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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0664370 | (X3) Date Survey Completed 07/24/2019 |
| Name of Provider or Supplier West Loop Laboratory | Street Address, City, State 300 North John Redditt Dr Suite #7, Lufkin, 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 |
|---------------------------|---|
| D2123 | <p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: . Based on review of College of American Pathologists (CAP) proficiency testing (PT) documentation for 2019, confirmed by staff interview, the laboratory failed to participate in PT for hematology in the 1st event of 2019. Findings: 1. During document preparation for the survey, it was noted that no PT results for hematology were available for the first event of 2019. 2. On inquiry, testing person 1 (CMS form 209) stated that in a telephone conversation with the vendor supplying PT near the end of the previous year, she had given verbal authorization to continue purchase of CAP PT for 2019, and that the vendor had failed to complete the order to reenroll. 3. In an interview at the site on 07-24-2019, testing person 1 confirmed that no PT for hematology was performed for the 1st event of 2019. .</p> |
| D5215 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance</p> |

(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

. Based on review of CAP PT documentation for 2017 and 2018, confirmed by staff interview, the laboratory failed to verify the accuracy of hematology testing assigned proficiency testing scores that did not reflect laboratory test performance. Findings: 1. CAP hematology PT results for the 3rd event of 2017 and 1st, 2nd and 3rd events of 2018 were reviewed. In all events for Centrifugal Hematology, scores for White Blood Cell Count, Hemoglobin, Hematocrit and Platelet Count were graded with a coded result, (20). 2. Review of the evaluation cover sheets for the above testing events revealed the following notation: LEGEND: Exception codes appearing in this evaluation: (20)=No appropriate target/response cannot be graded. 3. Review of the evaluation reports for the above testing events showed that in each case the number of laboratories participating was less than 10. A minimum of 10 reporting participants is required for PT providers to score any analyte. 4. In an interview at the site on 07-24-2019, testing person 1 stated that she was unaware of the requirement to verify the accuracy of unscored PT results. No alternate method was employed for accuracy verification of the analytes not scored. .

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

. Based on surveyor observation, review of CAP PT documentation for 2019 and staff interview, the laboratory director (CMS form 209) failed to ensure the laboratory was enrolled in an approved proficiency testing program for hematology in the first event of 2019. Refer to D2123.