19, 2017 recorded humidity 33% January 20, 2017 recorded humidity 39% January 23, 2017 recorded humidity 37% January 24, 2017 recorded humidity 36% January 25, 2017 recorded humidity 33% January 26, 2017 recorded humidity 39% January 30, 2017 recorded humidity 33% January 31, 2017 recorded humidity 37% February 1, 2017 recorded humidity 35% February 2, 2017 recorded humidity 35% February 3, 2017 recorded humidity 37% February 6, 2017 recorded humidity 33% February 7, 2017 recorded humidity 37% February 9, 2017 recorded humidity 36% February 10, 2017 recorded humidity 33% February 13, 2017 recorded humidity 36% February 14, 2017 recorded humidity 33% February 15, 2017 recorded humidity 33% February 20, 2017 recorded humidity 39% February 22, 2017 recorded humidity 37% February 23, 2017 recorded humidity 36% March 1, 2017 recorded humidity 33% March 2, 2017 recorded humidity 35% March 3, 2017 recorded humidity 35% March 6, 2017 recorded humidity 34% March 7, 2017 recorded humidity 37% March 8, 2017 recorded humidity 34% March 9, 2017 recorded humidity 36% March 10, 2017 recorded humidity 34% March 13, 2017 recorded humidity 34% March 14, 2017 recorded humidity 36% March 15, 2017 recorded humidity 34% March 16, 2017 recorded humidity 34% March 17, 2017 recorded humidity 31% March 21, 2017 recorded humidity 35% March 23, 2017 recorded humidity 39% March 24, 2017 recorded humidity 34% March 27, 2017 recorded humidity 35% March 28, 2017 recorded humidity 34% March 29, 2017 recorded humidity 39% March 30, 2017 recorded humidity 39% March 31, 2017 recorded humidity 38% April 6, 2017 recorded humidity 33% April 7, 2017 recorded humidity 37% April 10, 2017 recorded humidity 37% April 11, 2017 recorded humidity 37% April 12, 2017 recorded humidity 39% April 24, 2017 recorded humidity 39% April 25, 2017 recorded humidity 37% April 27, 2017 recorded humidity 39% April 28, 2017 recorded humidity 37% May 2, 2017 recorded humidity 39% May 3, 2017 recorded humidity 37% May 4, 2017 recorded humidity 37% May 5, 2017 recorded humidity 39% May 8, 2017 recorded humidity 37% May 9, 2017 recorded humidity 37% May 10, 2017 recorded humidity 38% May 12, 2017 recorded humidity 33% May 17, 2017 recorded humidity 39% May 18, 2017 recorded humidity 38% May 23, 2017 recorded humidity 33% May 24, 2017 recorded humidity 38% May 25, 2017 recorded humidity 34% May 26, 2017 recorded humidity 33% May 30, 2017 recorded humidity 38% May 31, 2017 recorded humidity 36% June 1, 2017

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D6023

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(6)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:
 Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.

D6024

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(7)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:
 Based on record review and interview with personnel, the Laboratory Director failed

to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to maintain records ensuring laboratory personnel met training requirements.

Findings: 1. Review of personnel records revealed orientation/training records were not maintained for the following one (1) of two (2) testing personnel reviewed: Personnel 5 2. In interview on April 17, 2018 at 9:53 am, Personnel 2 stated Personnel 5 was hired August 2017. Personnel 2 further stated the laboratory did not have documentation of orientation for Personnel 5.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.

D6096

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(7)

The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to maintain records ensuring laboratory personnel met training requirements.

Findings: 1. Review of personnel records revealed orientation/training records were not maintained for the following one (1) of two (2) testing personnel reviewed: Personnel 5 2. In interview on April 17, 2018 at 9:53 am, Personnel 2 stated Personnel 5 was hired August 2017. Personnel 2 further stated the laboratory did not have documentation of orientation for Personnel 5.