

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D1002185	<b>(X3) Date Survey Completed</b>  10/13/2020
<b>Name of Provider or Supplier</b>  Utica Park Clinic Locust Grove	<b>Street Address, City, State</b>  609 East Main, Locust Grove, 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>
<b>D0000</b>	The recertification survey was performed on 10/13/2020. 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.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the testing person failed to sign a proficiency testing attestation statement for 2 of 6 events. Findings include: (1) The surveyor reviewed 2019 and 2020 proficiency testing records and identified the following for 2 of 6 events: (a) First 2020 Hematology /Coagulation Event - The attestation statement had not been signed by the testing person performing the test; (b) Second 2020 Hematology/Coagulation Event - The attestation statement had not been signed by the testing person performing the test. (2) The surveyor reviewed the findings with the technical consultant, who stated to the surveyor on 10/13/2020 at 10:30 am, the attestation statements had not been signed by the person performing the test.</p>

**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 for 2 of 3 patient reports. Findings include: (1) On 10/13/2020 at 10:00 am, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic analyzer; (2) 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." (b) "If the sample volume is not sufficient for repeat analysis, another sample can be drawn OR the flagged result may not be reported in LabDaq and, if paper printouts are reviewed by the provider, the flagged results must be blacked out completely." (3) The surveyor reviewed 3 patient reports that had been tested between January 2020 through August 2020. For 2 of 3 patient reports there was no indication the laboratory staff followed their written procedure as follows: (a) Patient tested 07/24/2020 at 09:19 am - No evidence the provider reviewed the OM flag; (b) Patient tested 08/12/2020 at 11:01 am - No evidence the provider reviewed the OM flag. (3) The surveyor reviewed the findings with the technical consultant who stated on 10/13/2020 at 02:45 pm that the procedure had not been followed as indicated above.

**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 the technical consultant, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) On 10/13/2020 at 10:00 am, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic analyzer; (2) The surveyor reviewed the manufacturer's monthly maintenance requirement for the analyzer, as stated on the manufacturer's maintenance log which were: (a) Clean the aspiration probes using an alcohol wipe; (b) Fill a cup with 10 ml 2% hypochlorite (Bottle #2 from Boule Cleaning Kit) and one cup with 18 ml diluent. Aspirate the hypochlorite as a pre-dilute sample; (c) Run 2 blank samples by aspirating diluent as a pre-diluted sample; (d) Perform a background check, in pre-dilute mode, to verify all values are within range. (3) Maintenance records were reviewed by the surveyor for 12 months (January 2020 through December 2020). The monthly maintenance had not been documented as

performed between: (a) 08/10/2020 and 10/30/2020 (4) The surveyor reviewed the records with the technical consultant, who stated on 10/13/2020 at 10:30 am, there was no evidence the above maintenance had been performed as required.