Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505481	09/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
The Austin Diagnostic Clinic, Pllc, Circle C	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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, test reports, and interview, the laboratory failed to follow its own policy for redacting test results with Histogram flags performed on the Sysmex XP-300 for Complete Blood Counts (CBCs) for 3 of 5 test reports with flags reviewed. Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, revised May 2014, on chapter 8.3 Histogram Flags stated, "When the histogram flags are displayed, perform analysis again. If afterwards the flags are displayed, the sample is considered to correspond to one of the following." For the flag AG under "Probable Sample Cause," stated "Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc." and under Correction stated to "1). Check smear, etc." B. Review of the laboratory's policy and procedure titled CBC Sysmex XP-300, rev 4/17, on page 2 under Patient Testing stated, "g. Results will be transmitted to the EMR via the instrument interface. The report will print to the designated printer, if instrument is set for automatic printing. h. Review results for Histogram flags and critical results. If present repeat CBC testing if there is enough sample or recollect the patient upon Provider request. (Refer to the Instructions for Use manual for Histogram flag details and recommended actions). i. Reporting patient testing results. Results with Histogram flags cannot be reported. i. Upon completion of the test cycle, results are transmitted to the EMR. All results that have a Histogram Flag will reported as 'unable to report' in the EMR. If the testing is repeated, two CBC reports will appear in the EMR. Staff must review the

	reports and delete one with the 'filed in error' function. ii. In the event that the instrument interface or EMR is down, CBC results should be printed on the paper pre-printed with normal ranges. Results with Histogram flags must be marked through with a single dark line. Results are then subsequently entered in to the EMR (age specific normal will be applied for results flagging) when the problem is resolved." C. Review of 3 of 5 patient test reports with flags showed results were reported for indices with Histogram Flags as found below with the date of testing, and identifier, and the indices with the Histogram flagged on the instrument printouts: 1. 08/19/2021; Account # 8X702982583: Platelets flagged with AG+ and reported as 229 2. 08/23 /2021; Accession 10028373: Platelets flagged with AG+ and reported as 381 3. 08/28 /2021; Account # 8X720997000: Platelets flagged with AG+ and reported as 288 D. Interview with the technical consultant on September 9, 2021 at 1145 hours in the breakroom confirmed the flagged indices were reported and not redacted. KEY: EMR= Electronic Medical Record
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, humidity logs, patient testing records, and interview, the facility failed to ensure the humidity was within their established acceptable range and tested patients on 12 days out of 6 months where the humidity had exceeded manufacturer's specifications using the Sysmex XP-300 to test CBCs (Complete Blood Counts). Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, revised February 2013, under 14. Technical Information at 14.2 Specifications for "Operating Environment" stated, "Relative Humidity: 30% to 85%." B. Random review of the Temperature/Humidity Log from January 2021 - June 2021 showed the laboratory range was 30 - 85%, but the laboratory exceeded their range 12 days out of 6 months. Jan 2021: 1. 2nd at 28% humidity, 1 patient tested 2. 4th at 28% humidity, 2 patients tested 3. 5th at 29% humidity, 3 patients tested 4. 12th at 25% humidity, 1 patient tested 5. 13th at 26% humidity, 1 patient tested 6. 14th at 27% humidity, 2 patients tested 7. 15th at 25% humidity, 2 patients tested 8. 18th at 24% humidity, 1 patient tested 9. 28th at 29% humidity 10. 29th at 27% humidity Feb 2021: 11. 22nd at 28% humidity 12. 23rd at 28% humidity C. Interview with the technical consultant on September 9, 2021 at 1230 hours in the breakroom confirmed patient testing was performed on days humidity was out of range.