

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0385620	<b>(X3) Date Survey Completed</b>  01/10/2023
<b>Name of Provider or Supplier</b>  Crawford County Memorial Hospital	<b>Street Address, City, State</b>  100 Medical Parkway, Denison, IA	
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>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of microbiology policies and procedures and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 01/10/2023, the laboratory failed to have a microbiology quality control (QC) policy/procedure that specifies QC organisms to be used for bacterial identification and antimicrobial susceptibility testing performed in the laboratory.</p>
<b>D5471</b>	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 review of Microscan quality control (QC) records, the MicroScan Gram Positive Procedure Manual, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 01/10/2023, the laboratory failed to check each lot number of identification (ID) panels for positive and negative reactivity for one out of one lot of gram positive Pos Combo 34 panels (lot number 20221007). The findings include: 1. The day of the survey, the laboratory had in use lot 20221007 of Pos Combo 34 panels. The laboratory began using it on 08/02/2022. 2. The MicroScan Gram Positive Procedure Manual indicated the following organisms are to be used for new lot numbers of gram positive ID panels: Staphylococcus aureus 29213, Enterococcus faecalis 29212, Streptococcus gallolyticus 49147, and Micrococcus luteus 49732. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have QC records showing a check of positive and negative reactivity on the ID panel for Pos Combo 34 lot 20221007.