Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0404509	10/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gundersen Harmony Clinic	805 Main Avenue South, Harmony, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on laboratory record review, direct observation, and interview with laboratory personnel, the laboratory failed to meet the requirements as specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299 Findings are as follows: 1. The laboratory failed to include accurate quality control information in the procedure manual. Refer to D5403. 2. The laboratory director failed to approve, sign, and date the performance verification for two Chemistry analytes prior to implementation. Refer to D5407. 3. The laboratory failed to verify the reportable range of two Chemistry analytes prior to reporting patient test results. Refer to D5421. 4. The laboratory failed to perform quality control testing using two control materials of different concentrations at least once each day of patient testing. Refer to D5447. .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to include accurate quality control criteria in the procedure for one of two non-waived tests performed by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 10:00 a.m. on 10/05/21. 2. An i-STAT handheld blood analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed Sodium and Potassium testing with this analyzer as indicated by the TC during the tour. 3. Quality control (QC) testing with two levels of QC material of was required with every new lot or shipment of test kits as indicated in the Chemistry Testing Using the i-STAT EC8+, EG6+, Crea, Chem8+ Cartridge Types procedure found in the electronic procedure software PolicyStat. 4. An Individual Quality Control Plan (IQCP) to reduce the frequency of QC testing was not found during review of laboratory policies and procedures. The laboratory was unable to provide an IQCP upon request. 5. In an interview at 12:50 p.m. on 10/05/21, the TC confirmed the above finding. The TC stated the QC frequency indicated in the procedure was incorrect and QC testing was performed each day of patient testing. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of one performance verifications completed in 2021 were approved, signed, and dated by the laboratory director prior to implementation. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 10:00 a.m. on 10/05/21. 2. An i-STAT handheld blood analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed Sodium (Na) and Potassium (K) analysis with this analyzer beginning on 03/01/21 as indicated by the TC during the tour. 3. Performance verification documents were not available on-site on date of survey. The laboratory was given an opportunity to provide these records by 10/11/21. Performance verification documents were received via email at 3:29 p.m. on 10/11/21. 4. The laboratory director's approval signature and date were not found in the i-STAT Na and K performance verification documents. 5. The TC was notified of this finding via email at 12:19 p.m. on 10/12/21. .

D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 2 of 2 reportable ranges obtained during performance verification activities completed in 2021 were adopted by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:00 a.m. on 10/05/21. 2. An Abbott i-STAT handheld blood analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities for Sodium (Na) and Potassium (K) tested on the i-STAT were completed in February 2021. The laboratory began testing patient specimens using this analyzer on 03/01/21 as indicated by the TC and confirmed by laboratory records. 4. Performance verification documents were not available on-site on date of survey. The laboratory was given an opportunity to provide these records by 10/11/21. Performance verification documents were received via email at 3:29 p.m. on 10/11/21. 5. The upper and lower limit of the reportable ranges for Na and K in the Chemistry Testing Using the i-STAT EC8+, EG6+, Crea, Chem 8+ Cartridge Types procedure did not reflect the actual reportable range value obtained by the laboratory during the PV. See below. Analyte PV Procedure Na 102-178 100-180 K 2.3-7.8 2.0-9.0 6. The laboratory performed approximately 66 Chemistry tests annually as indicated on the Clinic Laboratory Improvement Amendments (CLIA) Application Form provided by the laboratory on date of survey. 7. The TC was notified of this finding via email at 12:19 p.m. on 10/12/21. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure quality control (QC) was performed one of four days of quantitative Chemistry testing in April 2021. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:00 a.m. on 10/05/21. 2. An Abbott i-STAT handheld blood analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed Sodium and Potassium analysis using this

	analyzer. 3. The Chemistry Testing Using the i-STAT EC8+, EG6+, Crea, Chem8+ Cartridge Types procedure, found in the electronic procedure software PolicyStat, indicated quality control (QC) testing with two levels of QC material of was required with every new lot or shipment of test kits. However, an Individual Quality Control Plan to reduce the frequency of QC testing was not found during review of laboratory policies and procedures. The TC indicated the procedure was incorrect and QC testing was performed each day of patient analysis. See D5403 4. A patient Potassium result from 04/09/21 was reviewed on date of survey. i-STAT QC records were not found for 04/09/21. The laboratory was unable to provide the documents upon request. QC records were found for the other three days patient testing occurred in April 2021. 5. In an interview at 12:50 p.m. on 10/05/21, the TC confirmed the above finding. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant (TC) failed to ensure one of two new testing personnel were evaluated for Hematology procedure competency prior to testing patient specimens in 2020. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:00 a. m. on 10/05/21. 2. A HemoCue WBC analyzer observed as present and available for use during the tour of the laboratory. 3. Testing Personnel 1 (TP1) began testing in October 2020 as indicated by the TC. 4. New employees were trained and evaluated prior to reporting patient test results as established in the Quality Assurance for Laboratory Testing procedure, found in the electronic procedure software PolicyStat. 5. A Hemocue WBC analyzer initial competency assessment for TP1 was not found during review of laboratory records. The laboratory was given an opportunity to provide the missing document by 10/11/21. 6. In an email received at 3:29 p.m. on 10 /11/21, the TC indicated the missing initial competency documentation could not be found. 7. The TC was notified of this finding via email at 12:19 p.m. on 10/12/21. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure competency was assessed at least semi-annually during the first year of patient specimen testing for one of two testing personnel hired in 2020. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:00 a. m. on 10/05/21. 2. A HemoCue WBC analyzer observed as present and available for use during the tour of the laboratory. 3. Testing Personnel 3 (TP3) received HemoCue

	WBC initial competency assessment in July 2020 as indicated in personnel records. 4. The Quality Assurance for Laboratory Testing procedure, found in the electronic procedure software PolicyStat, did not include criteria for semi-annual review. 5. A Hemocue WBC analyzer semi-annual competency assessment for TP3 was not found during review of laboratory records. The laboratory was given an opportunity to provide the missing document by 10/11/21. 6. In an email received at 3:29 p.m. on 10 /11/21, the TC indicated the missing semi-annual competency assessment documentation could not be found. 7. The TC was notified of this finding via email at 12:19 p.m. on 10/12/21. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure one of three testing personnel were annually evaluated for Hematology procedure competency in 2020. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:00 a.m. on 10/05/21. 2. A HemoCue WBC analyzer was observed as present and available for use during the tour of the laboratory. 3. Testing Personnel 5 (TP5) was previously listed as testing personnel on the Laboratory Personnel Report (CLIA) form during the 09/12/19 survey. 4. Employees were assessed for competency annually after the first year of testing as established in the Quality Assurance for Laboratory Testing procedure, found in the electronic procedure software PolicyStat. 5. A 2020 Hemocue WBC analyzer annual competency assessment for TP5 was not found during review of laboratory records. The laboratory was given an opportunity to provide the missing document by 10/11 /21. 6. In an email received at 3:29 p.m. on 10/11/21, the TC indicated the missing annual competency documentation could not be found. 7. The TC was notified of this finding via email at 12:19 p.m. on 10/12/21.