

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0975927	(X3) Date Survey Completed 10/30/2018
Name of Provider or Supplier Beachside Pediatrics Llc	Street Address, City, State 1145 Kane Concourse, Bal Harbour, 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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of API (American proficiency Institute) proficiency testing for two-year period (2016 to 2018), and interview with testing person, the laboratory failed to Score at least 80% for white blood cells (2016, 3rd event) and platelets (2017, 2nd event) in the hematology specialty in one out of six (2016-3rd, 2017-1st, 2nd, 3rd, 2018-1st, 2nd) testing events reviewed. The findings include: On October 30, 2018 at 12:30pm surveyor reviewed API proficiency testing result records for six test events (2016-3rd event, 2017-1st, 2nd, 3rd events, 2018-1st and 2nd event). It showed that laboratory scored 60% test scores for white blood cells for 2016, 3rd testing event, and 60% test scores for platelets for 2017, 2nd event, failing test scores for one out of six testing events. During an interview on October 30, 2018, at 2:45pm, the testing person confirmed the 60% - failing test scores for white blood cells for 2016, 3rd event, and platelets - 60% for 2017, 2nd event, one out of six testing events reviewed.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on API (American proficiency Institute) proficiency testing results review for years 2016 to 2018, and interview with testing person, the laboratory failed to have corrective action for 1) 80% test scores for cell identification (white blood cell</p>

differentiation), hemoglobin, and white blood cells for 2017, 2nd event, 2) 60% test scores for white blood cells for 2016, 3rd testing event, and 60% test scores for platelets for 2017, 2nd event, failing test scores for one out of six testing events (2016-3rd, 2017-1st, 2nd,3rd, 2018-1st, 2nd) reviewed. The findings include: On October 30, 2018 at 12:30pm surveyor reviewed API proficiency testing result records for six test events (2016-3rd event, 2017-1st, 2nd, 3rd events, 2018-1st and 2nd event). It showed that laboratory scored; -A)- 80% for cell identification (white blood cell differentiation), hemoglobin, and white blood cells for 2017, 2nd event, -B) - 60% for white blood cells for 2016, 3rd event, -C) - 60% test scores for platelets for 2017, 2nd event, - (d) - There was no corrective action for A and B. During an interview on October 30, 2018, at 2:45pm, the testing person confirmed that laboratory scored (a)- 80% for cell identification (white blood cell differentiation), hemoglobin, and white blood cells for 2017, 2nd event, (b) - 60% for white blood cells for 2016, 3rd event, (c) - 60% test scores for platelets for 2017, 2nd event, (d) - There was no corrective action for (a), (b), and (c) for API proficiency testing results.

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 observation, record review and the interview with testing person, the laboratory failed to monitor and record the daily room temperature and humidity from 10/2016 to 10/30/2018 (for two-year review period of 2016 to 2018) for hematology specialty. The findings include: 1) - During a laboratory tour on 10/30/18 at 1:30 pm, surveyor did not observe room temperature and humidity monitoring device. 2) - Surveyor did not see the records for daily temperature and humidity check in instrument maintenance and temperature record logs. 3) - Temperature/humidity ranges for; A) - ACT diff analyzer-Hematology analyzer system Temperature, ambient operating 16°C-35°C. (61°F- 95°F) Humidity 20%-85% without condensation. Hematology Controls- optimal temperature range 20°C- 25°C. B) - McKesson Consult Diagnostics Influenza A& B tests Kit storage and stability; 35°F- 86°F (2-30°C). C) - Siemens multistix 10SG Kit storage temperature 15*-30°C (59*- 86* F) On October 30, 2018 at 2:45pm, the testing person confirmed that the laboratory did not: - have the room temperature and humidity-monitoring device. - did not monitor the room temperature and humidity as part of the operating environment requirement for hematology analyzer, Consult Diagnostics influenza A & B tests, waived tests and kits storage.