Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0921162	07/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Contemporary Family Medicine	200 East Boothe Street Suite 100, Cleveland, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a review of the laboratory's test records, a review of the laboratory's policies, and staff interview, it was revealed that the laboratory failed to report a total of 584 SARS-CoV-2 patient test results, that contained both negative and positive

	antigen test results, as required by 400.200 for 198 of 198 days reviewed from October 1, 2020 to July 27, 2021. Findings include: 1. A review of the laboratory's test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 antigen patient testing using BD Veritor System for Rapid Detection of SARS-CoV-2 antigen test on 9/23/20. 2. A review of the laboratory's policies revealed no documentation of a policy/procedure related to SARS-CoV-2 test reporting. 3. A review of the laboratory's SARS-CoV-2 antigen patient test records from October 1, 2020 to July 27, 2021, revealed the laboratory failed to have documentation of reporting 489 negative and 95 positive test records for 198 of 198 days of testing. 4. An interview with the laboratory director on 7/27/21 at 11:27 a.m. in the laboratory, after review of the records, confirmed the above findings.
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's policies, a review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2021, and staff interview, it was revealed the laboratory failed to follow its policy for performing corrective action when the laboratory scored a 60% for MCV and RDW-CV analytes in 1 of 2 Hematology testing events for 2021. Findings include: 1. A review of the laboratory's policy titled 'Proficiency Survey Checklist' revealed the following: "Any test results that are out of acceptable limits must have remedial action performed- generally. - Retrieve the samples from the refrigerator and repeat any that are unacceptable. - Review the original instrument print out and the data submitted to the API to ensure there is not a clerical error. - Document this study on the cover sheet that is titled Proficiency Testing Performance Evaluation." 2. A review of the laboratory's API proficiency testing records for 2021 revealed the laboratory received a 60% for the analytes MCV and RDW- CV for the 2021 Hematology/Coagulation - 1st Event. 3. The laboratory was asked for documentation of corrective action for the 60% received for MCV and RDW- CV for the 2021 Hematology/Coagulation - 1st Event. No documentation was provided. 4. An interview with the office manager on 7/27/21 at 9: 30 a.m. in the laboratory, after review of the records, confirmed the above findings.
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 a review of the Medonic M- Series User's Manual, a review of the laboratory's policies, and staff interview, it was revealed that the laboratory failed to have a policy that defines the steps for laboratory personnel to follow for verifying flags on CBC (complete blood count) results. Findings include: 1. A review of the Medonic M- Series User's Manual (Article no. 1504248, 05/2009) revealed the following flags: " BD, NM, OM, TM flags - Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 2. A review of the laboratory's policies revealed no policy or procedure defining the steps for the laboratory personnel to follow for verifying flags for CBC results run on the Medonic hematology analyzer. 3. An interview with the office manager on 7/27/21 at 11:00 a. m. in the laboratory, after review of the records, confirmed the above findings
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the Medonic M- Series User's Manual, a review of the laboratory's policies, a random review of patient test records from August 2020 to November 2020, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for resolving flags on 6 of 20 patient's CBC (complete blood count) results reviewed from the Medonic M- Series hematology analyzer. Findings include: 1. A review of the Medonic M- Series User's Manual (Article no. 1504472, 02/2016) revealed the following: "The Medonic M- Series has several parameter and system information messages related to the measured parameters and the instrument. These messages alert the operator of possible pathologic samples and parameter value and instrument errors. OM flag - Only one WBC population found; slide review advised. Follow laboratory's protocol for verification of results. BD flag - High interference between populations; a blood smear is recommended. Follow laboratory's protocol for verification of results. TM flag - Too many WBC population found; slide review advised. Follow laboratory's protocol for verification of results." 