

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0505481	<b>(X3) Date Survey Completed</b> 02/22/2023
<b>Name of Provider or Supplier</b> The Austin Diagnostic Clinic, Pllc, Circle C	<b>Street Address, City, State</b> 5701 Slaughter Lane Bldg C, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plan of correction was discussed with the laboratory representatives at the exit conference. The laboratory representatives 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.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient final reports and confirmed in staff interview, the laboratory failed to follow its own policy for redacting histogram flags for 1 of 5 patients reviewed in February 2023. ***** This is a repeat deficiency from previous survey conducted 09/09/2021.***** Findings Included: 1. Review of laboratory policy, "CBC Sysmex XP-300" (Reviewed on 10/2021) revealed the following: "2. Patient Testing: i. Reporting patient testing results. Results with</p>

histogram flags cannot be reported. Upon completion of the test cycle, results are transmitted to the EMR if the interface is used. All results that have a histogram flag will not be reported in the EMR ... ii. In the event that the instrument interface or EMR is down or not used the CBC results should be 1) printed on the pre-printed paper with normal ranges, 2) a patient label is affixed to the report and, 3) any result with histogram flag must be marked through with a single dark line (use a Sharpie). The report is then scanned into the EMR and a notation is made to the order "see attached report".

2. Review of patient final reports revealed the following 1 of 5 patient final reports that failed to have the histogram flag redacted: a. Performed on: 02/15/2023 at 10:14 a.m. Sample Identification: 8X800295178 Histogram flag: Platelet AG No single dark line was marked through the flag on the report The laboratory failed to follow its own policy for redacting histogram flags for 1 of 5 patients reviewed in February 2023.

3. During an interview with the technical consultant (TC-1) on 02/22/2023 at 09:30 a.m. in the conference room, TC-1 confirmed the above findings.