

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0948461	(X3) Date Survey Completed 06/09/2021
Name of Provider or Supplier Brownsville Kiddie Health Center	Street Address, City, State 95 East Price Road Building F Suite A, Brownsville, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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	<p>CERTIFICATE OF WAIVER TESTS 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, patient test records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to include all authorized fact sheets when performing Covid testing using the Sophia analyzer for patient test results reviewed. The findings were: 1. Review of the manufacturer's instructions for use under, "Conditions of Authorization for Laboratory," it stated, "A. Authorized laboratories' using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 2. Review of 10 of 10 patient test results found the laboratory failed to follow the manufacturer's instructions to include the required fact sheets with the patient results. 3. An interview with the primary testing person on June 9, 2021 at 09:55 hours in the office confirmed the findings. She revealed she was not aware of the requirement but would make sure it was done.</p>

D5401**PROCEDURE MANUAL**

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, review of patient test records from September 2018, and staff interview, it was revealed the laboratory failed to have documentation of following its policy to invalidate differential results with flags. The findings were: 1. This is a repeat deficiency from the survey conducted on October 11, 2018. 2. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" (approved by the laboratory director on 09/01/2016) stated: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according to the procedure in the unit's operator's manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure is correctly followed. If the flags disappear, then report that result. If the flags persist, then it will be considered an abnormal differential and will be invalidated and/or should be sent out for analysis." 3. A sampling of patient test records from May 2021 identified the following patient results with flags which were reported to the provider: Date Sequence # Flag 05-01-2021 2956 BD 05-03-2021 2978 OM 05-03-2021 2979 BD 05-03-2021 2982 BD 05-04-2021 2994 OM 05-04-2021 3001 BD 05-07-2021 3051 OM 05-10-2021 3084 OM 05-11-2021 3107 BD 4. The laboratory was asked to provide documentation of invalidating the differential results with flags or of sending the samples out for additional testing as required by its policy. No documentation was provided. 5. An interview with the technical consultant on 06/09/2021 at 10:10 hours in the office - after his review of the records- confirmed the findings. Key: CBC - complete blood count