

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0950408	(X3) Date Survey Completed 10/18/2023
Name of Provider or Supplier Beverly Hills Pediatrics	Street Address, City, State 5555 Metro Parkway Ste 300, Sterling Heights, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #6, the laboratory failed to verify the accuracy of its nasal smear examinations at least twice annually for 2 (October 2021 to October 2023) of 2 years. Findings include: 1. A review of the laboratory's "Wright Staining Proficiency" policy revealed a section stating, "This testing shall take place on an annual basis for all providers who analyze smears for nasal cytology." 2. A review of the laboratory's competency assessment records revealed documentation of verification of accuracy was performed annually rather than twice annually. 3. An interview on 10/18/23 at 9:29 am with Testing Personnel #6 confirmed the laboratory had not verified the accuracy of its nasal smear testing at least twice annually from October 2021 to October 2023. **This is a repeated deficiency from the 11/9/17 recertification survey**</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #6, the laboratory failed to ensure patients with nasal smear testing had test requests from an authorized person for 3 (Patients 5, 8, and 11) of 4 nasal smear patient test records reviewed.</p>

Findings include: 1. A review of patient test records revealed the following patients had documented test reports for nasal smear testing without a test request from an authorized person: a. Patient #5 had testing performed on 10/4/22. b. Patient #8 had testing performed on 3/14/23. c. Patient #11 had testing performed on 9/7/23. 2. A review of the laboratory's "Quality Assurance Program" policy revealed a section stating, "Test tracking (requisitions)- Ensure the following are correct in EMR: a. Patient Name b. Date of collection c. Patient date of birth d. Name of provider ordering test" 3. An interview on 10/18/23 at 10:17 am with Testing Personnel #6 confirmed the patients listed above did not have test requests from an authorized person for the testing performed. **This is a repeated deficiency from the 3/2/2020 recertification survey**

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Testing Personnel #6, the laboratory failed to establish procedures to include maintenance and test performance for its Complete Blood Count (CBC) test system for 2 (October 2021 to October 2023) of 2 years. Findings include: 1. A review of the laboratory's procedure manual revealed a lack of maintenance and test performance process for its CBC testing using their Horiba analyzer. 2. An interview on 10/18/23 at 9:32 am with Testing Personnel #6 revealed the Horiba instrument requires a cleaning process every other day of use and confirmed a lack of procedure that included maintenance and test performance.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #6, the laboratory failed to assess staining materials for intended reactivity for its nasal smear testing for 2 (October 2021 to October 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's maintenance logs revealed the stain quality was initialed by personnel that did not have competency assessments for nasal smear analysis. 2. A review of the laboratory's procedure "Wright Stain Quality Procedure" approved by the Laboratory Director on 4/20/22 revealed a section stating, "Stain quality is assessed daily in the morning, the stain will be assessed for predictable staining characteristics." 3. An interview on 10/18/23 at 10:08 am with Testing Personnel #6 revealed the stain quality check that was documented was to check the bottle of stain for discoloration and was not to assess staining for intended reactivity. **This is a repeated deficiency from the 3/9/2022 recertification survey**