Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1046922	07/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Monte Christo Family Clinic	3002 N Business 281 Suite B, Edinburg, 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	Based on an announced validation inspection, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing records and interview, the laboratory failed to attain an acceptable score of 80% or higher for the CBC (Complete Blood Count) indices Red Blood Cells (RBC) in the 2nd event of 2021 resulting in unsatisfactory analyte performance. Findings follow. A. Review of the American Proficiency Institute (API) proficiency testing records from the 1st event of 2023, the 1st, 2nd, and 3rd events of 2022, and 2nd and 3rd events of 2021 showed in the 2021 Hematology 2nd Event the laboratory obtained a score of 60% for RBC. B. Interview with the Technical Consultant on July 20, 2023 at 1100 hours confirmed the failure.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on

	proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, COLA letter, verification of performance specifications records, patient testing records and interview, the laboratory failed to participate in the 2022 3rd Event resulting in a test score of 0% in for WBC, WBC differential, Granulocytes %, Lymphocytes %, Monocytes/Mid%, RBC, HCT, HGB, MCH, MCHC, MCV and PLT in the specialty of Hematology for one of six events reviewed. Findings follow. A. Review of the American Proficiency Institute (API) Hematology proficiency testing records from the 1st event of 2023, the 1st, 2nd, and 3rd events of 2022, and the 2nd and 3rd event of 2021 showed scores of 0% in the 3rd Event of 2022 for WBC, WBC differential, Granulocytes %, Lymphocytes %, Monocytes/Mid%, RBC, HCT, HGB, MCH, MCHC, MCV and PLT. B. Review of the letter from COLA dated 02/07/2023 stated, "The laboratory was recently sent a letter requesting that you send documentation of corrective action for the unsuccessful electronic PT score(s) received for PT event 2022-3. We have not received the required documentation. Please submit your completed root cause and corrective action response to COLA by 02/28/2023 with your COLA ID on all documents. Be sure to keep a copy with your PT records. If we do not receive your corrective action response, your laboratory will be considered for Pending Denial of Accreditation..." Review of their response showed "Instrument not in Service Failed to Notify API". C. Review of the verification of performance specifications records for the Medonic showed it was validated 11/15/2022. D. Review of the API PT records showed the samples were received on 11/09/2022, deadline for replacing samples was 11/15/2022, and the postmark date was 11/30/2022. E. Review of patient testing records for CBCs showed the laboratory began reporting patient tests on 11/18 /2022. F. Interview with the Technical Consultant on July 20, 2023 at 1020 hours acknowledged the testing personnel did not know to call API to ask for samples [suitable for the Medonic], and confirmed the laboratory began reporting patient testing on 11/18/2022. KEY: WBC = White Blood Cell Count RBC = Red Blood Cell Count HCT = Hematocrit HGB = Hemoglobin MCH = Mean Corpuscular Hemoglobin MCHC = Mean Corpuscular Hemoglobin Concentration MCV = Mean Corpuscular Volume PLT = Platelets
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 review of the manufacturer's instructions, laboratory policy and procedure, instrument print-outs, data logs, patient test reports, and interview, the laboratory failed to redact or verify flagged indices on the CBC (Complete Blood Count) test report using the Medonic M-Series for two out of four flagged patient test reports reviewed from 01/02/2023 to 01/31/2023 and 04/03/2023 - 04/28/2023 for 40 days of patient testing. A. Review of the Medonic M-Series User's Manual, July 2019 Article # 1504547, under 9.2 System Information Messages starting on page 84 stated, "The

