

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0362690	(X3) Date Survey Completed 05/10/2021
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
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to report SARS-Co-V-2 test results as required for 91 tests performed with a negative result since the laboratory started testing. Findings include: 1. A review of laboratory's testing records from two patients having SARS-CoV-2 testing with their BD Veritor system revealed the laboratory had not reported the results to the health department. 2. An interview with the Technical Consultant on 5/10/21 at 11:29 am revealed the laboratory is not reporting negative SARS-CoV-2 results from their BD Veritor system to the health department. 3. An interview with the Technical Consultant on 5/10/21 at 11:48 am revealed the laboratory had tested 91 patients with negative test results since the laboratory started testing on 10/27/20.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

. Based on observation and interview with the Office Manager, the laboratory failed to label a secondary container with the identity and expiration date for methyl alcohol used in nasal smear preparation for the current container in use. Findings include: 1. During a tour of the laboratory on 5/10/21 at 9:25 am, the surveyor observed a glass bottle with clear liquid inside that did not have the identity of the liquid or the expiration date. 2. An interview on 5/10/21 at 9:25 am with the Office Manager revealed the liquid inside the container was methyl alcohol that is used in the preparation of nasal smears and confirmed it did not contain the identity or expiration date.