

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1065302	(X3) Date Survey Completed 06/05/2019
Name of Provider or Supplier Weatherford Lab & X-Ray	Street Address, City, State 3733 Legacy Drive, Weatherford, OK	
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	The recertification survey was performed on 06/05/19. The findings were reviewed with testing person #2 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory failed to provide written instructions to clients collecting and referring hematology and urinalysis specimens. Findings include: (1) At the beginning of the survey, testing person #2 stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS 1000i analyzer; (i) Hematology specimens were transported to the laboratory from local home health agencies and the nursing home. (b) The laboratory performed routine urinalysis testing using the Clinitek Status (waived test method) and microscopic urine sediment examinations. (i) Urine specimens were transported to the laboratory from local home health agencies and the nursing home. (2) The surveyor asked testing person #2 if instructions (e.g., client service manual) had been written and provided to the home health agencies and nursing home which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). Testing person #2 stated specimen handling instructions had not been written and provided to the clients.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</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.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with testing person #2, the laboratory failed to follow the manufacturer's instructions for Hematology. Findings include: (1) At the beginning of the survey, testing person #2 stated CBC (Complete Blood Count) testing was performed on the Sysmex XS1000i analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer: (a) "Thrombocytosis" - " Verify on slide." (3) The surveyor randomly reviewed 9 patient records containing flags from CBC testing performed during 05/23/19 through 06/05 /19. For 1 of 9 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flag: (a) Patient #1 - Testing was performed on 05/29/19 at 11:13 am (4) The surveyor reviewed the records with testing person #2 who stated the flag obtained for the above patient had not been documented as verified.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with testing person #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) At the beginning of the survey, testing person #2 stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS1000i analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs: (a) Monthly Maintenance (i) Perform Monthly Rinse (1,200 cycles) (3) The surveyor then reviewed maintenance records from February 2019 through the day of the survey (06/05/19). There was no evidence the monthly maintenance had been performed: (a) Between 02/12/19 and 06/05/19 (4) The surveyor reviewed the records with testing person #2 , who stated the weekly maintenance had not been documented as performed as indicated above. D5429 was cited on the recertification survey performed on 11/01/17.