Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2071404	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	515 W Mayfield Rd Suite 201, Arlington, 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	An entrance conference was held 10/07/2020 with the Laboratory Director and Quality Manager. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 10/07/2020, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1441 High Complexity - Laboratory Director An exit conference was held on 10/07/2020 with the Laboratory Director and Quality Manager. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory policy, Centers for Disease Control and Prevention (CDC) guidelines, patient test records, personnel records, and staff interview, it was revealed the laboratory director failed to have documentation to qualify as a laboratory director overseeing high complexity testing (refer to D6078).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an

operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policy, Centers for Disease Control and Prevention (CDC) guidelines, patient test records, personnel records, and staff interview, it was revealed the laboratory director failed to have documentation to qualify as a laboratory director overseeing high complexity testing. Findings: 1. A review of the laboratory's Peripheral Blood Smear Examination policy page 7 revealed: "4. Scan counting field for WBC subpopulations (Refer to Hematology Standardized Abbreviations Policy for appropriate use of canned messages and REVIEW CRITERIA for review) Verify automated differential. Note degenerative changes. The automated analyzer count should be accepted unless increased (>2%) immature and/or abnormal cells are noted, and/or differential is grossly inaccurate (false increase in any cell line due to poor cell distribution (usually mixing error) or analyzer not recognizing degenerating cells, hypogranular, hyposegmented cells, etc.). Unless these observations are made a manual differential is not performed ... Metamyelocytes, Myelocytes: A manual differential is performed when >2% of any one or more are observed on scan of the counting field. 1-2 of either cell type observed on scan of the counting field or CellaVision is reported as OMET, OMYS. >5% Myelocytes must have further review prior to reporting." Page 10 revealed: "The most commonly encountered cells are segmented neutrophils, lymphocytes, monocytes, eosinophils, and occasional basophils and band neutrophils. Any unidentifiable, abnormal cell or immature WBCs and RBCs should be referred to the SH/Pathologist for review." 2. Review of CDC guidelines revealed: "Regulations for

	Implementing the Clinical Laboratory Improvement Amendments of 1988: A Summary ... CATEGORIES OF TESTS BY COMPLEXITY ... TABLE 3. Tests of high complexity, as specified in the preamble to the regulations for implementing the Clinical Laboratory Improvement Amendments of 1988 Clinical cytogenetics -- all procedures Histocompatibility -- all procedures Histopathology -- all procedures Cytology -- all procedures Bacteriology ... Manual white blood cell differentials with identification of atypical cells" 3. Review of patient records from 10/05-10/07/2020 revealed 4 of 40 peripheral blood smear differentials were performed and reported with immature white blood cells. The patients are as follows: Patient ID: 279-M62-0020-0 Collection date: 10/05/2020; Final report date: 10/05/2020 final report stated "Neutrophils ...2% Metamyelocytes" Patient ID: 279-M62-0010-0 Collection date: 10 /05/2020; Final report date: 10/05/2020 final report stated "Neutrophils ...2% Metamyelocytes 1% Myeolcytes" Patient ID: 279-M62-0023-0 Collection date: 10/05 /2020; Final report date: 10/05/2020 final report stated "Neutrophils ...1% Metamyelocytes" Patient ID: 281-M62-0005-0 Collection date: 10/07/2020; Final report date: 10/07/2020 final report stated "Neutrophils ...1% Metamyelocytes" During an interview on 10/07/2020 at 9:10 am, the Laboratory Director stated the most immature cell reported from the peripheral blood smear was a band. 4. A review of the laboratory's personnel records revealed the laboratory director was NOT a Texas licensed physician certified in anatomical or clinical pathology or both, or a PhD in chemical, physical, biological, or clinical laboratory science. 5. During an interview on 10/07/2020 at 12:43 pm, the Laboratory Director and Quality Manager confirmed the above findings.