Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0950408	03/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Beverly Hills Pediatrics	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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review and interview with Testing Personnel #6 (TP6), the laboratory failed to report all SARS-CoV-2 test results every day of patient testing for 4 (patients 2, 5, 14, and 15) of 4 patient test records for SARS-CoV-2 testing reviewed. Findings include: 1. The surveyor observed the laboratory's Abbott ID NOW SARS-CoV-2 test system on 3/9/22 at 9:06 am. 2. A review of the laboratory's test records revealed only positive patients tested using the Abbott ID NOW SARS-CoV-2 test system had been reported to the health department. 3. The surveyor requested documentation of the submission of test results to the health department for patients 2, 5, 14, and 15 receiving testing on 11/22/21, 9/21/21, 2/28/22, and 1/14/22 respectively on 3/9/22 at 11:05 am and they were not made available. 4. An interview on 3/9/22 at 11:05 am with TP6 confirmed the laboratory had not reported all SARS-CoV-2 patient test results to the health department.
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 (TP6), the laboratory failed to test the Wright Stain used in the nasal smear procedure to ensure predictable staining characteristics for 2 (March 2020 to March 2022) of 2 years. Findings include: 1. A review of patient test records revealed the following patients had nasal smears performed: a. Patient 3 had testing performed on 10/27/21 b. Patient 7 had testing performed on 7/30/21 c. Patient 9 had testing performed on 4/23/21 d. Patient 10 had testing performed on 3/11/21 e. Patient 11 had testing performed on 11 /12/20 f. Patient 13 had testing performed on 6/12/20 g. Patient 15 had testing performed on 1/14/22 2. The surveyor requested documentation of the assessment of staining characteristics for the dates listed above on 3/9/22 at 11:08 am and it was not made available. 3. An interview on 3/9/22 at 11:08 am with TP6 revealed the laboratory had not performed and documented staining characteristics each day of patient testing.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #6 (TP6), the Laboratory Director failed to ensure the approved corrective action plan was followed when proficiency testing was found to be unacceptable for 1 (FH2-A 2020) of 6 testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' (CAP) proficiency testing records revealed the laboratory received a grade of unacceptable for the following analytes from the FH2-A 2020 testing event: a. White Blood Cell Count specimen FH2-04 b. Hemoglobin specimen FH2-04 c. Mean Corpuscular Hemoglobin (MCH) specimen FH2-04 d. Mean Corpuscular Hemoglobin Concentration (MCHC) specimen FH2-04 e. Mean Platelet Volume (MPV) specimen FH2-05 f. Granulocytes (absolute and percent) specimen FH2-04 g. Lymphocyte percent specimen FH2-04 h. Monocyte percent specimen FH2-04 2. An review of the laboratory's "Quality Assurance Program" policy revealed a section stating, "Unsatisfactory PT results must be documented including any corrective action taken and reviewed by the director. Please see additional documentation pertaining to individual unsatisfactory PT result. The PT procedure will be assessed and saved for 2 year period." 3. The surveyor requested documentation of corrective action performed as a result of the unacceptable results

	listed above on 3/9/22 at 11:12 am and it was not made available. 4. An interview on 3/9/22 at 11:12 am with TP6 confirmed corrective action was not performed and documented for the FH2-A 2020 proficiency testing event.