2. A review of the laboratory's policies revealed no documentation of a policy or procedure defining the steps for laboratory personnel to follow for resolving flags on CBC results. 3. A review of the laboratory's patient test records from August 2020 to November 2020 revealed the following 6 patients with flags present on their CBC report: Patient ID: 11011935 Run date: 8/17/20 TM flag present on Gra%, Mid%, Lym%, Gran, Mid, Lym Patient ID: 11031944 Run date: 8/31/20 BD flag present on Gra%, Mid%, Lym%, Gran, Mid, Lym Patient ID: 11241939 Run date: 11/2/20 TM

	flag present on Gra%, Mid%, Lym%, Gran, Mid, Lym Patient ID: 01121941 Run date: 11/9/20 BD flag present on Gra%, Mid%, Lym%, Gran, Mid, Lym Patient ID: 07211936 Run date: 11/9/20 OM flag present on Gra%, Mid%, Lym%, Gran, Mid, Lym Patient ID: 08082002 Run date: 11/18/20 BD flag present on Gra%, Mid%, Lym%, Gran, Mid, Lym 4. An interview with the office manager on 7/27/21 at 11:00 a.m. in the laboratory, after review of the records, confirmed the above findings. Key: WBC - white blood cell PLT - platelet LYM - lymphocytes MID - monocytes, basophils, eosinophils GRAN - granulocytes
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, surveyor observation, a review of the laboratory's freezer temperature logs, and staff interview, it was revealed that the laboratory failed to ensure the Quidel Triage Total Controls 1 and 2 were stored at temperatures required by the manufacturer. Findings include: 1. A review of the Quidel Triage Total Control Product Insert (26601 Rev. A, 05/2018) revealed the following: "Store frozen at -20C or colder in a non-defrosting freezer." 2. Surveyor observation on 7/27/21 at 9:20 a.m. of the laboratory's freezer (Frigidaire Elite Model: FPES19TIP) found the following boxes of controls inside: - 2 boxes of Triage Total Control level 1 Lot number: C3663AN exp: 1/9/22 - 1 box of Triage Total Control level 2 Lot number: C3789AN exp: 3/30/21 - 1 box of Triage Total Control level 2 Lot number: C3792AN exp: 5/27/21 3. A review of the laboratory's Freezer Temperature logs from January 2021 to July 2021 revealed the acceptable temperature for the freezer was 5C or colder. The laboratory documented the freezer temperature as 5C for every day of patient testing during those 7 months (January to July 2021). 4. An interview with the office manager on 7/27/21 at 11:40 a.m. in the laboratory, after review of the records, confirmed the above findings. Key: C = degrees Celsius
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 a review of the laboratory's verification records, a review of the laboratory's

	reference ranges for analytes tested on the Quidel Triage meter, and staff interview, it was revealed the laboratory failed to have documentation of verifying its patient normal ranges Troponin testing on the Quidel Triage meter. Findings include: 1. A review of the laboratory's verification records for the Quidel Triage meter (Serial number 00084433WW) revealed verification studies were performed in August 2020. 2. The laboratory was asked to provide documentation of verifying the following patient normal ranges for Troponin testing on the Quidel Triage meter. No documentation was provided. TNI (Troponin) Normal range: 0.00 - 0.40 ng/mL 3. An interview with the office manager on 7/27/21 at 9:45 a.m. in the laboratory, after review of the records, confirmed the above findings.
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 a review of the laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of establishing an IQCP (Individualized Quality Control Plan) for the Quidel Triage meter to support the modification in quality control testing for Troponin. Findings include: 1. A review of the laboratory's records revealed the facility added a Quidel Triage meter (Serial number 00084433WW) in August 2020. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of an IQCP for the Quidel Triage meter. 3. An interview with the office manager on 7/27/21 at 10:00 a.m. in the laboratory, revealed she was unaware an IQCP had to be developed for the Triage meter. This confirmed the above findings.
