Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0948461	10/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Brownsville Kiddie Health Center	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
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of patient test records, and confirmed in interview of laboratory personnel, the laboratory's quality assurance plan failed to identify and correct that the laboratory failed to follow its own policy for resolution of abnormal flags on Complete Blood Count (CBC) results for 12 of 12 abnormal patient results from September 2, 2022 to October 11, 2022. The findings included: 1. Based on review of laboratory policy titled, "Policy for Handling Flagged CBC Differentials" approved by the laboratory director on September 1, 2016 it stated, " ... 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." 2. Based on review of 12 of 12 patient CBC results with abnormal flags from September 2, 2022 to October 11, 2022 found the laboratory failed to follow its policy in its entirety. a. The following patient results did not have all flagged results invalidated per its own policy. Test Date: 09-02-2022 Sequence #: 5150 Flag: OM Test Date: 09-09-2022 Sequence #: 5241 Flag: OM Test Date: 9-13-2022 Sequence #: 5322 Flag: OM Test Date: 09-15-2022 Sequence #: 5362 Flag: BD Test Date: 09-18-2022 Sequence #: 5408 Flag: OM Test Date: 09-21-2022 Sequence #: 5457 Flag: OM Test Date: 09-24-2022 Sequence #: 5495 Flag: OM Test Date: 09-27-2022 Sequence #: 5537 Flag: OM Test Date: 09-29-2022 Sequence #: 5612 Flag: OM Test Date: 10-05-2022 Sequence #: 5641 Flag: OM Test Date: 10-07-2022 Sequence #: 5688 Flag:

	OM Test Date: 10-11-2022 Sequence #: 5690 Flag: OM 3. Review of the laboratory's quality assurance reports from August, September, and October 2022 found no documentation that the laboratory identified and corrected the reported abnormal flagged results. 4. The findings were confirmed in interview with the technical consultant and testing personnel #1 (as listed on Form CMS-209) on October 18, 2022 at 11:15 hours in the office. Key: OM - White Blood Cell Differential: only one WBC population found; slide review advised BD - White Blood Cell Differential: High interference between population CMS - Centers for Medicare and Medicaid Services