

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0450807	<b>(X3) Date Survey Completed</b>  08/02/2018
<b>Name of Provider or Supplier</b>  Cloud County Health Center	<b>Street Address, City, State</b>  155 West College Drive, Concordia, KS	
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>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: A review of manufacture's Mono Rapid Test package insert revealed this assay has not been established for patients under 18 years of age and that the laboratory failed to follow manufactures instructions. Findings: 1. Based upon a review of the Mono Rapid patient test records from July 1, 2017 to June 26, 2018; 30 of 61 patients tested were under 18 years of age. Therefore, the accuracy cannot be verified.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: A review of manufacture's package insert for MEDTOX revealed the laboratory failed to follow manufacture's instructions for positive drug screen results. . Findings were as follows a. Based upon MEDTOX package insert states " The Profile-II/verdict-II drugs of abuse provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result"The General Supervisor stated" not all positive result are sent out". . This was</p>

confirmed in interview with General Supervisor #1 from the CMS form 209 #2 on 08/02/2018 at 10:30 hrs.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

A review of Quality Control (QC) records and interview with the general supervisor revealed the laboratory failed to perform QC for Immunocard Toxins A & B Clostridium difficile before performing patient testing. Finding were as follows: 1. Based upon QC records, the laboratory failed to perform (QC) on day of testing before patient testing. Kit Lot #712050J530 with expiration date 6/8/2018 had documented external QC performed only on November 21, 2017. Review of patient /specimen log revealed 21 patient samples were tested from 11/22/2017 to 6/7/2018. This was confirmed by general supervisor on 08/2/2018 at 3:30 PM. Therefore patient results can not be verified.

**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 review of laboratory policies/procedures, lack of quality control (QC) results during 1/1/2017 to 7/31/2018, and interview with the general supervisor, the laboratory failed to check each batch of bacteriology media to ensure it supported the growth, or as appropriate, selected or inhibited specific organisms to produce the intended biochemical responses. Findings were: 1. A review of the laboratory's procedure for QC of microbiology culture media and the IQCP did not include performing QC for each batch and/or shipment for the following microbiology media in use: Blood agar, MacConkey agar; anaerobic reduced blood agar, HBT Bilayer Medium, Kanamycin Bile Esculin Agar, Columbia CNA Agar w/5% Sheep Blood, XLD Agar, and Haemophilus ID Quad Plate agar. 2. Interview with the general supervisor on 8/2/2018 at 3:00 PM confirmed the lab was not performing quality

control on each batch of media with controlled organisms to ensure the media supported intended growth and/or the intended response.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results. Finding were as follows a. Interview with General Supervisor #1 from the CMS 209 08/02//2018 at 09:30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).