Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D2264700	04/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hometown Family Health Pllc	104 West Commerce St, Plankinton, 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	An initial survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 4/12/23. Hometown Family Health PLLC laboratory was found not in compliance with the following requirements: D5445.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 perform the following: *Perform two levels of external controls to verify the accuracy of two of five non-waived test methods (prostate specific antigen [PSA] and total 25-hydroxy Vitamin D) each day patient testing was performed on the Nano Entek FREND analyzer. *Perform two levels of external controls or establish an equivalent quality control (QC) method to verify the accuracy of three of five non-waived test methods (thyroid stimulating hormone [TSH], free thyroxine [FT4], and total testosterone) each day patient testing was performed on the Nano Entek FREND analyzer. Findings include: 1. Review on 4/12/23 of the laboratory's records revealed: a. The laboratory processed patient PSA specimens on the Nano Entek FREND analyzer. *External QC results had been documented on 9/4/22 and 10/5/22. There had been no documentation additional external QC had been run in 2022 and to date in 2023. *Review of the laboratory's 2022 and 2023 quality assurance (QA) records revealed

QC had been marked as reviewed each month. There had been no documentation of the failure to document acceptable external QC for the months of November and December 2022 and of January, February, March and to date in April 2023. Review of the manufacturer's FREND PSA Plus product insert, last revised 8/22, revealed, "External quality control testing: It is recommended that external controls be run at least once per day when testing is scheduled for the FREND PSA Plus on the FREND system. A minimum of two (2) levels of control, normal and abnormal, should be used." b. The laboratory processed patient total 25-hydroxy Vitamin D specimens on the Nano Entek FREND analyzer. *External QC results had been documented on 9/4 /22, 10/30/22, 11/15/22, and 1/18/23. There was no documentation additional external QC had been run in 2022 and to date in 2023 for the total 25-hydroxy Vitamin D test method. *Review on 4/12/23 of the laboratory's 2022 and 2023 QA records revealed QC had been marked as reviewed each month. There had been no documentation of the failure to document acceptable external QC for the months of December 2022 and of February, March and to date in April 2023. Review on 4/12/23 of the manufacturer's FREND Total 25-hydroxy Vitamin D product insert, last revised 5/22, revealed, "External quality control testing: It is recommended that a minimum of two (2) levels of control be run once per day on days when assaying patient samples on the FREND Vitamin D test." Review of the laboratory's annual test volume form revealed a total of 98 PSA, total 25-hydroxy Vitamin D, and total testosterone patient specimens had been reported since testing had begun in September 2022 without QC having been performed each day of patient testing to ensure the accuracy of the patient test results. c. The laboratory processed patient TSH specimens on the Nano Entek FREND analyzer. *External QC results had been documented 9/4/22, 9/28/22, 12/28/22, 1/9/23, 3/2/23, and 4/10/23. There was no documentation additional external QC had been run in 2022 and to date in 2023. *Review on 4/12/23 of the laboratory's 2022 and 2023 QA records revealed QC had been marked as reviewed each month. There had been no documentation of the failure to document acceptable external QC for the months of October and November 2022 and of February 2023. Review on 4/12/23 of the manufacturer's FREND TSH product insert, last revised 10 /20, revealed, "External quality control testing- It is recommended that a minimum of two (2) levels of control be run at least once per month or once for each new lot or shipment, whichever comes earlier." The laboratory had not developed an individual quality control plan (IQCP) which would have allowed the laboratory to process QC at the minimum number and frequency required by the manufacturer. Review of the laboratory's annual test volume form revealed 371 TSH patient specimens had been reported since testing had begun in September 2022 without QC having been performed each day of patient testing to ensure the accuracy of the test results. d. The laboratory processed patient FT4 specimens on the Nano Entek FREND analyzer. *External QC results had been documented 9/14/22 and 1/9/23. There was no documentation additional external QC had been run in 2022 and to date in 2023. *Review on 4/12/23 of the laboratory's 2022 and 2023 QA records revealed QC had been marked as reviewed each month. There had been no documentation of the failure to document acceptable external QC for the months of October, November and December 2022 and of February, March and to date in April 2023. Review on 4/12/23 of the manufacturer's FREND FT4 product insert, last revised 5/22, revealed, "External quality control testing- It is recommended that a minimum of two (2) levels of control be run at least once per month or once for each new lot or shipment, whichever comes earlier." The laboratory had not developed an individual quality control plan (IQCP) which would have allowed the laboratory to process QC at the minimum number and frequency required by the manufacturer. Review of the laboratory's annual test volume form revealed 93 FT4 patient specimens had been reported since testing had begun in September 2022 without QC having been

	performed each day of patient testing to ensure the accuracy of the test results. e. The laboratory processed patient total testosterone specimens on the Nano Entek FREND analyzer. *External QC results had been documented 9/27/22 and 10/30/22. There had been no documentation additional external QC had been run in 2022 and to date in 2023. *Review on 4/12/23 of the laboratory's 2022 and 2023 QA records revealed QC had been marked as reviewed each month. There had been no documentation of the failure to document acceptable external QC for the months of November and December 2022 and of January, February, March and to date in April 2023. Review on 4/12/23 of the manufacturer's FREND Total Testosterone product insert, last revised 5/22, revealed, "External quality control testing- It is recommended that a minimum of two (2) levels of control be run at least once per month or once for each new lot or shipment, whichever comes earlier." The laboratory had not developed an individual quality control plan (IQCP) which would have allowed the laboratory to process QC at the minimum number and frequency required by the manufacturer. Review of the laboratory's annual test volume form revealed a total of 98 PSA, total 25-hydroxy Vitamin D, and total testosterone patient specimens had been reported since testing had begun in September 2022 without QC having been performed each day of patient testing to ensure the accuracy of the test results. Review of the laboratory director's onsite visit report included mention of development of a IQCP for the Nano Entek FREND analyzer. There was no documentation an IQCP had been developed. Interview on 4/12/23 at 9:50 AM with testing personnel A revealed: *The laboratory had begun testing patient specimens in September 2022. *She confirmed the laboratory had been processing and reporting PSA, 25-hydroxy Vitamin D, TSH, FT4, and total testosterone patient specimens. *She confirmed QC testing was to have been performed monthly and with new shipments or changes of the reagent lot number on the FREND analyzer. *She reviewed the QC records monthly as part of the QA process. *She had not been aware the manufacturer required two levels of QC to be performed each day PSA and 25-hydroxy Vitamin D patient testing had been performed. *She confirmed the laboratory had not developed an IQCP plan for TSH, FT4, and total testosterone testing on the Nano Entek FREND analyzer. The laboratory director had been unavailable for interview at the time of the survey.