

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 43D0407513	<b>(X3) Date Survey Completed</b> 11/29/2022
<b>Name of Provider or Supplier</b> Huron Regional Medical Center	<b>Street Address, City, State</b> 172 Fourth Street Se, Huron, SD	
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>	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 11/29/22. Huron Regional Medical Center laboratory was found not in compliance with the following requirements: D5215 and D5407.
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to review proficiency testing (PT) results to ensure the accuracy of results not graded as acceptable and whether this issue could have affected the accuracy of patient care results, in 6 of 18 American Proficiency Institute (API) PT testing events reviewed (2022 Hematology /Coagulation second event; 2022 Immunology/Immunochemistry first and second events; and 2022 Microbiology first, second, and third events). Findings include: 1. Review on 11/29/22 at 8:30 am of the API PT records revealed: * The evaluation and corrective action documentation for specimens not graded due to lack of consensus was absent for the following PT events: a. 2022 Hematology/Coagulation second event -UM-02 Crystals (Iris, semi-quant) [semi-quantitative] -UM-02 Non-Squamous Epi (Iris, semi quant) -UA-03 Bilirubin (Urinalysis) -VA-02 Vaginal Wet Preparation b. 2022 Immunology/Immunochemistry first event -Ser-05 Compatibility c. 2022 Immunology/Immunochemistry second event -Ser-06 Compatibility d. 2022 Microbiology first event -GS-05 Gram Stain -UR-01 Urine Culture MIC [minimum inhibitory concentration]/Zone Diameter Value e. 2022 Microbiology second event -UR-06 Urine Culture MIC/Zone Diameter Value f. 2022 Microbiology third event -</p>

UR-011 Urine Culture MIC/Zone Diameter Value Review on 11/29/22 of the laboratory's General External Assessments policy, last revised 8/11/21, revealed: \*Review report and investigate any 'unsatisfactory' results". \*The policy did not include any reference to reviewing ungraded results. Interview on 11/29/22 at 8:40 a. m. with the laboratory manager revealed: \*She confirmed the ungraded results had not been reviewed. \*She confirmed she did review the PT result reports and investigations of results not graded as acceptable. \*She was not aware the ungraded PT results had not been reviewed.

D5407

PROCEDURE MANUAL  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the current laboratory director (A) failed to ensure 8 of 10 individualized quality control plans (IQCP) had been reviewed for their effectiveness, approved, and signed by the current laboratory director prior to their continued use. Failure to evaluate the IQCPs for their continued effectiveness could create the potential for inaccurate patient results to be reported. Findings include: 1. Review of the following IQCPs revealed there was no documentation the plans had been reviewed, approved, and signed by the current laboratory director (A) prior to use: \*Sure-View Mono test- was last reviewed and signed on 12/30/15 by laboratory director B. -During 2021, 53 patient specimens were reported using the Sure-View Mono test kit. \*Amnisure ROM Test- was last reviewed and signed on 12/30/15 by laboratory director B. -During 2021, 37 patient specimens were reported using the Amnisure ROM test kit. \*Abbott I-Stat CG4 Cartridge- was last reviewed and signed on 12/30/15 by laboratory director B. -Abbott I-Stat CG4 Cartridge is used as a backup methodology for basic metabolic panels. \*Alere Triage D-Dimer Test- was last reviewed and signed on 12/30/15 by laboratory director B. -During 2021, 645 patient specimens were reported using the Triage D-Dimer test method. \*Meridian ImmunoCard Cryptosporidium/Giardia lamblia Test- was last reviewed and signed on 12/30/15 by laboratory director B. -During 2021, 55 patient specimens were reported using the Meridian ImmunoCard test kits. \*Meridian Rotavirus Test- was last reviewed and signed on 12/30/15 by laboratory director B. \*Beckman Coulter MicroScan WA-40- was last reviewed and signed on 1/1/16 by laboratory director B. - During 2021, 1,534 patient microbiological organism identifications and antibiotic susceptibility panels were reported using the MicroScan WA-40 analyzer. \*BD BBL Prepared Media- was last reviewed and signed on 1/1/16 by laboratory director B. - During 2021, 5,112 individual patient culture specimens were reported after having been inoculated to various BD or BBL prepared media. \*Review of the Laboratory-Individualized Quality Control Plan IQCP, last revised and signed by laboratory director A revealed: \*"B. Individual IQCP will be reviewed for effectiveness and modified as necessary when failures occur." \*"C. Individual IQCP's will be routinely reviewed annually for effectiveness." Review of the CLIA database revealed: \*Laboratory director A had taken over as laboratory director on 11/1/16. \*Laboratory director C had taken over as laboratory director on 5/15/17. \*Laboratory director A returned as laboratory director on 8/17/19. An interview on 11/29/22 at 11:40 a.m. with laboratory manager revealed: \*She confirmed the listed IQCPs had not been reviewed, approved, and signed by the current laboratory director since they had been written. \*She stated there had been at least one additional laboratory director between

laboratory director A and laboratory director B. \*Procedures and policies were entered into Policy Stat to ensure all procedures and policies were reviewed and signed by the current laboratory director. \*The old IQCPs had not been entered into Policy Stat. \*She was not aware the IQCP plans needed to be signed by the current laboratory director. \*She stated laboratory director A had signed the "general IQCP policy" later identified as the Laboratory- Individualized Quality Control Plan IQCP. \*She was unaware the IQCPs needed to be reviewed periodically to ensure their continued effectiveness.