| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D0722545 | 09/27/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Babies & Childrens Clinic | 900 West Sam Houston Suite 1, Pharr, TX | |

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 |
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| **D0000** | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of manufacturer's instructions, laboratory policy and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions to monitor the room temperature where Silaris test cartridges are stored. The findings were: 1. Surveyor observation made on September 27, 2019 at 11:25 hours in the Office Manager's office found 3 unopened boxes of Silaris test cartridges (Lot Number: 0201). Further observations made in the office revealed no means to monitor the room temperature. 2. Review of the manufacturer's instructions for the Silaris Influenza A&B Test (catalog #1027) states "All kit components must be stored at room temperature (15 C - 30 Celsius, 59 F- 86 |

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| | Farenheit). 3. Review of laboratory policy "Instrument Operation and Maintenance" states "This laboratory will follow procedures as the manufacturer describes for testing, reporting, calibrating controls, specialty protocols and for performing /documenting remedial action." 3. An interview with Testing Personnel #6 (as listed on Form CMS-209) on September 27, 2019 at 11:25 hours confirmed the findings. When asked if the laboratory was documenting the room temperature of the office where the cartridges were stored, she pointed to the thermostat. She revealed that they kept the cartridges in the office to keep up with inventory. . Key CMS - Centers for Medicare and Medicad Services |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Form CMS-209, laboratory policy, review of the laboratory's proficiency testing records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to test proficiency samples in the same manner as routine patient samples. The findings were: 1. A review of the laboratory's submitted Form CMS-209, signed by tthe laboratory director on September 23, 2019, revealed the laboratory identified six testing personnel. 2. A review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing records for 2018 (events 1, 2, and 3) and 2019 (events 1 and 2) revealed specimens were tested by multiple testing persons. 2018 Event 2 Performed by: Testing Personnel #3 and #4 2018 Event 3 Performed by: Testing Personnel # 1 and #5 2019 Event 1 Performed by: Testing Personnel #6, #2 and #1 3. A review of the laboratory policy "Proficiency Testing Program states under Principle #3 "The usual laboratory verification procedures for PT survey samples will be followed where specified or applicable for patient samples. Replicate testing is allowed only if patient specimens are analyzed in this manner when Panic Values are reported of if the Laboratory Director requests repeat testing." 4. An interview with the TP #1 and TP #6 on 09/27/2019 at 11:15 hours in the office confirmed the findings. TP #1 was performing PT testing with TP # 6. When asked if patients were tested in duplicate, they answered, "No." They went on to explain this was used as training on how to perform proficiency testing. Key: CMS - Centers for Medicare and Medicaid Services TP - Testing Personnel |