Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0651409	(X3) Date Survey Completed 02/04/2021
Name of Provider or Supplier Minnesota Department Of Health	**Street Address, City, State** 601 Robert Street N, Saint Paul, MN	
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish a specimen storage and transport procedure that followed the manufacturer's instructions for one of one SARS-CoV-2 serology tests reviewed. Findings: 1. Record review of the laboratory's procedure "SARS-CoV2 IgG detection in human sera by InBios SCoV-2 Detect ELISA" revealed in section "7.0 Specimen Requirements" under 7.5.1 to "Transport samples to MDH at refrigeration temperature (on ice packs, or at 2-8 C). If transport to MDH is delayed more than 7 days, specimens should be stored and shipped frozen." 2.. Review of the InBios SCoV-2 Detect (Trademark) IgG ELISA Instructions for Use (IFU) revealed under the section "Specimen Collection and Preparation" that "If assays are not completed within 8 hours, serum should be refrigerated at 2-8C. If assays are not completed within 48 hours, or the separated serum is to be stored beyond 48 hours, serum should be frozen at or below -20C." 3. In interview on February 4, 2021 at approximately 2:42 P.M., the laboratory's Quality Improvement Specialist and Clinical Quality Assurance Officer confirmed that specimens should be stored and transported according to the manufacturer's IFU.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on record review and interview, the laboratory failed to follow their procedure for viral cell culture selection for two of three specimens reviewed. Findings: 1. Record review of the"Viral Culture and Identification Worksheet" revealed two samples (147XX and 149XX) with the following cell lines inoculated: PRMK, MRC-5, and A549. 2. Review of procedure "Viral Specimen Preparation and Inoculation" revealed a section titled "11.2 Cell Culture Selection For Specimen Inoculation". The section included a chart listing the following headings: specimen type, request, RHMK, MRC-5, A549, HEP-2, Comments. The cell lines to inoculate for each specimen type and request was indicated. The chart did not indicate inoculation of PRMK, MRC-5, and A549 for any specimen type or request. 3. In interview on February 3, 2021 at approximately 12:00 P.M., GS#1 and the Quality Improvement Specialist confirmed the above findings. B. Based on record review and interview, the laboratory failed to follow their procedure for one of one specimens reviewed for PCR detection of Shiga-like Toxigenic Escherichia Coli (STEC). Findings: 1. Record review of specimen H20-XXXXX revealed that STEC Real-time Multiplex PCR was performed on July 13, 2020 and July 14, 2020. a. On July 13, 2020, the CT values were the following: stx1 = 34.05, eae = N/A, stx2 = 35.06, uidA = 20.18. b. On July 14, 2020, the CT values were the following: stx1= 35.25, eae - N /A, stx2 = 34.15, and uidA = 18.51. 2. Review of the final report for specimen H20-XXXXX for STEC PCR Panel - Culture Sweep revealed a result of "Shiga-like toxin present by PCR. Strongly Indicates presence of Shiga toxin-producing Escherichia coli." 3. Review of procedure "Real-time Multiplex PCR for Detection of Shiga-like Toxigenic Escherichia coli (STEC)" indicated in section "12.0 Interpretation" under "Table 5 STEC PCR assay results for specimen sample sweeps" that the Ct value for stx1 and stx2 should be less than or equal to 33. 4. During interview on February 4, 2021 at approximately 2:00 P.M., TS#1 confirmed the above findings.