

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D2020809	<b>(X3) Date Survey Completed</b> 05/02/2022
<b>Name of Provider or Supplier</b> Cpn West Clinic	<b>Street Address, City, State</b> 781 Grand Casino Blvd, Suite 134 Lab, Shawnee, 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 05/02/2022. 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>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H 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 review and evaluate proficiency testing results for one of 16 events. Findings include: (1) On 05/02/2022, a review of 2021 and 2022 proficiency testing records and revealed the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) 2022 First Chemistry Core Event (i) Free Thyroxine - four of five results exhibited a negative bias (aa) Sample THY-01- SDI of -2.4 (bb) Sample THY-03- SDI of -2.4 (cc) Sample THY-04- SDI of -2.9 (dd) Sample THY-05- SDI of -3.1 (2) There was no evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the technical consultant. The technical consultant stated on 05/02/2022 at 12:00 pm the bias had not been addressed.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as</p>

determined under 493.1253.

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 follow the manufacturer's instructions for verifying white blood cell flags for one of three patient reports. Findings include: (1) On 05/02/2022 at 11:00 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XP-1000i analyzer. (2) A review of the manufacturer's instructions was performed for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) NRBC? - "Verify presence on slide, correct WBC count if necessary" (3) A review was performed of three patient records that contained flags from CBC testing. For one of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags as follows: (a) Patient Sample #9806 - Testing was performed on 01/10/2022 at 09:19 am, with an NRBC? flag obtained. (4) The records were reviewed with the technical consultant, who stated on 05/02/2022 at 01:35 pm that the flag obtained for the patient had not been verified as shown 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 follow the manufacturer's instructions for weekly maintenance procedures for one of four months. Findings include: (1) On 05/02/2022 at 11:00 am, the technical consultant stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XP-1000i analyzer. (2) A review of the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs: (a) Weekly: (i) Power Down IPU (3) A review of maintenance records for four months (January 2022 through April 2022) revealed the following: (a) There was no evidence the weekly maintenance had been performed (i) Between 03/18/2022 and 04/01/2022 (4) The records were reviewed with the technical consultant who stated on 05/02/2022 at 01:50 pm, the maintenance had been performed but not documented.