Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number | (X3) Date Survey Completed |
|---|---|---|
| | 37D0669872 | 03/25/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sapulpa Indian Health Center | 1125 E Cleveland, Sapulpa, 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 03/25/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the quality improvement specialist, health administrator, technical consultant #2, and testing person #1 during an exit conference performed at the conclusion of the survey. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with testing person #1, technical consultant #1, and technical consultant #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of four analyzers. Findings include: CLINITEK ADVANTUS (1) On 03/25/2024 at 10:45 am, testing person #1 stated Urinalysis testing was performed using the Clinitek Advantus analyzer; (2) A review of the "Clinitek Advantus Operator's Guide", Chapter 5 "Maintenance", stated the following under the heading "Perform the Daily Cleaning": (a) "Clean the following parts at least once each day or after running 300 strips, whichever is more frequent": (i) "Push Bar" (ii) "Fixed Platform" (iii) "Moving Table" (iv) "Reagent Strip Holddown Plate" (3) A review of maintenance logs from 1/01/2023 through 01/31/2024 identified no documentation the daily maintenance had been performed as follows: (a) Between 11/06/2023 and 11/13 /2023 (b) Between 11/13/2023 and 11/21/2023 (c) Between 11/21/2023 and 11/27 /2023 (d) Between 11/27/2023 and 12/04/2023 (e) Between 12/04/2023 and 12/11 /2023 (f) Between 12/11/2023 and 12/18/2023 (g) Between 12/18/2023 and 12/27 /2023 (h) Between 12/27/2023 and 01/03/2024 (i) Between 01/03/2024 and 01/08 /2024 (j) Between 01/08/2024 and 01/16/2024 (k) Between 01/16/2024 and 01/23 |

| | |
|---|---|
| | /2024 (l) Between 01/23/2024 and 01/29/2024 (m) After 01/29/2024 (4) The records were reviewed with technical consultant #1 and technical consultant #2. Both stated on 03/25/2024 at 01:30 pm, the daily maintenance had not been documented as performed as shown above. CELL DYN RUBY (1) On 03/25/2024 at 10:50 am, testing person #1 stated CBC (Complete Blood Count) testing was performed using the Cell Dyn Ruby analyzer; (2) A review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) "Clean Loader Compartments" (3) A review of maintenance logs from December 2023 through February 2024 identified no documentation weekly maintenance had been performed between: (a) 12/15/2023 and 12/27/2023 (b) 01/12/2024 and 01/23/2024 (c) 02/16 /2024 and 02/26/2024 (4) The records were reviewed with technical consultant #2 who stated on 03/24/2024 at 02:25 pm, the weekly maintenance had not been documented as performed as shown above. |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #2, the laboratory failed to ensure the urine centrifuge was functioning properly for two of four function checks performed during the review period of January 2022 through the current date. Finding include: (1) On 03/25/2024 at 02:00 pm, technical consultant #2 stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in the Horizon Mini E 642 VES centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes. (2) A review of centrifuge function check records from January 2022 through the current date identified the centrifuge speed had not been checked at the speed urines were processed for two of four checks performed as follows: (a) 03/17/2023 - The speed had been checked at 4205 rpm (b) 09/12/2023 - the speed had been checked at 4205 rpm (3) The records were reviewed with technical consultant #2 who stated on 03/25/2024 at 02:45 pm, the laboratory had not ensured the centrifuge was functioning properly. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test |

| | |
|---|---|
| | system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #2 and testing person #1, the laboratory failed to perform calibration verification procedures at least once every six months for two of two analytes requiring calibration verification using the OCD (Ortho Clinical Diagnostics) Vitros ECi analyzer during the review period of April 2022 through the current date. Findings include: (1) On 03/25/2024 at 10:40 am, technical consultant #2 and testing person #1 stated Vitamin D and Vitamin B12 were performed on the OCD Vitros Eci analyzer; (2) A review of calibration records for 2023 identified the calibration procedures for the above analytes were performed with less than three levels of calibrators. Therefore, calibration verification procedures using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of records from April 2022 through the current date identified calibration verifications had not been performed at least once every six months as follows: (a) Vitamin D - Not performed between 04/07 /2022 and 03/03/2023; (b) Vitamin B12 - Not performed between 04/07/2022 and 02 /22/2023, and between 02/22/2023 and 09/28/2023. (4) The records were reviewed with technical consultant #2 who stated on 03/25/2024 at 04:33 pm, calibration verification procedures had not been performed every six months as shown above. |