Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999081	04/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	106 Vision Park Blvd, Shenandoah, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) 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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) Performance Evaluations from American Proficiency Institute (API) for 2020, 2021 and 2022 and staff interview it was determined the laboratory failed to document self-evaluation follow up per PT agency's requirements for 3 of 3 results with "Not Graded" designation of performance evaluation. Findings included: 1. Review of the laboratory's PT Performance Evaluation records from API for 2020, 2021 and 2022 revealed: "Laboratories should review the performance Summary and Comparative Evaluation Thoroughly for failure or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Further review of the laboratory's PT

	Performance Evaluation records from API for 2020, 2021 and 2022 revealed the following "Not Graded" PT results which did not have documentation of self-evaluation by the laboratory: 2021 Hematology/Coagulation - 1st Event: Sample: ECl-03 Reported Result:Platelet(s), normal Expected Result: See commentary Performance: Not Graded 2021 Hematology/Coagulation - 2nd Event: Sample: BCl-07 Reported Result: Promyelocyte Expected Result: See Data Summary Performance: Not Graded Sample: ECl-07 Reported Result: Equinocyte (Burr, crenated) Expected Result: See commentary Performance: Not Graded 3. In an interview on 04/12/2022 at 1030 hours in the conference room the laboratory's Quality Manager and Laboratory Director, after review of the data, confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 manufacturer's instructions for use for the Sysmex XS1000i hematology analyzer, review of laboratory's policies, review of random patient records from April of 2022 and staff interview it was determined the laboratory failed to follow it's own policy for addressing flagged results for 1 of 19 patient records reviewed. Findings included: 1. Review of manufacturer's instructions for use for the Sysmex XS1000i hematology analyzer titled "XS-Series Flagging Interpretation Guide" (document number 1269-LSS, Rev. 1, September 2016) revealed: "Any asterisk (*) next to a parameter indicates these results may be unreliable, and should be confirmed according to your laboratory's protocol prior to reporting." 2. Review of laboratory's policy "Hematology Confirmation Criteria and Procedures" (document KHE-P(1).009.008) revealed: " B. REVIEW WBC MORPHOLOGY 1. When abnormalities are detected in the WBC count or morphology a REVIEW WBC MORPHOLOGY is required." And, "D. REVIEW PLATELETS 1. When abnormalities are detected in the PLT count or morphology, a REVIEW PLATELETS is required. A blood smear is made of the patient's sample and stained." 3. Review of random patient records from April of 2022 revealed the following 1 of 19 patients's records reviewed contained results that were flagged with an asterisk (*) by the instrument and were transcribed to a final report without documentation of smear review: Patient ID: 94196466 Patient Alternate Control Number: 107948834126764895 Collected: 04/12/2022 Date reported: 04/12/2022 Instrument Printout: Analyte: Results: WBC 4.44* [10^3/uL] PLT 185* [10^3/uL] NEUT 2.51* [10^3/uL] 56.5* [%] LYMPH 1.33* [10^3/uL] 30.0* [%] MONO 0.49* [10^3/uL] 11.0* [%] EO 0.07* [10^3/uL] 1.6* [%] BASO 0.04* [10^3/uL] 0.9* [%] Final Report: Analyte: Results: WBC 4.4 [10^3/uL] PLT 185 [10^3/uL] NEUT 2.5 [10^3 /uL] 56 [%] LYMPH 1.3 [10^3/uL] 30 [%] MONO 0.5 [10^3/uL] 11 [%] EO 0.1 [10^3/uL] 2 [%] BASO 0.0 [10^3/uL] 1 [%] 4. In an interview on 04/12/2022 at 1210 hours in the conference room the laboratory's Quality Manager and Laboratory Director, after review of the data, confirmed the findings. Legend: WBC = White blood cells PLT = Platelets NEUT = Neutrophils MONO = Monocytes EO = Eosinophils BASO = Basophils
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of personnel's competency assessments for 2020,2021 and 2022 and staff interview it was determined the laboratory's technical consultant failed to document semiannual competency assessment in the first year of employment for Testing Person number 3 (TP3), one of eight testing personnel. Findings included: 1. Review of the laboratory's personnel records revealed there were 8 testing personnel employed by the laboratory, out of which TP3 was hired in October of 2020. 2. Review of personnel's competency assessments for 2020,2021 and 2022 revealed TP3 did not have documentation of semiannual competency assessment within the first year of testing. Competency assessment dates for TP3 were as follows:Initial: 10/22/2020 Annual: 12/06/2021 3. In an interview on 04/12/2022 at 1000 hours in the conference room the laboratory's Quality Manager and Laboratory Director, after review of the data, confirmed the findings.