Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0407501	11/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Huron Clinic Foundation Ltd	111 Fourth St Se, Huron, SD	

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 recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 11/17/21. The Huron Clinic Foundation LTD laboratory was found not in compliance with the following requirements: D5477, D5807, and D6028.
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 observation, record review and interview, the laboratory failed to verify one of one microbiology culture media (Streptococcus selective media) for its sterility, optimum ability to support growth and inhibit specific microorganisms. Quality control (QC) had not been documented as performed on this media for 31 months (4/24/19 through 11/17/21). Findings include: 1. Observation of the microbiology incubator on 11/17/21 at 11:45 a.m. revealed Streptococcus selective agar plates labeled with patient identification. Observation at this time of the laboratory's refrigerator revealed 2 packages of Streptococcus selective media. One package was open and currently in use. Review of the 2021 QC log revealed there was no documentation indicating the laboratory had checked the Streptococcus selective media (lot number 492879, expiration date 12/23/21) for sterility and its ability to support and inhibit growth. There was no documentation previous lots of the media had been verified prior to use testing patient specimens. Inability of this culture media

	to support and inhibit specific microorganisms could affect the accuracy of patient results. Review of the reported laboratory test volumes revealed 332 throat culture Group A Streptococcus confirmation tests had been performed using the Streptococcus selective media. Interview with testing personnel A on 11/17/21 at 11: 45 a.m. revealed the Streptococcus selective media was used to confirm all Group A Streptococcus antigen tests performed on patient throat swab specimens. She confirmed there was no documentation of QC having been performed on the media prior to its use for patient specimen testing. She was unaware new lots or shipments of the media needed to be verified for sterility and the ability to support and inhibit growth of specific microorganisms.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient laboratory test reports and interview with laboratory personnel, the laboratory failed to provide normal patient ranges for red cell distribution width (RDW), mean platelet volume (MPV), globulin, albumin/globulin ratio (A/G ratio), anion gap (AGAP), cholesterol/high density lipoprotein ratio (Chol /HDL), and blood urea nitrogen/creatinine ratio (BUN/Crea) for three of three sampled patient laboratory test reports (complete blood count [CBC], comprehensive metabolic panel [CMP], and lipid panel) to assist the provider in interpreting the reported patient test results. Findings include: 1. Review of completed patient test reports and the annual test volume form on 11/17/21 at 11:30 a.m. revealed: *The CBC patient laboratory test report did not have a documented normal range for RDW and MPV. In 2020, the laboratory reported 2,035 patient specimens, whose test reports included RDW and MPV results. *The CMP patient laboratory test report did not have a documented normal range for globulin, A/G ratio, AGAP, and BUN/Crea ratio. In 2020, the laboratory reported 3,029 patient specimens whose test reports included globulin and A/G ratio results and 4,228 patient specimens whose reports included AGAP and BUN/Crea ratio results. *The Lipid panel patient laboratory test report did not have a documented normal range for Chol/HDL ratio. In 2020, the laboratory reported 2,366 patient specimens whose test reports included Chol/HDL ratio results. Interview with testing personnel A on 11/17/21 at 11:30 a.m. confirmed the above specified test results lacked documentation of normal patient ranges.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure competency evaluations for two of two laboratory personnel (A and B) were completed by a qualified individual for the non-waived test methods they performed under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificate. Findings include: 1. Review of employees' files for laboratory personnel revealed: *Laboratory personnel A had competency evaluations performed in July 2020 and July 2021. These competency assessments had been performed and signed by laboratory personnel B. *Laboratory personnel B had competency evaluations performed in August 2020 and July 2021. These competency assessments had been performed and signed by laboratory personnel A. Review of the the Centers for Medicare Services 209 Laboratory Personnel Report Form signed by the laboratory director on 11/10/21 revealed laboratory personnel A and B had been listed as testing personnel only. The laboratory director was listed as the technical consultant. Review of laboratory personnel A and B's education records revealed they had received an associates degree. There was no documentation a higher degree had been obtained. Interview on 11/17/21 at 11:30 am with laboratory personnel A revealed: *She confirmed she had performed the competency evaluations for laboratory personnel B and that laboratory personnel B had performed her competency evaluations. *She confirmed neither she nor laboratory personnel B had a minimum of a bachelor's degree as required by CLIA to qualify as a technical consultant. *She was not aware they would need to qualify as a technical consultant to perform employee competency evaluations.