

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2168136	(X3) Date Survey Completed 03/29/2021
Name of Provider or Supplier Premier Plus Urgent Care	Street Address, City, State 2804 Sw 134th St, Oklahoma City, 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 initial survey was performed on 03/29/2021. The findings were reviewed with testing person #1 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 testing person #1, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for 3 of 3 patient specimens. Findings include: (1) On 03/29/2021 at 11:45 am, testing person #1 stated the following to the surveyor: (a) The laboratory performed COVID-19 Testing using the following instrument (i) Abbott ID Now - qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal swabs. (2) The surveyor reviewed the manufacturer's product insert titled, "ID NOW COVID-19 PRODUCT INSERT". Under Specimen transport and storage, the manufacturer stated, "Direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, the nasal, throat or nasopharyngeal swab can be held in its original package (or placed in a conical tube and capped tightly) at room temperature (15-30C) for up to two (2) hours prior to testing. If a direct nasal, throat or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8C and tested within 24 hours from the time of sample collection." (3) The surveyor reviewed 3 test reports for patients tested between 12/29/2020 and 12/31/2020. The reports did not include the following to ensure patient specimens followed manufacturer's instructions: (a) Date and time of specimen collection; (b) Date and time of specimen receipt into the laboratory; (c)</p>

Date and time of specimen testing. (4) The reports were reviewed with testing person #1, who stated on 03/29/2021 at 03:05 pm the patient reports did not include a specimen information 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 testing person #1, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) On 03/29/2021 at 11:45 am, testing person #1 stated to the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex pocH-100i analyzer; (b) A replacement pocH analyzer was put into use on 06/21/2021. (2) The surveyor reviewed the manufacturer's quarterly maintenance requirement for the analyzer, as stated on the manufacturer's maintenance log titled "pocH-100i (Trademark) MAINTENANCE LOG", which was: (a) Clean Waster Chamber (3) Maintenance records were reviewed by the surveyor for 6 months (July 2020 through December 2020). The quarterly maintenance for the 3rd and 4th quarter had not been documented as performed; (4) The surveyor reviewed the records with testing person #1. The testing person stated on 03/29/2021 at 03:00 pm, there was no evidence the above maintenance had been performed as required.