

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0716134	(X3) Date Survey Completed 07/12/2021
Name of Provider or Supplier Utica Park Clinic Elliott	Street Address, City, State 562 S Elliott, Pryor, 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 07/12/2021. 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	<p>CERTIFICATE OF WAIVER TESTS 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 and interview with the technical consultant, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for 3 of 3 patient specimens. Findings include: (1) On 07/12/2021 at 10:30 am, the technical consultant stated the following to surveyor #2: (a) The laboratory performed COVID-19 Testing using the following instrument: (i) Sofia 2 Flu + SARS Antigen FIA (Fluorescent Immunoassay) - qualitative detection of nucleocapsid protein from influenza A and influenza B, and SARS-CoV-2 from direct nasal swabs. (2) Surveyor #2 reviewed the manufacturer's product insert titled, "Sofia 2 Flu + SARS Antigen FIA". Under the section titled, "USING SOFIA 2" the manufacturer stated, "Warning: Results must not be interpreted past 30 minutes after inoculation. Using the Sofia 2 past this time may result in false results"; (3) Surveyor #2 reviewed 3 test reports for patients tested between 06/24/2021 and 07/07/2021 and identified the following: (a) Patient Report #1 -Specimen collection date and time (06/24/2021 at 11:41 am) was the same as the result date and time (06/24/2021 at 11:41 am); (b) Patient Report #2 - Specimen collection date and time (06/24/2021 at 03:16 pm) was the same as the result date and time (06/24/2021 at 03:16 pm); (c) Patient Report #3 - Specimen collection date and time (07/07/2021 at 11:46 am) was the same as the result date and time (07/07/2021 at 11:46 am). (4) Surveyor #2 was not able to</p>

determine if the results had been interpreted within the 30 minutes after inoculation since the specimen collection date and time was the same as the result date and time; (5) Surveyor #2 reviewed the records with the technical consultant. The technical consultant stated on 07/12/2021 at 12:50 pm the laboratory could not prove the results had been interpreted within 30 minutes after inoculation as indicated above.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or 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 verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 1 of 18 events. Findings include: (1) On 07/12/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2020 Third Event - Urine Sediment sample US-06 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) Surveyor #2 asked the technical consultant if the result had been documented as evaluated. The technical consultant reviewed the records and stated on 07/12/2021 at 12:45 pm the non-graded result had not been documented as reviewed.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

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 calibration procedures as required by the manufacturer. Findings include: (1) On 07/12/2021 at 10:25 am, the technical consultant stated to surveyor #2 CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) Surveyor #2 reviewed the manufacturer's instructions, contained in the "Medonic M-Series Users Manual" for performing calibration procedures. The section on page 59 titled, "Section 7: Calibration" stated, "This section describes the step-by-step procedure for calibration

of the Medonic M-Series. The instrument has been calibrated by Boule prior to shipment. Good laboratory practice, however, requires regular checks and calibration of the measured parameters. It is recommended to calibrate the instrument every 6 months"; (3) Surveyor #2 reviewed records from 10/25/2019 through 04/29/2021. There was no evidence the calibration procedure had been performed between 10/25/2019 and 10/12/2020; (4) Surveyor #2 reviewed the findings with the technical consultant who stated on 07/12/2021 at 12:50 pm, the calibration procedure had not been performed as indicated above.

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 a patient report and interview with the technical consultant, the laboratory failed to provide normal reference intervals for 1 of 1 urine sediment examination test reports. Findings include: (1) On 07/23/2021 at 10:25 am, the technical consultant stated to surveyor #2 Urine Sediment examinations were performed; (2) Surveyor #2 reviewed one Urine Sediment examination report for a patient tested on 05/03/2021 at 03:11 pm. The report did not include a normal reference range for the urine sediment examination; (3) Surveyor #2 reviewed the report with the technical consultant, who stated on 07/12/2021 at 12:52 pm Urine Sediment examination reports did not include a normal reference range as indicated above.