Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1076263	10/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Utica Park Clinic Chouteau	108 W Main St, Chouteau, 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 10/12/2020. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, observation of the laboratory, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) At the beginning of the survey, the technical consultant stated the laboratory performed patient glucose testing using the Contour analyzer; (2) The surveyor reviewed the manufacturer's instructions for the test strips which stated, "Check the expiration dates on your test strips and control solution. It is important to not use the test strips or control solution if the expiration date printed on the bottle label and carton has passed."; (3) The surveyor then observed one bottle of expired test strips available for patient use (lot# DW83J3D01D with an expiration date of 02/29/2020); (4) The surveyor reviewed the above findings with the technical consultant who stated on 10/12/2020 at 12:15 pm the test strips were expired.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the technical consultant, the laboratory failed to follow written procedures for CBC (Complete Blood Count) testing. Findings include: LOT VERIFICATION (1) At the beginning of the survey, the technical consultant stated to the surveyor: (a) CBC testing was performed on the Medonic M-Series hematology analyzer; (b) The laboratory tested 3 levels (Low, Normal, High) of Boule Con-Diff Quality Control (QC) materials each day of patient testing. (2) Later during the survey, the surveyor reviewed the written procedure titled, "Quality Control" which stated, (a) "New lot will be tested in parallel with previous lot to verify the manufacturer's stated ranges." (3) The surveyor reviewed records for 6 control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 3 of 6 lot numbers as follows: (a) Low control (lot #2202-31), normal control (lot #2202-32), and high control (lot #2202-33) put into use on 06/10/2020. (3) The findings were reviewed with the technical consultant who stated on 10/12/2020 at 03:45 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use. CRITERIA FOR REPEATING CBC SAMPLES (1) The surveyor reviewed the written procedures titled, "Medonic Flagged Results Policy", which stated, (a) "WBC Differential results may be flagged BD, NM, OM, and TM If the patient sample is flagged the sample is held for 5-10 minutes and the test repeated. If the flags have been removed or are still present in the same location the results are reported. At the physician's discretion the sample may be referred for further testing." (2) The surveyor reviewed 2 patient records that had been tested between August 2020 through September 2020. For 1 of 2 patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient tested 08/25 /2020 at 09:47 am - OM flag. (3) The surveyor reviewed the findings with technical consultant who stated on 10/12/2020 at 03:00 pm that the procedure had not been followed as indicated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory failed to ensure the verified reportable range was used by the laboratory. Findings include: (1) At the beginning of the survey, the technical consultant stated the laboratory began using the Medonic M-Series analyzer to perform routine CBC (Complete Blood Count) testing beginning 07/19/2018; (2) The surveyor reviewed the validation records for the analyzer. The reportable range was verified as follows: (a) Platelet 30 - 959 x 10 ^ 9 /L (3) The surveyor then reviewed the analyzer's reportable

	range and identified the following reportable range used by the laboratory was wider than the verified reportable range: (a) Platelet 30 - 1800 x 10 ^ 9 /L (4) The surveyor reviewed the result with the technical consultant who stated on 10/12/2020 at 03:45 pm the laboratory analyzer 's reportable range was wider than the verified reportable range.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) Later during the surveyor, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 10/12/2020 at 10:15 am; the second report was for an adult female patient with the testing performed on 12/12/2020 at 09:15 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 4.10 - 5.50 M /L (b) Hemoglobin - 14.0 - 18.0 g/dL (c) Hematocrit - 42.0 -52.0 % (3) The surveyor reviewed the findings with the technical consultant, who stated on 10/12/2020 at 02: 15 pm the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.