Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1009444	03/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Marilyn S Norton Md Inc	769 Medical Center Ct Ste 202, Chula Vista, CA	

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
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) testing result reports, and interview with the laboratory staff, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent was unsatisfactory performance. The findings included: a. The laboratory uses Horiba EX 60 analyzer to perform Complete Blood Count (CBC) reporting WBC with automated cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct), and Platelet Count (Plt). b. The laboratory enrolled with MLE (Medical Laboratory Evaluation) proficiency testing program to ensure accuracy and reliability of the patient testing result reports. c. The laboratory attained an overall testing event score of 0 % for CBC in the M-3, 2021 PT event, which was unsatisfactory performance. d. The laboratory staff attested (3/9/2023 @ 11:35 AM) that the laboratory attained an overall testing event score of 0% for CBC in the M-3, 2021 PT event, which was unsatisfactory performance. e. The laboratory performed CBC in approximately 1650 patient samples monthly.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) testing result reports, and

	interview with the laboratory staff, it was determined that the laboratory failed to review and evaluate the results obtained on proficiency testing performed. The findings included: a. The laboratory failed to review and evaluate the results obtained on proficiency testing performed. b. The laboratory uses Horiba EX 60 analyzer to perform Complete Blood Count (CBC) reporting WBC with automated cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct), and Platelet Count (Plt). c. The laboratory enrolled with MLE (Medical Laboratory Evaluation) proficiency testing program to ensure accuracy and reliability of the patient testing result reports. d. Review of the MLE 2022 M3 PT records including analyte scores, the laboratory attained scores of 80% for Erythrocyte Count (RBC), Hematocrit, and Leukocyte (WBC), respectively. e. The laboratory failed on the sample HD-11 for RBC, Hematocrit, and WBC with a "*" mark, where "*" indicates result unacceptable. f. There were no evidence or documents to indicate that the PT score records ever been reviewed and/or discussed the failures with the appropriate laboratory personnel who perform CB routinely. g. The laboratory staff attested (3/9/2023 @ 11:45 am) that the laboratory failed to review and evaluate the results obtained on proficiency testing performed with appriopriate testing personnel.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) testing result reports, and interview with the laboratory staff, it was determined that the laboratory failed to document all activities of reviewing, evaluating and verification the testing and the scores when received after the proficiency testing performed. The findings included: a. The laboratory failed to document all activities of reviewing, evaluating and verification the testing and the scores when received after the proficiency testing performed b. The laboratory uses Horiba EX 60 analyzer to perform Complete Blood Count (CBC) reporting WBC with automated cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct), and Platelet Count (Plt). c. The laboratory enrolled with MLE (Medical Laboratory Evaluation) proficiency testing program to ensure accuracy and reliability of the patient testing result reports. d. There were no evidence or documents to indicate that the PT scores ever been reviewed and/or discussed the failures with the appropriate laboratory personnel who perform CBC daily, see D-5211 and D-6018.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient result reports, and interview with the laboratory staff, it ws determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, to ensure accuracy, reliability of the patient test result reports. The findings included: a. The laboratory

	failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and to ensure accuracy, reliability of the patient test result reports. b. The laboratory uses Horiba EX 60 analyzer to perform Complete Blood Count (CBC) reporting WBC with automated cell differentials, RBC, Hemoglobin (Hgb), Hematocrit (Hct), and Platelet Count (Plt). c. The laboratory personnel manually data entered each of CBC analyte out of the Horiba analyzer print-out result report to its office computer system and the provider/health personnel will review the manually entered CBC results from the computer terminal to treat the patients. d. Randomly review of 6 manually data entry FINAL patient results report against the Horiba analyzer print-out patient result report sheet, an inaccurate result manually entered was found in a patient FINAL report. e. The patient, Patient Number 26311, Report Date: 2/27/2023 10:16 AM with DOB: 6/11/1996, the FINAL report for Hgb was manually entered as 13. with respect to the Horiba instrument print-out result of Hgb 13.9, which was incorrectly manually entered. f. The laboratory staff attested (3/9 /2023 @ 12:25 PM) that an inaccurate patient FINAL result report of Hgb was noted and incorrect. This FINAL report has been "Audit" (QA) by the laboratory personnel according to the "Audit" policies and procedures once before, but did not catch it.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's patient result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required. The findings include: a. The laboratory director failed to ensure that the proficiency testing samples were tested as required. b. The laboratory uses Horiba EX 60 analyzer to perform Complete Blood Count (CBC) reporting WBC (Leukocyte) with automated cell differentials, RBC (erythrocyte), Hemoglobin (Hgb), Hematocrit (Hct), and Platelet Count (Plt). c. The laboratory enrolled with MLE (Medical Laboratory Evaluation) proficiency testing program to ensure accuracy and reliability of the patient testing result reports. d. The laboratory attained an overall testing event score of 0 % for CBC in the M-3, 2021 PT event, which was unsatisfactory performance see D-2122.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) testing result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; The findings included: a. The laboratory director failed to ensure that all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. b. The laboratory enrolled with MLE (Medical Laboratory Evaluation) proficiency testing program to ensure accuracy and reliability of the patient testing result reports. c. Review of the MLE 2022 M3 PT result records including analyte scores, the laboratory attained scores of 80% for Erythrocyte Count (RBC), Hematocrit, and Leukocyte (WBC), see D-5211 and D-5221.