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 a review of the laboratory's quality control records for the Quidel Triage meter for August 2020 to July 2021, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running two levels of quality control material for each day of patient testing from August 2020 to July 2021 for Troponin testing on the Quidel Triage meter. Findings include: 1. A review of the laboratory's quality control records for the Quidel Triage meter from

	August 2020 to July 2021 revealed the laboratory failed to have documentation of running two levels of quality control material each day of patient testing for Troponin. 2. Further review of the laboratory's quality control records for the Quidel Triage meter revealed the laboratory runs two levels of control material every 30 days. 3. The office manager was asked on 7/27/21 at 10:00 a.m. to provide documentation of an IQCP defining the laboratory's quality control procedure for an alternate QC option (two levels every 30 days). No documentation was provided. (Refer to D5445) 4. A random review of patient test records from August 2020 to July 2021 revealed the following 7 patient's samples were resulted on days when there was no documentation of two levels of quality control material run on the Quidel Triage meter for Troponin testing: Date: 8/13/20 Patient: 12251962 Date: 9/3/20 Patient: 01301990 Date: 10/5 /20 Patient: 09141957 Date: 1/5/21 Patient: 01291045 Date: 2/4/21 Patient: 08111955 Date: 4/9/21 Patient: 11261936 Date: 4/22/21 Patient: 04011983 5. An interview with the office manager on 7/27/21 at 10:20 a.m. in the laboratory, after review of the records, confirmed the above findings. Key: QC = Quality Control
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control records for the Medonic M-Series hematology analyzer from May 2019 to April 2020, and staff interview, it was revealed that the laboratory failed to verify new lot numbers of external quality control for complete blood count (CBC) testing on the Medonic M- Series hematology analyzer before placing them into use. Findings include: 1. A review of the laboratory's quality control records for the Medonic M- Series hematology analyzer from May 2021 to July 2021 revealed there was no documentation of the laboratory performing lot to lot verifications for the following lot numbers of external quality control materials: Con-Diff Low Lot number: 22101-51 exp: 6/16/21 Con-Diff Norm Lot number: 22101-52 exp: 6/15/21 Con-Diff High Lot number: 22101-53 exp: 6/16/21 Con-Diff Low Lot number: 22104-31 exp: 9/3/21 Con-Diff Norm Lot number: 22104-32 exp: 9/7/21 Con-Diff High Lot number: 22104-33 exp: 9/7/21 Con-Diff Low Lot number: 22105-31 exp: 10/12/21 Con-Diff Norm Lot number: 22105-32 exp: 10/12/21 Con-Diff High Lot number: 22105-33 exp: 10/12/21 2. An interview with the office manager on 7/27/21 at 11:10 a.m. in the laboratory, after review of the records, confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed the laboratory failed to have a quality assessment program that could identify and correct problems in analytic systems. Findings include: 1. The laboratory failed to follow its policy for performing corrective action when the laboratory scored a 60% for MCV and RDW-CV analytes in testing events for 2021. (Refer to D5401) 2. The laboratory failed to have a policy that defines the steps for laboratory personnel to follow for verifying flags on CBC (complete blood count) results. (Refer to D5403) 3. The laboratory failed to follow the manufacturer's instructions for resolving flags on patient's CBC results from the Medonic M- Series hematology analyzer. (Refer to D5411) 4. The laboratory failed to ensure the Quidel Triage Total Controls 1 and 2 were stored at temperatures required by the manufacturer. (Refer to D5413) 5. The laboratory failed to have documentation of verifying its patient normal ranges for Troponin testing on the Quidel Triage meter.(Refer to D5421) 6. The laboratory failed to have documentation of establishing an IQCP for the Quidel Triage meter to support the modification in quality control testing for Troponin. (Refer to D5445) 7. The laboratory failed to have documentation of running two levels of quality control material for each day of patient testing for Troponin testing on the Quidel Triage meter. (Refer to D5447) 8. The laboratory failed to verify new lot numbers of external quality control for complete blood count (CBC) testing on the Medonic M- Series hematology analyzer before placing them into use. (Refer to D5469)