Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2158577	08/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Escandon Diagnostic Clinic	1300 S Bryan Road, Suite 100 A, Mission, 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	The Escandon Diagnostic Clinic laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an announced validation survey on August 18, 2026 and recertification is recommended. Standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 review of the manufacturer's instructions, laboratory policy and procedure, test reports, pre-survey paperwork, and interview, the laboratory failed to follow its own policy and procedure for handling flagged Complete Blood Count (CBC) indices using the Medonic analyzer for two out of five test reports reviewed from January - April 2026. Finding follow. A. Review of the Medonic M-series User Manual, installed 06/2010 (no revision date), under Section 9: Parameter and System Information Messages at the chart for WBC Differential Abnormalities stated, "Indicator OM Message 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." B. Review of the laboratory's policy and procedure titled Policy for Abnormal Differentials, revised 5/25/2012, stated, "If your CBC instrumentation is showing alarms (R1, R2, M3, etc) in the differential section of the report, do not report the diff. Notify the provider of these flags so he/she can decided if they need a slide

	differential. Slide differentials will be send out." C. Review of randomly selected reports showing flags from the data logs showed two out of five reports were reported that included flags on the WBC differential as listed by Date of Service, Accession number, and flags: 1. 4/22/2026, 231900 LYM # OM LYM % OM MID OM MID % OMGRAN # OMGRAN % OM 2. 4/22/2026, 231909 LYM # OM LYM % OM MID OM MID % OM GRAN # OM GRAN % OM D. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual test volume of 52,692 for the CBC. E. Interview with the technical consultant on August 18, 2026 at 1600 hours confirmed the differential should not have been reported. KEY: WBC = White Blood Cell Count WBC DIFF = White Blood Cell Differential LYM = Lymphocytes MID = Monocytes/Mid GRAN = Granulocytes
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 calibration verification, test reports, policy and procedures, verification of performance specifications records, pre-survey paperwork, and interview, the laboratory failed to verify the performance specifications for accuracy, precision, reportable range, and normal reference range for the Triage Creatinine Kinase- Myocardial Band (CK-MB) test using the Triage Biosite for two of two years reviewed. Findings follow. A. Review of the laboratory's calibration verification from 07/31/2025 with a linearity of 1.5 - 57.2 ng/mL. B. Random review of elevated test reports selected from a generated report from November 2025 - April 2026 showed one test report from 12/01/2025, Accession number 226216, with a CK-MB result of 80 ng/mL. C. The laboratory's policy and procedure defining reportable range was requested on August 18, 2026 at 1645 hours but not provided. D. The laboratory's verification of performance specifications was requested on August 18, 2026 at 1645 hours but not provided. E. Review of the presurvey paperwork titled CMS Form 116 showed an annual test volume of 686. Review of the presurvey paperwork titled Annual Test Volume & Proficiency Testing Programs Worksheet showed the Triage Biosite was added 08/28/2019. F. Interview with the technical consultant on August 18, 2026 at 1645 hours confirmed they did not have a procedure defining the reportable range because the verification of performance specifications was not performed. Correspondence with the technical consultant on August 25, 2026 at 0915 hours confirmed the validation was performed in 2019, but not when the unit was replaced on 07/03/2023.