| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D0670712 | 03/09/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pediatric Associates At Ridge Road | 1200 East Ridge Road # 12, Mcallen, 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. |
| **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 review of manufacturer's instructions, review of patient test records from November 2020 to March 2021, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions when performing Quidel Sofia SARS Antigen testing. The findings were: 1. Review of the manufacturer's instructions for the QUIDEL Sofia SARS Antigen stated, "All operators using your product must be appropriately trained in performing and interpreting the results of your product in accordance with the authorized labeling." 2. Review of patient test records from November 2020 to March 2021 (see patient alias list) found the laboratory tested the patients when the laboratory failed to provide documentation of training operators. 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to train operators in performing and interpreting results for Sofia SARS Antigen testing. No documentation was provided. 4. The results were confirmed in interview with the technical consultant on March 9, 2021 at 14:15 hours in the office. |
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| **D5785** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(3)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer's instructions, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing corrective action when the laboratory documented refrigerator temperatures outside of its own established range of 35 to 46 degrees Fahrenheit. The findings were: 1. Review of the manufacturer's instructions for XN-L Check (350658-2, 11/2018, Rev. 3) under "Storage and shelf life of unopened product" stated, " ...Storage outside the recommended temperature range causes damage to the product. Do not use damaged material for control or calibration verification." 2. Review of the laboratory's environmental records from January 1, 2021 to March 8, 2021 found the following 18 of 259 days when the laboratory documented temperatures outside the acceptable range: January 17, 2020 48 degrees Fahrenheit March 10, 2020 47 degrees Fahrenheit March 19, 2020 48 degrees Fahrenheit March 20, 2020 47 degrees Fahrenheit March 26, 2020 47 degrees Fahrenheit March 27, 2020 48 degrees Fahrenheit March 30, 2020 48 degrees Fahrenheit March 31, 2020 48 degrees Fahrenheit April 29, 2020 48 degrees Fahrenheit April 30, 2020 48 degrees Fahrenheit June 16, 2020 48 degrees Fahrenheit July 10, 2020 48 degrees Fahrenheit September 18, 2020 48 degrees Fahrenheit September 21, 2020 48 degrees Fahrenheit September 22, 2020 48 degrees Fahrenheit September 23, 2020 48 degrees Fahrenheit September 24, 2020 48 degrees Fahrenheit October 22, 2020 47 degrees Fahrenheit 3. The laboratory was asked to provide documentation of corrective action for the days it documented temperatures outside of its own acceptable range. No documentation was provided. 4. The findings were confirmed in interview with the testing person and technical consultant on March 9, 2021 at 14: 40 hours in the office. |