

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D1054775	<b>(X3) Date Survey Completed</b>  05/16/2022
<b>Name of Provider or Supplier</b>  Koweta Indian Health Facility	<b>Street Address, City, State</b>  31870 East State Highway 51, Coweta, 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 05/16/2022. The findings were reviewed with the laboratory consultant and technical consultant #2 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D1001</b>	<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 consultant, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for four of four patient specimens. Findings include: (1) On 05/16/2022 at 11:00 am, the laboratory consultant stated: (a) The laboratory performed COVID-19 testing using the following instrument (i) Abbott BinaxNOW COVID-19 Ag Card - qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal swabs. (2) A review of the manufacturer's product insert titled, "BinaxNOW COVID-19 Ag" under the section titled, "TEST PROCEDURE", which stated: (a) "4. Peel of adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes." (3) A review of four test reports for patients tested on 05/11/2022, 05/12/2022, 05/13/2022 and 05/16/2022 identified the following: (a) Patient Report #4004153415 - Specimen collection date and time (05/11/2022 at 02:01 pm) and the result date and time (05/11/2022 at 02:05 pm), four minutes later; (b) Patient Report #4004245892 - Specimen collection date and time (05/12/2022 at 04:15 pm) and the result date and time (05/12</p>

/2022 at 04:19 pm), four minutes later; (c) Patient Report #4003818605 - Specimen collection date and time (05/13/2022 at 02:22 pm) and the result date and time (05/13/2022 at 02:23 pm), one minute later; (d) Patient Report #4002185786 - Specimen collection date and time (05/16/2022 at 11:09 am) and the result date and time (05/16/2022 at 11:10 am), one minute later; (4) The records were reviewed with the laboratory consultant. The laboratory consultant stated on 05/16/2022 at 12:05 pm the laboratory could not prove the results had been interpreted according to manufacturer's instructions 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 laboratory consultant, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of 18 proficiency testing events reviewed. Findings include: (1) On 05/16/2022, a review of 2021 and 2022 proficiency testing records revealed the following for one of 18 testing events: (a) Second 2021 Hematology Event for Blood Cell Identification - one of five results had not been graded by the proficiency testing program: (i) For the result (BCI-07), the following was identified: (aa) BCI-07 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The records were reviewed with the laboratory consultant who stated on 05/16/2022 at 12:52 pm, the laboratory had not documented the review of the non-graded result as indicated above.

**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 laboratory 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 18 events. Findings include: (1) On 05/16/2022, a review of 2021 and 2022 proficiency testing events revealed for one of 18 events, the attestation statements had been signed approximately two months after the samples had been tested, (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Third 2021

Hematology Event - The sample testing had been completed on 11/12/2021 and the attestation statement had not been signed by the laboratory director/designee until 01/19/2022. (2) The findings were reviewed with the laboratory consultant who stated on 05/16/2022 at 01:25 pm the attestation had been signed approximately two months after the proficiency samples had been tested.