# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 17D0450524	**(X3) Date Survey Completed** 07/09/2024
Name of Provider or Supplier Fredonia Regional Hospital	**Street Address, City, State** 1527 Madison Street, Fredonia, KS	
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 validation survey was completed on July 7, 2024. The Fredonia Regional Hospital laboratory was found not in compliance with the following CONDITIONAL LEVEL DEFICIENCIES: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the failure to have written procedures, availability of procedures with required information, testing performed prior to approved procedures, failure to include corrective action when quality control (QC) fails to meet acceptance criteria, and interview with technical consultant #3 (TC#3) and general supervisor #4 (GS#4), the laboratory failed to have written approved procedures or instructions for unacceptable QC (refer to D5401); failed to have QC data substantiating Individual Quality Control Plans (IQCP)s defaulting to performing qualitative QC day of patient testing for microbiology, parasitology, virology and general immunology (refer to D5447); failed to have QC data substantiating Individual Quality Control Plans (IQCP) s defaulting to performing quantitative QC day of patient testing for microbiology, virology and hematology (refer to D5449); failed to have QC data substantiating IQCP and failed to perform QC with approved control organisms each day prior to use for patient testing for microbiology (refer to D5507); arterial blood gas quality control (refer to D5537); and failed to evaluate patient results after QC failure (refer to D5783).

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: Based on a review of the laboratory procedures, interview with the testing personnel #3 (TP#3), the laboratory failed to have written procedures to include corrective action processes after unacceptable QC. Findings: 1. Procedures were requested for review. Review the "Failed QC" policy revealed there were no instructions to evaluate patient results (patient lookback) since last acceptable QC when a change in reagent, mechanics, testing kits or calibration of instrumentation were required to obtain acceptable QC. 2. No documentation could be provided to evaluate patient results after QC failure for patients results performed since 7/9/23. 3. Interview with the TP#3 on 7/9/24 at 2:30 p.m. confirmed, the laboratory failed to have written procedures to include corrective action processes after unacceptable QC.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of QC documentation and lack of QC data for an unsubstantiated Individualized Quality Control Plans (IQCP)s for Biofire Diagnostics Film Array and Biosite testing, and interview, the laboratory failed to have acceptable QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency and failed to perform a negative and positive control on each day of patient testing from 7/9/23 to time of survey. Findings: 1. Review of the facility's IQCP documents of the BioFire Diagnostics FilmArray for Gastrointestinal (GI Panel) revealed the laboratory only performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment could be presented per the IQCP, making the IQCP invalid. Two levels of QC were not performed every day of patient testing. 2. Review of the facility's IQCP documents of the BioFire Diagnostics FilmArray for Respiratory Panel 2.1 revealed the laboratory only performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment could be presented per the IQCP, making the IQCP invalid. Two levels of QC were not performed every day of patient testing. 3. Review of the facility's IQCP documents of the BioFire Diagnostics FilmArray for Blood Culture Identification Panel (BCID2 Panel) testing revealed the laboratory only performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment could be presented per the IQCP, making the IQCP invalid. Two levels of QC were not performed every day of patient testing. 4. Review of the facility's IQCP documents of the Biosite, Inc. Triage for D-Dimer testing revealed the laboratory only performed QC new lot, new shipment or every 30

