

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0691052	(X3) Date Survey Completed 03/21/2019
Name of Provider or Supplier Trigg County Hospital	Street Address, City, State 254 Main Street, Cadiz, KY	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 03/19/2019, 03/20/2019, and 03/21/2019, the laboratory failed to follow manufacturer's requirements for the performance of weekly maintenance on the Dimension EXL LM and EXL 200 chemistry analyzer for fifteen (15) of twenty (20) weeks from 10/14/2018 through 02/23/2019. The findings include: Manufacturer of the chemistry analyzer requires "Cleaning the Outside of R2 Probes" and Cleaning Outside of HM Wash Probes" to be performed weekly. Review of the maintenance logs revealed weekly maintenance was only performed five (5) of twenty (20) weeks (10/14/2018, 11/02/2018, 12/29/2018, 01/26/2019, and 02/23/2019). The Technical Supervisor acknowledged in an interview at 10:45 AM on 03/20/2019, the laboratory failed to have a system to ensure the manufacturer's established maintenance schedule was followed.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following</p>

for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 03/19/2019, 03/20/2019, and 03/21/2019, the laboratory failed to include a positive and negative control material for drugs of abuse for eight (8) of nine (9) days (10/20/2018 through 10/29/2018) of patient testing on the MEDTOX Scan Reader System. The findings include: Record review revealed drugs of abuse results were reported on 10/20/2018, 10/21/2018, 10/24/2018, 10/25/2018, 10/26/2018, 10/27/2018, 10/28/2018, and 10/29/2018. There was no evidence of positive and negative control materials tested on these days. The Technical Supervisor acknowledged in an interview at 2:30 PM 03/20/2019, the laboratory failed to have a system in place to ensure positive and negative control materials were run and documented on all days of patient testing for drugs of abuse.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 03/19/2019, 03/20/2019, and 03/21/2019, the laboratory failed to test each lot number of catalase reagent for positive and negative reactivity prior to use. The findings include: There was no positive and negative control documentation for Catalase reagent lot #7335917 used on 01/18/2019 to differentiate Streptococcus species from Staphylococcus species. There was no positive and negative control documentation for Catalase reagent lot #7207624 used on 06/01/2018 to differentiate Streptococcus species from Staphylococcus species. The Technical Supervisor acknowledged in an interview at 11:50 AM on 03/20/2019, the laboratory failed to have a system in place to ensure positive and negative reactivity were tested on bacteriology reagents prior to use.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview on 03/19/2019, 03/20/2019, and 03/21/2019, the laboratory failed to check each new batch of Blood Agar Plates, MacConkey Plates, and Chocolate Plates for sterility prior to use for patient testing. The findings include: Review of the Microbiology Policy and Procedure Manual revealed the Microbiology Quality Control Policy states "Perform sterility check of the media by incubating one plate overnight." Review of quality control documentation failed to reveal results for sterility on new batches of media prior to patient testing. The Technical Supervisor acknowledged in an interview at 11:25 AM on 03/20/2019, the laboratory failed to have a system in place to ensure policy was followed when new batches of media were received.

D5555

IMMUNOHEMATOLOGY
CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on record review and staff interview on 03/19/2019, 03/20/2019, and 03/21/2019, the laboratory failed to monitor the 24-hour chart recorder on the blood bank refrigerator to ensure storage temperatures were in range for the storage of Packed Red Blood Cells for fourteen (14) of thirty-one (31) days in October 2018. The findings include: Review of the Blood Bank Maintenance Log revealed the 24-hour Recorder Chart should read between one (1) degree and six (6) degrees centigrade. Daily documentation on the Blood Bank Maintenance Log showed readings of three (3) degrees or four (4) degrees centigrade for the Recorder Chart from October 5 through October 19. Review of the 24-hour Recorder Charts revealed temperatures read seven (7) degrees centigrade continuously from October 5 through October 12 and continuously from October 12 through October 19. The Technical Supervisor acknowledged in an interview at 2:45 PM on 03/19/2019, the personnel responsible for changing the 24-hour charts every seven (7) days failed to recognize the temperature on the charts were not being maintained within acceptable limits.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on review of the laboratory General Policy and Procedure Manual, review of proficiency testing results from American Proficiency Institute proficiency testing agency and staff interview on 03/19/2019, 03/20/2019, and 03/21/2019, the laboratory director failed to ensure proficiency test results in four (4) of fourteen (14) testing events were reviewed by appropriate staff to evaluate the laboratory's performance . The findings include: Review of the Policy and Procedure Manual failed to reveal an

established policy to ensure proficiency testing results were reviewed when received from the proficiency testing agency There was no documentation of review for the Hematology second testing event in 2018. There was no documentation of review for the Immunohematology second testing event in 2018. There was no documentation of review for the Microbiology third testing event in 2018. There was no documentation of review for the Immunohematology third testing event in 2018. The Laboratory Director acknowledged in an interview at 11:45 AM on 03/20/2019, the laboratory failed to establish a policy to ensure proficiency testing results were reviewed by appropriate staff to evaluate the laboratory's performance.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of personnel records and staff interview on 03/19/2019, 03/20/2019, and 03/21/2018, the technical supervisor failed to evaluate and document the performance for one of twelve individuals responsible for laboratory testing at least semiannually during the first year the individual performed patient testing. Findings include: Personnel #4 was hired 03/23/2018. There was no record of competency evaluations performed as of 03/20/2019. The Technical Supervisor acknowledged in an interview at 8:30 AM on 03/20/2019, laboratory procedure had not been followed in the performance of a semi-annual competency on testing personnel responsible for patient testing and reporting.