

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0362690	(X3) Date Survey Completed 02/05/2018
Name of Provider or Supplier Beverly Hills Pediatrics	Street Address, City, State 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory submitted results for proficiency testing event FH2-C in 2017 under another CLIA number. Refer to D2013.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director and testing personnel failed to attest to the routine integration of the hematology proficiency testing samples into the patient workload for three (A, B, and C in 2017) of six events reviewed in 2016 and 2017. Findings include: 1. On February 5, 2018 at 11:00 a.m., record review</p>

of the College of American Pathologists (CAP) hematology proficiency testing program documents revealed the laboratory director and the testing personnel did not sign the attestation statement sheets for three of six events in 2016 and 2017. 2. During the phone interview on February 5, 2018 at 4:39 p.m., testing personnel #15 confirmed the attestation statement sheet was not signed.

D2013

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory submitted results for event FH2-C in 2017 hematology complete blood cell count proficiency testing samples under another CLIA 23D0950408 (CAP# 7205731-01) number. Findings include: 1. On February 5, 2018 at 11:00 a.m., record review of event FH2-C 2017 in the proficiency testing binder revealed the final graded results for CLIA# 23D0950408 CAP# 7205731-01. The report showed the facility crossed out the address and the the CAP# and hand wrote the Bingham Farms, Mi 48025 and the CAP # 6299401-01 on the report. 2. On February 5, 2018 at 11:00 a.m., record review revealed the results sent into CAP for evaluation for CLIA# 23D0950408 CAP# 7205731-01 were the results from the five instrument generated print outs from CLIA# 23D0362690 CAP# 6299401-01. 3. During the phone interview on February 5, 2018 at 4:39 p.m., testing personnel #15 as listed on the CMS-209 confirmed the results from their facility were entered incorrectly into the CAP proficiency testing system for their other facility.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to review and evaluate the hematology proficiency testing results for five (A and C in 2016 and A, B, and C in 2017) of six events reviewed in 2016 and 2017. Findings include: 1. On February 5, 2018 at 11:00 a.m., record review of the College of American Pathologists proficiency

testing CMS summary report revealed for five of six events reviewed in 2016 and 2017 the following: a. event A in 2016 - no testing personnel review b. event C in 2016 - no laboratory director review c. events A and B in 2017 - no laboratory director and testing personnel review d. event C in 2017 - missing two of three testing personnel review 2. During the phone interview on February 5 2018 at 4:39 p.m., testing personnel #15 confirmed the CMS summary report were not reviewed or evaluated.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to maintain a record system that included the identity of the testing personnel performing the College of American Pathologists hematology proficiency testing for five (A, B, and C in 2016 and B and C in 2017) of six events reviewed in 2016 and 2017. Findings include: 1. On February 5, 2018 at 9:20 a.m., record review for five of six hematology proficiency testing events in 2016 and 2017 revealed the laboratory did not have a record system in place that included the identity of the testing personnel who ran the specimen on the hematology analyzer as follows: a. event B in 2017 only on specimens FH-06 and FH-07 b. events A, B, and C in 2016 and event C in 2017 2. During the interview on February 5, 2018 at 9:20 a.m., testing personnel #15 confirmed a record system was not in place to identify the testing personnel performing the hematology complete blood cell count testing.