Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1089530	06/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center At Renaissance	5300 N G Street Ste 140, 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
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 certification 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.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing reports from 2016, 2017, and 2018, and confirmed in staff interview, it was revealed the laboratory failed to provide documentation of evaluating proficiency testing results returned ungraded by the proficiency testing agency. The findings were: 1. A review of the laboratory's API proficiency testing reports from 2016 (event 3), 2017 (events 1, 2, and 3), 2018 (event 1) revealed the laboratory failed to have documentation of accurately evaluating 1 of 5 testing events that were returned to the

	laboratory ungraded: 2018 (event 1) Sample ID: BCI-01 Score: Not Graded 2. Review of the laboratory's own review of the proficiency results revealed the laboratory had inaccurately self-graded the analyte as 100%. 3. Review of the scoring sheet revealed the laboratory had submitted a result of "Lymph, plasmacytoid" and the participant summary majority documented a "hairy cell." 4. An interview with the technical consultant on 06/06/2018 at 1040 hours in the break room confirmed the findings.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of patient reports, and confirmed in interview of facility personnel revealed the laboratory failed to have a policy to resolve flags on CBC (complete blood count) results. The findings were: 1. Attempted review of laboratory policy on June 6, 2018 revealed no policy was available for review that would instruct testing personnel on how to resolve flags on CBC results prior to their release to the healthcare provider. 2. Review of the manufacturer's Automated Hematology Analyzer for the Sysmex XS-1000i/SX-800i on page 15 stated, "* indicates data of low reliability-the value may have been influenced" and under, "Action" it stated, "Count DIFF-CH, Add a DIFF and repeat the analysis." 3. Random review of patient results from patients tested on 06/06/2018 (the day of the survey) revealed the following patient results were finalized when CBC flags had not been verified: Patient ID: 28676 Flag(s): Neut (*), Mono (*), Neut % (*), Lymph % (*), Mono % (*) Patient ID: 28292 Flag(s): Neut (*), EO (*), Baso (*), Neut # (*), Eo # (*), Baso # (*) 4. The findings were confirmed in interview of testing person four (as listed on Form CMS-209) on 06/06/2018. She confirmed the results had flags and were finalized.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions for the Sysmex XS-1000i/XS800i hematology analyzer, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to define an acceptable room humidity range for the laboratory. The findings were: 1. Direct observation made in the laboratory during the initial tour of the laboratory on 06/06/2018 revealed that according to the laboratory's room temperature monitor, the room

	humidity in the laboratory was 71%. 2. Review of the manufacturer's instructions for the Sysmex XS-1000i/XS800i hematology analyzers (Revised March 2013), under, "11.11 Installation Environment" stated, "Relative humidity should be within the range of 30%-85%." 3. Review of the laboratory's environmental records for June 2018 revealed the laboratory had an established unacceptable humidity range of 20-85%. 4. The laboratory was asked to provide documentation of defining an acceptable room humidity range according to the manufacturer's instructions. No documentation was provided. 5. An interview with the technical consultant on 06/06/2018 at 1145 hours in the break room confirmed the findings.
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 direct observation, review of media quality control logs, and confirmed in interview of facility personnel, the laboratory's quality assurance plan failed to identify that testing personnel were damaging media during inoculation. The findings were: 1. Direct observation in the laboratory on 06/06/2018 at 1045 hours revealed each patient plate was stabbed 15-20 times. 2. Review of the laboratory's "Culture Media Control Sheet" revealed upon receipt of media, testing persons were to document "Appearance" of media. 3. Interview of testing persons two and four (as listed on Form CMS-209) on 06/06/2018 in the laboratory revealed this was done so hemolysis could be determined. The testing persons agreed that when media was received one thing they looked for was if it was damaged by cracks.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in interview of facility personnel, the laboratory director failed to ensure a policy was available for testing sterility of media plates upon their arrival. The findings were: 1. A laboratory policy instructing testing persons on how to perform sterility testing for newly received media was unavailable for review on 06/06/2018. 2. When testing person four (as listed on Form

	CMS-209) was asked how sterility was performed she revealed that upon arrival, the media was observed for contamination. When asked if the laboratory incubated a blank plate upon arrival, she stated, "No." 3. The above findings were confirmed in interview of the technical consultant on 06/06/2018 at 1330 hours in the break room.