

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D2227560	<b>(X3) Date Survey Completed</b>  09/21/2023
<b>Name of Provider or Supplier</b>  Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b>  17050 W 96th St, Lenexa, KS	
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>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 the review of the procedure "Proficiency Testing", proficiency testing (PT) submission forms, corrective action document and interview with the site supervisor, the laboratory failed to follow procedure and review PT submission forms prior to uploading to the PT provider, American Proficiency Institute (API). Findings: 1. The procedure "Proficiency Testing" signed by the laboratory director (LD) 11/18/21, page 2, item 2 f) (3) states: "Verify each printed result entry against original raw data (manual recording or instrument tape). Place a small check mark beside each result verified. Initial the top of the print preview form, include a large R after your initials to indicate results were reviewed, and date." 2. Evaluation of API PT results of Hematology 1st Event 2022, signed by the LD 4/28/22, included unacceptable results for Neutrophil (%) for sample XE-02, White Cell Count for sample XE-02, and Ketones for UA-01. The LD noted that the three errors were caused by "clerical error." The LD noted "tech counseled." No documentation of review of the submission page prior to submitting to API was provided at the time of survey. 3. Evaluation of API PT results of Hematology 3rd Event 2022, signed by the LD 12/27/22, included unacceptable results on samples XE-11, XE-12, XE-13, XE-14 and XE-15 for: Basophils %, Eosinophils %, Lymphocytes %, Monocytes % and Neutrophils %. The LD noted "Tech entered absolute values instead of percentages. All values on analyzer printoffs would have been acceptable." No documentation of review of the submission page prior to submitting to API was provided at the time of survey. LD noted: " Coached up tech to see what values API was expecting." 4. Interview with the</p>

site supervisor 9/21/23 at 12:25 p.m. confirmed, the laboratory failed to follow procedure and review PT submission forms prior to uploading to the PT provider, API.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based upon a review of the CMS 209 form, laboratory's personnel competency assessment records, daily status report and staff interview, the technical consultant (TC) failed to ensure that three of three testing personnel (TP) performing moderate complexity testing were assessed for all required elements of competency. Findings:

1. The CMS209 form lists three testing personnel for 2023: TP #1, TP #2, and TP #3.
2. Review of all three TP annual competency forms revealed that all three were completed on 8/23/23. a. Each competency form "TECHNICAL PERSONNEL COMPETENCY DOCUMENTATION" has "DIRECT OBSRVATION-Routine test performance, patient preparation, specimen handling, processing and testing." i. All non-waived assays (CBC, HCG serum, Mono, UA micro and Wet Prep) for patient testing are marked. ii. Signature of the TC, who is also the laboratory director on the three 2023 competencies are dated 9/14/23. b. The surveyor asked if the TC was at the site on 8/23/23. The site supervisor stated the TC was not present at the site on 8/23/23. c. Surveyor asked for documentation of testing performed at the site on 9/14/23. The document provided was the Daily Status Report and showed that the only possible non-waived test performed on 9/14/23 was one Urinalysis. The document does not include whether a urine sediment was examined.
3. The competency form included "DIRECT OBSERVATION OF INSTRUMENT PERFORMANCE, MAINTENANCE AND FUNCTION CHECKS." a. TP#1 and TP#3 competency forms stated, "All routine instrument maintenace (sp) Logs are signed off." b. TP#2 competency form stated, "Watched (TP #2) perform routine instrument maintenace (sp)." 4. The surveyor asked if all three TP were at the lab on 9/14/23. The site supervisor checked the monthly schedule and stated that TP#3 was at the site on 9/14/23. TP #1 and TP#2 were not at the site on 9/14/23. 5. No documentation was made available at the time of survey for the direct observation by the TC for TP#1, TP #2 and TP #3: i. For routine patient test performance. ii. For instrument maintenance and function checks. 6. Interview with the site supervisor on 9/21/23 at 12:25 p.m. confirmed the technical consultant (TC) failed to ensure that three of three testing personnel (TP) performing moderate complexity testing were assessed for all required elements of competency.