	days. No substantiated QC data of new lot, new shipment or every thirty (30) could be presented per the IQCP. Two levels of QC were not performed every day of patient testing. 5. Interview with GS #4 on 7/9/24 at 11:45 a.m. confirmed the laboratory failed to have acceptable IQCP documentation to allow QC to be performed at the manufacturer's number and frequency from 7/9/23 to time of survey, therefore requiring performing QC at least once each day of patient testing for quantitative procedures, to include two control materials.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of QC documentation and lack of QC data for an unsubstantiated Individualized Quality Control Plans (IQCP)s, the MB ImmunoCard Stat, McKesson Consult Diagnostics hCG Combo, Meridian Bioscience, Inc. Curian, Meridian Diagnostics ImmunoCard, Quidel Solana, Cepheid GeneXpert, COVID 19 (SARS-COV-2) and TechLab C.Diff Quick Chek Complete for patient testing, and interview, the laboratory failed to have acceptable QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency and failed to perform a negative and positive control on each day of patient testing from July 9, 2023 to time of survey. Findings: 1. Review of the facility's IQCP documents of the MB ImmunoCard Stat for Giardia lamblia and Cryptosporidium revealed the laboratory performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment interval was presented for the IQCP. Two levels of QC were not performed every day of patient testing. 2. Review of the facility's IQCP documents of the McKesson Consult Diagnostics hCG Combo for qualitative serum hCG revealed the laboratory performed QC new lot, new shipment or every thirty (30) days. No substantiated QC data of new lot, new shipment or every 30 days could be presented per the IQCP. Two levels of QC were not performed every day of patient testing. 3. Review of the facility's IQCP documents of the Meridian Bioscience, Inc. Curian for Helicobacter pylori and Escherichia coli testing revealed the laboratory only performed QC new lot. No substantiated QC data of new lot or new shipment could be presented per the IQCP. Two levels of required QC were not performed every day of patient testing. 4. Review of the facility's IQCP documents of the Meridian Diagnostics ImmunoCard for Mycoplasma testing revealed the laboratory performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment could be presented per the IQCP. Two levels of required QC were not performed every day of patient testing. 5. Review of the facility's IQCP documents of the Quidel Solana for Streptococcus, Groups A, C, G testing revealed the laboratory performed QC new lot or new shipment. Twenty-eight (28) days of QC was performed for the IQCP. New lot or new shipment could not be substantiated per the QC data for the IQCP. Two levels of QC were not performed every day of patient testing. 6. Review of the facility's IQCP documents of the Cepheid GeneXpert for SARS-CoV-2, Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Respiratory syncytial virus (RSV), Influenzae A/B, Trichomoniasis, Streptococcus Group B, Bacterial Vaginosis and Vulvovaginal Candidaiasis testing revealed the laboratory performed QC new lot

	or new shipment. Twelve days of SARS-CoV-2 QC was performed, no other QC data was presented on Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Respiratory syncytial virus (RSV), Influenzae A/B, Trichomoniasis, Streptococcus Group B, Bacterial Vaginosis and Vulvovaginal Candidaiasis for the IQCP. New lot or new shipment could not be substantiated per the QC data for the IQCP. Two levels of QC were not performed every day of patient testing. 7. Review of the facility's IQCP documents of the TechLab C. Diff Quick Chek Complete for Clostridioides difficile (C. diff) testing revealed the laboratory performed QC new lot or new shipment. No substantiated QC data of new lot or new shipment was presented per the IQCP. Two levels of QC were not performed every day of patient testing. 8. Interview with GS #4 on 7/9/24 at 11:45 a.m. confirmed the laboratory failed to have acceptable QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency and failed to perform a negative and positive control on each day of patient testing from July 9, 2023 to time of survey.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of QC documentation and lack of QC data for the unsubstantiated Individualized Quality Control Plans (IQCP)s, for the antimicrobial susceptibility tests (AST) and organism identification cards for patient testing on the Vitek2, and interview with general supervisor #4 (GS#4), the laboratory failed to have acceptable QC data for IQCP documentation to allow QC to be performed at the manufacturer's number and frequency and failed to perform QC with approved control organisms each day prior to use for patient testing. Findings: 1. Review of the facility's IQCP documents of the bioMerieux Vitek2 Systems for the Gram-negative bacilli (GN) identification card revealed the laboratory only performed QC new lot or new shipment. Only six (6) days of QC data of new lot or new shipment could be presented per the IQCP, making the IQCP invalid. Two QC organisms with approved control organisms each day prior to use for patient testing were not performed every day of patient testing at time of survey. 2. Review of the facility's IQCP documents of the bioMerieux Vitek2 Systems for the Gram-Positive (GP) identification card revealed the laboratory only performed QC new lot or new shipment. Only four (4) days of QC data of new lot or new shipment could be presented per the IQCP, making the IQCP invalid. Two QC organisms with approved control organisms each day prior to use for patient testing were not performed every day of patient testing. 3. Review of the facility's IQCP documents of the bioMerieux Vitek2 Systems for the AST GN card revealed the laboratory performed QC new lot or new shipment. Twenty-nine (29) days of QC data of new lot or new shipment could be presented per the IQCP, making the IQCP invalid. Two QC organisms with approved control organisms each day prior to use for patient testing were not performed every day of patient testing. 4. Review of the facility's IQCP documents of the bioMerieux Vitek2 Systems for the

