

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1018588	<b>(X3) Date Survey Completed</b> 03/09/2021
<b>Name of Provider or Supplier</b> All Childrens Pediatric Clinic	<b>Street Address, City, State</b> 626 North Texas Blvd, Weslaco, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient test records from March 8, 2021, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of following the manufacturer's instructions when performing Quidel Sofia2 Flu+SARS Antigen testing. The findings were: 1. Review of the manufacturer's instructions for the QUIDEL Sofia2 Flu+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 March 8, 2021 (the first day of patient testing) found the laboratory tested the following patients when the laboratory failed to provide documentation of training operators: Specimen #1 Date of Service: 03-08-2021 Result: Negative Specimen #2 Date of Service: 03-08-2021 Result: Negative Specimen #3 Date of Service: 03-08-2021 Result: Positive Specimen #4 Date of Service: 03-08-2021 Result: Negative Specimen #5 Date of Service: 03-08-2021 Result: Negative 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to train operators in performing and interpreting results</p>

for Sofia 2 Flu+SARS Antigen testing. No documentation was provided. 4. The results were confirmed in interview with the technical consultant on March 9, 2021 at 10:00 hours in the patient exam room.

**D5305**

**TEST REQUEST**  
CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on surveyor observation, review of laboratory policies, and confirmed in interview of facility personnel, the laboratory failed to document specimen collection time for Group A, C, and G testing on the Solana analyzer for 8 of 8 specimens collected from March 5, 2021 to March 8, 2021. The findings were: 1. Surveyor observation on March 9, 2021 at 08:55 hours in the laboratory found the following throat swab specimens in the laboratory refrigerator: Specimen 1 Date Collected: 03-06-2021 No Time of Collection Specimen 2 Date Collected: 03-08-2021 No Time of Collection Specimen 3 Date Collected: 03-05-2021 No Time of Collection Specimen 4 Date Collected: 03-05-2021 No Time of Collection Specimen 5 Date Collected: 03-08-2021 No Time of Collection Specimen 6 Date Collected: 03-08-2021 No Time of Collection Specimen 7 Date Collected: 03-08-2021 No Time of Collection Specimen 8 Date Collected: 03-08-2021 2. Review of the laboratory's policy titled "Test Requisitions" stated, " ...It should also have the specimen collection date and time, the specimen source, and the patient's name, age, gender, as needed for identification, and patient clinical information." 3. Review of the manufacturer's instructions for the Solana Complete Strep Assay (PIM305000EN00 (10/16) under "Specimen Collection, Storage and Handling" it stated, "... Analytical studies performed with contrived specimens containing Streptococcus pyogenes and Streptococcus dysgalactiae, near LOD (2x LOD) demonstrated that samples can be stored at 25C 2C for 2 days and then at 2C to 8C Solana Strep Complete Assay Page 5 of 18 for up to 6 more days before testing or at ? -15C or ? -70C for up to 32 days before testing with the Solana Strep Complete Assay. Specific requirements for shipping specimens should follow recommendations found in section 42 and 49 of the Code of Federal Regulation, CFR." 4. Interview with the testing person at 08:40 hours in the laboratory confirmed the findings. She confirmed that the time of collection was not documented. She went on to say that the specimens were pending testing due to the facility being out of molecular grade reagent water necessary to perform the testing. Key: LOD - Limit of Detection CFR - Code of Federal Regulations