| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 34D0860475 | 07/24/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Cajah's Mountain Medical Associates | 1766 Connelly Springs Road, Lenoir, NC | |

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 |
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| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 2024 American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with testing personnel (TP) #1, 07/24/25, the laboratory failed to review "Not Graded" PT results to determine if the laboratory PT results met the consensus of the participant summary results. Findings: Review of 2024 API PT Hematology/Coagulation - 2nd event revealed the laboratory received a "Not Graded" result for PT sample #VA-02. There PT records failed to include documentation of the review of the "Not Graded" PT result. Interview with TP #1 at approximately 12:30 p.m. confirmed the laboratory did not review the "Not Graded" PT result. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of 2025 DXH520 hematology analyzer reports and corresponding electronic medical record reports, review of the DXH520 validation records, and interview with testing personnel (TP), the laboratory failed to provide appropriate |

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| | reference ranges to the ordering provider. Findings: 1. Review of 2025 patient test reports revealed reference range discrepancies between the DXH520 hematology analyzer printout and the electronic health record hematology report. Examples: Specimen 133297278, 82 year old female: Red Blood Cell (RBC) reported as 4.15 x 10^12 per Liter (L) DXH520 analyzer RBC reference range = 3.72 - 4.93 x 10 ^6 per microliter (uL) Electronic Medical Record RBC reference range = 3.72 - 5.24 x 10^12 per Liter (L) Hemoglobin (HGB) reported as 12.1 grams per deciliter (g/dl) DXH520 analyzer HGB reference range = 11.50 - 15.00 g/dl Electronic Medical Record HGB reference range = 10.8 - 15.5 g/dl Specimen 133296803, 74 year old male: Red Blood Cell (RBC) reported as 4.05 x 10^12 per Liter (L) DXH520 analyzer RBC reference range = 4.16 - 5.83 x 10 ^6 per microliter (uL) Electronic Medical Record RBC reference range = 3.95 - 5.72 x 10^12 per Liter (L) Hemoglobin (HGB) reported as 12.6 grams per deciliter (g/dl) DXH520 analyzer HGB reference range = 13.00 - 17.40 g/dl Electronic Medical Record report contains a HGB reference range = 12.1 - 17.4 g/dl Specimen 133234833, 13 year old male: Red Blood Cell (RBC) reported as 4.78 x 10^12 per Liter (L) DXH520 analyzer RBC reference range = 3.70 - 5.48 x 10 ^6 per microliter (uL) Electronic Medical Record RBC reference range = 4.50 - 5.30 x 10^12 per Liter (L) Hemoglobin (HGB) reported as 14.9 grams per deciliter (g/dl) DXH520 analyzer HGB reference range = 10.60 - 15.40 g/dl Electronic Medical Record HGB reference range = 13.0 - 16.0 g/dl 2. Review of the DXH520 hematology analyzer's validation records revealed the analyzer's current age and sex specific reference ranges were adopted during the analyzers initial validation. During an interview at approximately 11:45 a.m., TP#1 verified that providers review patient results in the electronic medical record. TP#1 also verified that reference ranges were not part of the chart review process for quality assessment. |