	AST GP card revealed the laboratory only performed QC new lot or new shipment. Twenty-seven (27) days of QC data of new lot or new shipment could be presented per the IQCP, making the IQCP invalid. Two QC organisms with approved control organisms each day prior to use for patient testing were not performed every day of patient testing. 7. Interview with GS#4 7/9/24 at 11:45 a.m. confirmed the laboratory from 7/9/23 to time of survey failed to have an approved IQCPs or perform QC on antimicrobial susceptibility testing (AST) and organism identifications with approved control organisms each day prior to use for patient testing.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's i-STAT procedure, quality control (QC) requirements, QC records, the facility's unsubstantiated Individual Quality Control Plan (IQCP) and interview with general supervisor #4 (GS#4), the laboratory failed to perform required QC every eight hours using the Abbott G3+ cartridge for pO2, pCO2 and pH testing on the i-STAT system. Findings: 1. Review of the laboratory's i-STAT IQCP states under QC: "Run external controls each new lot number or every thirty (30) days." 2. Review of the IQCP records for i-STAT pO2, pCO2 and pH data showed 2 levels of QC performed once daily for sixteen (16) days from September 2017 to October 2017. No QC was performed every eight hours prior to or after September 2017. 3. Interview with GS#4 on 7/9/2024 at 10:15 a.m. stated that they run QC for pO2, pCO2 and pH once a month. 4. Interview with GS#4 on7/9/2024 at 11:45 a.m. confirmed, the laboratory failed to perform QC every eight hours for pO2, pCO2 and pH testing on the i-STAT system.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and "Testing Issues" documents for lactic acid and troponin II performed on the Abbott Architect C 4000, failed QC and lack of patient result review for unacceptable lactic acid QC, troponin II QC and interview with testing personnel #4 (TP#4), the laboratory failed to evaluate and document patient results evaluation since the last acceptable QC test run for five of five patients results at time of survey. Findings: 1. Review of lactic acid QC records from the Architect C 4000 analyzer revealed unacceptable QC values for BioRad

	Level 2 on 3/7/24, 3/8/24, and 3/9/24. Repeat QC testing was not performed. The last lactic acid Level 2 QC that was acceptable was 3/6/24. 2. Review of the "Testing Issues" on 3/7/24 document for lactic acid did state calibration was performed, but QC was not repeated after calibration and one (1) lactic acid patient result was released on 3/7/24. No evaluation of previous patient results was documented. 3. Review of troponin II QC records on 5/17/24 from the Architect C 4000 chemistry analyzer revealed unacceptable QC value on BioRad Cardiac Level 1 and no QC values performed on BioRad Cardiac Levels 2 and 3. No repeat QC testing on BioRad Cardiac Level 1 was documented. 4. The last acceptable troponin II QC was obtained on 5/16/24. Review of the "Testing Issues" document on 5/17/24 revealed no documentation of unacceptable QC or corrective actions taken. The "Testing Issues" document stated that all Troponin II QC was performed. No documentation could be presented that BioRad Level 2 or 3 was performed for troponin II test on 5/17/24. 5. Four (4) patient results for troponin were reported on 5/17/24. No documentation to demonstrate troponin II patient testing was evaluated for possible corrective action at the time of survey. 6. Review of patient test results revealed patient results were reported without evaluation for the unacceptable QC for lactic acid and troponin II tests. 7. Interview with TP#4 on 7/9/24 at 12:15 p.m. confirmed, the laboratory failed to evaluate and document QC failures and an evaluation of patient results of lactic acid and troponin II testing since the last acceptable test run to determine if patient results had been adversely affected and may require corrective action for five of five patients results at time of survey.