Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0939396	04/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
San Antonio Preventive & Diagnostic Med	2829 Bobcock Rd, Suite 500, San Antonio, 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 laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results not graded by the proficiency testing agency. The findings include: 1. A review of the laboratory's American Proficiency Institute's Hematology proficiency testing records from 2021 (Events 1, 2 and 3) revealed the following proficiency testing results which were not graded by the proficiency testing agency: a) 1st Event Platelet Estimate (DIF) DIF-01 Blood Cell ID - educational EC1-01 EC1-02 EC1-03 EC1-04 EC1-05 b) 2nd Event Blood Cell ID BC1-07 Platelet Estimate (DIF) DIF-02 Blood Cell ID - educational

	EC1-06 EC1-07 EC1-08 EC1-09 EC1-10 c) 3rd Event Blood Cell ID - educational EC1-11 EC1-12 EC1-13 EC1-14 EC1-15 2. The laboratory was asked to provide documentation of evaluating the identified results. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/20 /2022 at 1015 hours in the laboratory - after her review of the records- confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records for sodium, potassium and chloride from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documention of performing calibration verifications every six months. The findings include: 1. Based on review of the calibration verification records for sodium, potassium, and chloride from 2021 and 2022 revealed the laboratory performed calibration verifications on the following days: January 21, 2021 September 30, 2021 (7 months later) none as of April 20, 2021 (7 months later) 2. The laboratory was asked to provide documentation of performing the calibration verifications every six months as required. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/20 /2022 at 1109 hours in the laboratory - after her review of the records- confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)

	Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records from January 2021 to March 2022, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control over time for 11 of 15 months reviewed. The findings include: 1. A review of the laboratory's hematology quality control records from January 2021 to March 2022 revealed the laboratory failed to have documentation of monitoring control values over time for 11 of 15 months reviewed. The months were: April 2021 May 2021 June 2021 July 2021 August 2021 September 2021 October 2021 November 2021 December 2021 January 2021 March 2022 2. The laboratory was asked to provide documentation of monitoring quality control values for the months identified. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/20/2022 at 1049 hours in the office revealed she did know how to submit the quality control values to the manufacturer's CDS eCQAP program until February 2022. The laboratory utilized this service to monitor quality control values over time. This confirmed the 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 review of the laboratory's CDS eCQAP quality control monitoring records from March 2021 and February 2022 and staff interview, it was revealed the laboratory's quality assessment plan failed to ensure quality control results flagged by the manufacturer were investigated. The findings include: 1. A review of the laboratory's CDS eCQAP quality control monitoring records from March 2021 and February 2022 identified the following quality control parameters which were flagged by the manufacturer indicating further investigation was necessary: a) March 2021 HGB low control flag: S1 Gran # high control flag: S1 RDW low control flag: S1 RDW normal control flag: S1 RDW high control flag: S1 b) February 2022 MCH normal control flag: S1 MCHC normal control flag: S1 Lymph % high control flag: S1 Gran % high control flag: S1 MID % high control flag: S1 S1 = SDI +/- 2.0, results are outside of defined reference limits 2. The laboratory was asked to provide documentation of investigating the identified control values. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/20/2022 at 1049 hours in the office revealed she was unaware of what the S1 flags meant or that the manufacturer required further investigation. This confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421

	The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 4 testing personnel to performed moderate complexity testing (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 4 testing personnel to performed moderate complexity testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified four testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify testing personnel number 4 (as listed on Form CMS 209) to perform moderate complexity testing. Testing personnel number 4 was employed by the laboratory from July 2021 to November 2021. 3. The laboratory was asked to provide documentation of education. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 04/20 /2022 at 0955 hours in the laboratory - after her review of the records- confirmed the findings.