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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>37D0471917 | <b>(X3) Date Survey Completed</b><br>11/18/2021 |
| <b>Name of Provider or Supplier</b><br>Schafer Medical Center  | <b>Street Address, City, State</b><br>800 Isabel Sw, Ardmore, OK       |   |
| 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>  |
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| <b>D0000</b>              | The recertification survey was performed on 11/18/2021. The findings were reviewed with testing person #1 and the laboratory director at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.   |
| <b>D5411</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to follow the manufacturer's instructions for verifying automated differential flags for 8 of 9 patient reports. Findings include: (1) On 11/18/2021 at 09:45 am, testing person #1 stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (2) The surveyor reviewed the manufacturer's operator's manual for information regarding flagged results. The following was identified: (a) For [AG] flag the instructions stated, "Check smear, etc."; (3) The surveyor then reviewed patient records and identified that for 8 of 9 records reviewed, the laboratory had not verified the results when automated differential flags were obtained as follows: (a) [AG] flag obtained on a patient sample tested on 01/04/2021 at 09:11 am; (b) [AG] flag obtained on a patient sample tested on 01/08/2021 at 11:18 am; (c) [AG] flag obtained on a patient sample tested on 01/11/2021 at 10:08 am; (d) [AG] flag obtained on a patient sample tested on 01/20/2021 at 10:22 am; (e) [AG] flag obtained on a patient sample tested on 01/20/2021 at 10:24 am; (f) [AG] flag obtained on a patient sample tested on 01/20/2021 at 10:25 am; (g) [AG] flag obtained on a patient sample tested on 01/22/2021 at 11:21 am; (h) [AG] flag obtained on a patient sample tested on 01/29/2021 at 11:44 am. (5) The findings</p> |

were reviewed with testing person #1 who stated on 11/18/2021 at 12:45 pm, the laboratory had not followed the manufacturer's instructions as indicated above.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with testing person #1, the laboratory failed to perform at least two levels of control materials each day of patient hematology testing using the Sysmex XP-300 analyzer for 1 of 23 days of patient testing. Findings include: (1) On 11/18/2021 at 09:50 am, testing person #1 stated to the surveyor: (a) The laboratory performed hematology testing using the Sysmex XP-300 analyzer; (b) Three levels of Eightcheck - 3WP X-TRA quality control (QC) materials were performed each day of patient testing. (2) The surveyor reviewed QC and patient testing records from 03/01/2021 through 03/31/2021; The documentation showed at least two levels of QC testing had not been performed each day of patient CBC testing for 1 of 23 days of patient testing. The specific day was 03/17/2021; (3) The surveyor reviewed the records with testing person #1. Testing person #1 stated on 11/18/2021 at 01:00 pm, at least two levels of QC materials had not been performed each day of patient CBC testing as indicated above.