

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D1002185	<b>(X3) Date Survey Completed</b>  07/10/2024
<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 07/10/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, observation of the laboratory, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for expiration dates of mononucleosis testing kits. Findings include: (1) On 07/10/2024 at 1:45 pm an observation of the laboratory revealed the following expired materials which appeared to be available for use: (a) Three Clarity mononucleosis tests, lot #222D11A, with a manufacturer's expiration date of 12/2023. (2) The findings were reviewed with the technical consultant, who stated on 07/10/2024 at 1:45 pm the test kits had expired and were available for use.</p>
<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</p>

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.

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 proficiency testing attestation records had been signed by the laboratory director for one of five events reviewed. Findings include: (1) On 7/10/2024 at 1:50 pm, a review of 2023 and 2024 proficiency testing records identified the following for one of five events: (a) 2023 Hematology - Second Event (i) The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the technical consultant, who stated on 07/10/2024 at 1:50 pm, the attestation statement had not been signed by the laboratory director.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

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 patient test reports included the facility name, as stated on the CLIA certificate for one of one report reviewed. Findings include: (1) On 07/10/2024 at 2:00 pm, the technical consultant stated CBC testing was performed using the Medonic M-Series analyzer; (2) A review of a patient report identified the facility name, as stated on the CLIA certificate, was not included on the report: (a) Patient CBC testing resulted on 07/03/2024 (3) The findings were reviewed with the technical consultant, who stated on 07/10/2024 at 2:00 pm, the laboratory name had not been included on the patient test reports.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the

laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of five proficiency testing events reviewed in 2023 and 2024. Findings include: (1) A review of 2023 and 2024 proficiency testing events identified attestation statements had been signed up to three months after the samples had been tested for one of five events reviewed: (a) First Hematology Event 2024 - The sample testing had been completed on 03/15/2024 and the attestation statement had not been signed by the laboratory director until 07/8/2024. (2) The records were reviewed with the laboratory director who stated on 7/10/2024 at 02:00 pm the attestation statements had not been signed timely as stated above.