

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473884	(X3) Date Survey Completed 08/18/2021
Name of Provider or Supplier Utica Park Clinic-Family Medical	Street Address, City, State 3316 E 21st, Suite A, Tulsa, 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 08/18/2021. The findings were reviewed with the laboratory director 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 laboratory director, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for 3 of 3 patient specimens. Findings include: (1) On 08/18/20201 at 10:20 am, the laboratory director stated the following to the surveyor: (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) The surveyor 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) The surveyor reviewed 3 test reports for patients tested between 08/11/2021 and 08/16/2021 and identified the following: (a) Patient Report #1 -Specimen collection date and time (08/11/20201 at 03:08 pm) was after the result date and time (08/11/2021 at 01:13 pm); (b) Patient Report #2 - Specimen collection date and time (08/13/20201 at 02:12 pm) was after the result date and time (08/13/2021 at 12:17 pm); (c) Patient Report #3 - Specimen collection date and time (08/16/20201 at 11:01 am) was after the result date and time (08/11/2021 at 09:06 am). (4) The surveyor was not able to determine if the results</p>

had been interpreted within the 30 minutes after inoculation since the specimen collection date and time was after the results date and time; (5) The surveyor reviewed the records with the laboratory director. The laboratory director stated on 08/18/2021 at 12:50 pm the laboratory could not prove the results had been interpreted within 30 minutes after inoculation as indicated above.

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 laboratory director, the laboratory failed to perform calibration procedures as required by the manufacturer. Findings include: (1) On 08/18/2020 at 10:15 am, the laboratory director stated to the surveyor CBC (Complete Blood Count) testing was performed using the Medonic CA-620 analyzer; (2) The surveyor reviewed the manufacturer's instructions, contained in the operator's manual which were as follows: (a) Section 10.4 titled, "Calibration through a Certified Calibrator" described the step-by-step procedure for calibration of the Medonic CA-620 analyzer and stated, "Recommended calibration periods is twice a year with a "Hematology Blood Calibrator" certified by Boule. Good laboratory practice involves regular daily checks with blood controls to assure the analyzer and reagents are fully functional. Calibration procedures are carried out to minimize any possible drift caused by tolerances in reagents, environment-changes or instrument."; (3) The surveyor reviewed records from 07/13/2019 through 07/14/2021. There was no evidence the calibration procedure had been performed between 07/13/2019 and 12/31/2020; (4) The surveyor reviewed the findings with the laboratory director who stated on 08/18 /2021 at 12:15 pm, the calibration procedure had not been performed as indicated above.