	system software monitors a number of analytical and system functions and will display information that indicates the possible attention of the operator. This information will alert the operator to check the system or sample or institute selected troubleshooting procedures. This information is presented on the touch screen as a code next to one or more parameters. Additional detail and recommendations may be accessed by either pressing the i-button on the touch screen or reviewing the printed report. System Information Messages... 1. Indicator Message DM WBC DIFF: High interference between populations. Description The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 2. Indicator Message OM WBC DIFF: Only one WBC population found; slide review advised. Description There was only one mode in the WBC distribution between the LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 3. Indicator Message TM WBC DIFF: Too many WBC population found; slide review advised. Description There were more than two modes in the WBC distribution between the LYM-L and GRAN -H settings. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results". B. Review of the laboratory's policy and procedure titled Policy for Abnormal Differentials, approved 02/15/2010, stated "It will be the policy of this laboratory to send out all abnormal differentials. This laboratory will perform only normal differentials. A normal differential will be described as having only normal cells: Lymphocytes, Monocytes, Basophils, Eosinophils, Neutrophils, and normal size and shape RBC and Platelets. If your CBC instrumentation is showing alarms (R1, R2, M3, etc) in the differential section of the report, it will be considered an abnormal differential and should be send out." C. Instrument print-outs were requested on July 20, 2023 at 1245 hours, but unavailable for review. D. Review of the CBC Medonic data logs from January and April 2023, 40 days of patient testing, showed an * for flags/alerts: 1. sample ID 11233 run on 01/03/2023 at 09:33 with asterisks for LYM, MID, GRAN, LYM%, MID%, GRAN %. 2. sample ID 14128 run on 01/06/2023 at 14:02 with asterisks for LYM, MID, GRAN, LYM%, MID%, GRAN %. E. Review of the patient reports showed the samples with the asterisks were reported. F. Interview with the Technical Consultant on July 20, 2023 at 1245 hours confirmed testing personnel should not be reporting results with flags and can send the sample out if the doctor wants the results. KEY: WBC = White Blood Cell Count WBC DIFF = White Blood Cell Differential LYMPH/LYM = Lymphocytes MID = Monocytes/Mid GRAN = Granulocytes
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 review of verification of performance specification records, patient testing records, pre-survey paperwork, and interview, the laboratory failed to ensure the verification of performance specifications was performed on the Medonic for verifying patient normal ranges for the Complete Blood Count (CBC) prior to patient testing on 11/18/2022 for eight of eight months reviewed. A. Review of the verification of performance specification records performed on 11/15/2022 showed the normal reference range study was not performed. B. Review of patient testing records showed patient testing began 11/18/2022. C. Review of the CMS form 116 showed an estimated 9,000 tests were performed annually. D. Interview with the Technical Consultant on July 20, 2023 at 1115 hours confirmed the laboratory did not verify the normal reference ranges.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, calibration records, manufacturer's instructions, and interview, the laboratory failed to perform calibrations at least every 6 months on the Drew Hematology analyzer for two out of five events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Calibration Validation, approved 02/15/2010, stated, "It is policy of this lab to validate calibrations: Every 6 month Following a complete reagent change Following major preventive maintenance Following replacement of a critical part or when Shifts or Trends in QC are seen". B. Review of calibrations records showed calibrations were performed on: 04/08/2021 09/21/2021* 12/10/2021* 03/25/2022 (11 months, 17 days elapsed)** * Review of the calibration reports on 09/21/2021 and 12/10/2021 still showed the last calibration was 04/08/2021, so the calibrations performed on 09/21/2021 and 12/10/2021 were not accepted prior to leaving the calibration screen. C. ** The calibration performed on 03/25/2022 had the wrong target value for MCV (Mean Corpuscular Volume) entered as 89 versus 87 as shown in the EX-CAL package insert for lot #EX0422-CAL. D. Interview with the Technical Consultant on July 20, 2023 at 1135 hours confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure, quality control (QC) testing records and interview, the laboratory failed to document corrective action taken when QC failed on the Medonic CBC (Complete Blood Count) analyzer for two of two events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled "It is the policy of this laboratory to do the following when controls are not within range:", approved 02/15/2010, stated, "...Ensure that all remedial action steps are documented." B. Random review of QC records from January and April 2023 showed 2 out of 2 days of repeating QC with no documentation of corrective action: 1. 04/06/2023: Level 2 was repeated 4 times 2. 04/20/2023: Level 1 was repeated 2 times C. Interview with the Technical Consultant on July 20, 2023 at 1210 hours confirmed the findings
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Review of test reports, data logs, and interview, the laboratory failed to verify that patient results for the Complete Blood Count (CBC) were correctly entered into the Electronic Medical Record (EMR) for one of eight test reports reviewed. Findings follow. A. Review of the CBC test report for patient ID #27624 performed on 03/07 /2023 against the Medonic data logs (the instrument print-outs were not retained), showed a transcription error in the report for absolute Granulocytes. The data log showed a result of 12.1 K/uL, but was reported as 87.4 K/uL in the EMR. B. Interview with the Technical Consultant on July 20, 2023 at 1300 hours confirmed there was a transcription error, and the %Granulocytes was reported for both the absolute and %, and he would have to start doing QA on that [test reports].
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance

	characteristics of the method; This STANDARD is not met as evidenced by: Based on review of verification of performance specification records, patient testing records, pre-survey paperwork, and interview, the laboratory director failed to ensure the verification of performance specifications was performed on the Medonic for verifying patient normal ranges for the Complete Blood Count (CBC) prior to patient testing on 11/18/2022 for eight of eight months reviewed (refer to D5421).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of verification of performance specification records, patient testing records, pre-survey paperwork, and interview, the technical consultant failed to ensure the verification of performance specifications was performed on the Medonic for verifying patient normal ranges for the Complete Blood Count (CBC) prior to patient testing on 11/18/2022 for eight of eight months reviewed (refer to D5421).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, COLA letter, verification of performance specifications records, patient testing records and interview, the technical consultant failed to ensure the laboratory participated in the 2022 3rd Event resulting in a test score of 0% in for WBC, WBC differential, Granulocytes %, Lymphocytes %, Monocytes/Mid%, RBC, HCT, HGB, MCH, MCHC, MCV and PLT in the specialty of Hematology for one of six events reviewed (refer to D2123).
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 review of competency evaluations and interview, the technical consultant failed to evaluate and document the performance of individuals responsible for performing Complete Blood Counts (CBC) at least semiannually during the first year

	the individual tests patient specimens for one of one new employees. Findings follow. A. Review of competency evaluations showed testing personnel #1 was hired 09/01 /2021 and had one semiannual competency evaluation performed 03/17/2022. The next competency evaluation was performed on 02/22/2023. B. Interview with the Technical Consultant on July 20, 2023 at 0955 confirmed the findings.