| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D0362690 | 09/05/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Beverly Hills Pediatrics | 32100 Telegraph Rd Suite #110, Bingham Farms, MI | |

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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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2, the laboratory failed to verify the accuracy of its nasal smear for eosinophils testing at least twice annually for two (September 2022 to September 2024) of two years reviewed. Findings include: 1. A review of the laboratory's verification of accuracy records revealed one event was performed on 9/5/24. No other verification of accuracy events were present between September 2022 and September 2024. 2. An interview on 9/5 /24 at 1:10 pm with Technical Consultant #2 confirmed the laboratory had not verified the accuracy of its nasal smears for eosinophils testing at least twice annually. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, record review, and interview with Technical Consultant #2, the laboratory failed to follow its specimen labeling policies for one patient specimen |

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| | observed. Findings include: 1. The surveyor observed the laboratory's ABX Micros 60 Complete Blood Count (CBC) analyzer on 9/5/24 at 12:57 pm with a lavender microtainer in the sample chamber with blood in it and no label or patient identifier on it. 2. A review of the laboratory's "CBC Patient Sample" policy revealed a section stating, "Label Safe-T-Fill with patient last name or patient initials." 3. An interview on 9/5/24 at 12:57 pm with Technical Consultant #2 confirmed the specimen observed had not been labeled in accordance with the laboratory's policy. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation and interview with Testing Personnel #7, the laboratory failed to label its Minotrol hematology control materials with expiration dates to reflect the open stability for three of three opened control materials observed. Findings include: 1. The surveyor observed a box with four sets of three Minotrol hematology control vials in the refrigerator on 9/5/24 at 1:03 pm. None of the vials included and expiration date. 2. An interview on 9/5/24 at 1:03 pm with Testing Personnel #7 revealed the laboratory had recently opened the box and had opened the first set of three control vials. She also revealed that, once opened, the vials are only stable for two weeks. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Testing Personnel #7, the laboratory failed to perform calibration verification for its Complete Blood Count (CBC) testing at least every six months for three (3/24/23, 10/18/23, and 6/27/24) of four calibration verification events in the previous two years. Findings include: 1. A review of the laboratory's Horiba CBC analyzer's calibration records revealed the following dates when calibration verification was performed less frequently than every six months: a. 7 /9/22 to 3/24/23, 8 months. b. 3/24/23 to 10/18/23, 7 months. c. 10/18/23 to 6/27/24, 8 months. 2. A review of the laboratory's "Calibration Procedure" revealed a section stating, "CBC machine to be calibrated bi-yearly using S-Cal from Beckman Coulter." 3. An interview on 9/5/24 at 2:04 pm with Testing Personnel #7 confirmed the laboratory had not performed calibration verification at least every six months. |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.<br><br>This CONDITION is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2, the laboratory failed to ensure testing personnel were qualified. Refer to D6065. |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with Technical Consultant #2, the laboratory failed to ensure testing personnel were qualified for 4 (Testing Personnel 11-14) of 14 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel qualification records revealed a lack of documentation for the following laboratory personnel performing moderate-complexity hematology testing: a. Testing Personnel 11 b. Testing Personnel 12 c. Testing Personnel 13 d. Testing Personnel 14 2. The surveyor requested the four testing personnel's qualification records on 9/5/24 at 2:51 pm and they were not made available. 3. The laboratory was granted 7 days to provide the missing records and none were received. |