

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2099494	(X3) Date Survey Completed 07/01/2021
Name of Provider or Supplier Allison H Henderson Md Pa	Street Address, City, State 1112 N Floyd Road, Suite 8, Richardson, 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	<p>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 deficiencies and plans of correction were 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.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, American Association of Bioanalysts (AAB) Proficiency Testing (PT) records (2019) and staff interview, the laboratory director and testing person failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 Hematology events in 2019. Findings Included: 1. Review of laboratory records revealed the laboratory tested hematology samples on the Sysmex pocHi-100i (Serial Number: G5131) for the following analytes which were included in the American Association of Bioanalysts Proficiency Testing: Leukocytes; Erythrocytes; Hemoglobin; Hematocrit; Platelets; Lymphocytes; Monocytes 2. Review of the "AAB Proficiency Testing Service 2019" attestation form, revealed the following statement: "Attestations The undersigned analyst attests that samples were tested in the same manner as patient samples." Further review revealed the proficiency testing analyst and laboratory director failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 events</p>

in 2019. 3. In an interview with the laboratory representative at 10:28 AM on 7/1/21, in the exam room, the representative was asked to provide documentation of the testing person and laboratory director attesting to the routine integration of PT samples into the patient workload. No documentation was provided. This confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of Sysmex pocHi-100i operator's manual and confirmed in staff interview, the laboratory failed to document performance of maintenance for the Sysmex pocHi-100i hematology analyzer for 52 of 52 weeks in 2019 and 2020, and 26 of 26 weeks in 2021. Findings Included: 1. Review of Sysmex pocHi-100i operator's manual stated the following maintenance requirements prior to patient sample analysis: "4 Maintenance.. 4.1.3 Shutdown- Daily.. 4.1.4 Clean Transducer- Every 2 weeks or 150 samples.. 4.1.5 Clean waste chamber- Every 3 months or 1500 samples.." The laboratory failed to provide documentation of performing maintenance on the Sysmex pocHi-100i hematology analyzer (Serial Number: G5131). 2. In an interview with the laboratory representative at 10:48 AM on 7/1/21, in the exam room, the representative was asked to provide documentation of maintenance performance for the Sysmex pocHi-100i hematology analyzer. The representative stated the laboratory performed all required maintenance but could provide no documentation of performing maintenance on the Sysmex pocHi-100i for 52 of 52 weeks in 2019 and 2020, and 26 of 26 weeks in 2021. This confirmed the above findings.