Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0675401	10/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Gables Pediatrics Llc	358 San Lorenzo Ave Ste 3230, Coral Gables, FL	

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
D0000	An announced CLIA recertification survey was conducted at Gable Pediatrics LLC on 10/14/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of College of American Pathology (CAP) proficiency testing and interview with Testing Person #D the laboratory failed to test the Proficiency Testing the number of times that Patients are tested for 5 (1st, 2nd Testing Event in 2020 and 1st, 2nd, 3rd Testing Event in 2019) out of 5 Testing Events. Findings Included: Review of the CAP proficiency testing instructions revealed that "Proficiency Testing (PT) specimens must be tested with the laboratory's regular workload, using routine methods, and testing the PT specimens the same number of times it routinely tests patient specimens." Review of CAP proficiency testing revealed that the 1st Testing Event in 2020 was due no later than 02/18/20. The Laboratory received five samples to be tested. All 5 samples were ran 2 times on 02/11/20 and 1 time on 02/12/20 by 3 separate Testing Personnel for a total of 3 times each. Review of CAP proficiency testing revealed that the 2nd Testing Event in 2020 was due no later than 06/09/20. The Laboratory received five samples to be tested. All 5 samples were ran 3 times on

	05/06/20, 1 time on 05/07/20, and 1 time on 06/03/20 by 5 separate Testing Personnel for a total of 5 times each. Review of CAP proficiency testing revealed that the 1st Testing Event in 2019 was due no later than 02/19/19. The Laboratory received five samples to be tested. All 5 samples were ran 4 times on 01/29/19 by 4 separate Testing Personnel for a total of 4 times each. Review of CAP proficiency testing revealed that the 2nd Testing Event in 2019 was due no later than 05/28/19. The Laboratory received five samples to be tested. All 5 samples were ran 4 times on 05/21 /19 by 4 separate Testing Personnel for a total of 4 times each. Review of CAP proficiency testing revealed that the 3rd Testing Event in 2019 was due no later than 10/15/19. The Laboratory received five samples to be tested. All 5 samples were ran 4 times on 10/10/19 by 4 separate Testing Personnel for a total of 4 times each. Interview on 10/14/20 at 10:50 AM Testing Person #D confirmed that the Proficiency testing was not ran like Patient specimens.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director the laboratory failed to perform competency evaluations on 7 (#TP-A, TP-B, TP-C, TP-D, TP-E, TP-F, and TP-G) out of 7 Testing Personnel, 2 (#CC-B and CC-C) out of 3 (#CC-A, CC-B, and CC-C) Clinical Consultants, and 1 (#TC-B) out of 2 (#TC-A and TC-B) Technical Consultants for 2 out of 2 (2019-2020) years reviewed. Findings Included: Review of the CMS 209 signed by the Laboratory Director 10/13/20 revealed that there are 3 Clinical Consultants (CC-A is the Laboratory Director), 2 Technical Consultants (TC-A is the Laboratory Director), and 7 Testing Personnel. Review of Personnel files revealed no competency evaluations for 2 Clinical Consultants (CC-B and CC-C), 1 Technical Consultant (TC-B), or 7 Testing Personnel (TP-A, TP-B, TP-C, TP-D, TP-E, TP-F, and TP-G). Interview on 10/14/20 at 11:57 AM the Laboratory Director confirmed that there were no competency evaluations performed on the aforementioned staff in 2019 or 2020.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director and Testing Person #D the laboratory failed to store Hematology quality control (QC) per the manufacturer's instructions (MI) 48 days out of 98 days reviewed and failed to

	document room temperature for 2 (2019-2020) out of 2 years reviewed. Findings Included: Review of the MI for the Hematology controls revealed that they should be stored 2-8 degrees Celsius or 35.6-46.4 degrees Fahrenheit. Review of refrigerator temperature log revealed that it had an incorrect range of 30-40 degrees Fahrenheit. The months selected for review were January 2019, September 2019, February 2020, and July 2020. In January 2019 the laboratory was open 26 days and the refrigerator temperature was out of the 35.6-46.4 degree Fahrenheit range for 11 days (01/02=35 degrees, 01/04=35 degrees, 01/14=35 degrees, 01/17=34 degrees, 01/18=35 degrees, 01/19=35 degrees, 01/21=34 degrees, 01/22=32 degrees, 01/23=34 degrees, 01/25=35 degrees, and 01/26=34 degrees). In September 2019 the laboratory was open for 22 days and the refrigerator temperature was out of the 35.6-46.4 degree Fahrenheit range for 10 days (09/03=34 degrees, 09/04=34 degrees, 09/06=35 degrees, 09/09=34 degrees, 09/11=34 degrees, 09/12=34 degrees, 09/18=33 degrees, 09/25=32 degrees, 09/26=34 degrees, and 09/28=34 degrees). In February 2020 the laboratory was open for 25 days and the refrigerator temperature was out of the 35.6-46.4 degree Fahrenheit range for 13 days (02/01=34 degrees, 02/03=34 degrees, 02/05=35 degrees, 02/06=34 degrees, 02/07=35 degrees, 02/08=35 degrees, 02/12=34 degrees, 02/14=34 degrees, 02/18=34 degrees, 02/22=34 degrees, 02/25=34 degrees, 02/27=32 degrees, and 02/28=34 degrees. In July 2020 the laboratory was open for 25 days and the refrigerator temperature was out of the 35.6-46.4 degree Fahrenheit range for 14 days (07/02=34 degrees, 07/04=34 degrees, 07/06=34 degrees, 07/07=34 degrees, 07 /13=32 degrees, 07/14=32 degrees, 07/15=34 degrees, 07/16=34 degrees, 07/20=34 degrees, 07/22=35 degrees, 07/23=33 degrees, 07/28=35 degrees, 07/29=35 degrees, and 07/31=35 degrees). Interview on 10/14/20 at 11:57 AM the Laboratory Director and Testing Person #D confirmed that the range needed to be changed and that the temperature reading were not within manufacturer's guidance for storage. Review of the procedures for the Sysmex XP-300 Automated Hematology Analyzer revealed that the CELLPACK reagent needs to be stored at a controlled temperature of 15-30 degrees Celsius. Interview on 10/14/20 at 11:57 AM the Laboratory Director and Testing Person #D confirmed that the room temperature was not being documented.