Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0699412	03/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cute Pediatrics, Pllc	18 Paseo Plaza Blvd, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing Personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
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: A review of the laboratory's policies, review of the manufacturer's instructions for the Sysmex XP300 hematology analyzer, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for the resolution of flags on CBC (complete blood count) results. The findings were: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" (approved by the laboratory director on 01/12/2017) revealed: "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 tot he

	procedures in the unit's operator 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 persists, then it will be considered an abnormal differential and will be invalidated and/or should be sent out for analysis." 2. A review of the manufacturer's instructions for the Sysmex XP300 hematology analyzer (Code no AU553517, May 2014) revealed the manufacturer identified the following flags: WL T1 T2 F1 F2 F3 WU AG 3. Further review of the manufacturer's instructions revealed the AG flag indicated: "The particle count equal to or less than the LD exceeds the prescribed range. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count." 4. A review of patient test records from February 26 -28, 2018 identified the follow patient results which were reported out with AG flags: Date ID 02 /26 10366 02/26 9317 02/26 9534 02/27 13342 02/28 9425 5. The laboratory was asked to provide documentation of resolving the identified flags prior to reporting the results. No documentation was provided. 6. An interview with the technical supervisor on 03/08/2018 at 1230 hours in the break room - after his review of the records- confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing two competency assessments within the first year of employment for 1 of 1 testing personnel. The findings were: 1. A review of the laboratory's personnel records revealed testing personnel number 3 (as listed on Form CMS 209) was employed by the laboratory from September 2016 to November 2017. Thus, two competency assessments were required by September 2017. 2. A review of the personal records for testing personnel number 3 revealed the technical consultant performed a competency assessment in December 2016. The file did not contain documentation of a second competency assessment. 3. The laboratory was asked to provide documentation of the technical consultant performing a second competency assessment within the first year. No documentation was provided. 4. An interview with the technical consultant on 03/08/2018 at 1015 hours in the break room - after his review of the records- confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory

	failed to have documentation of education to qualify 2 of 4 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 4 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 03/08 /2018 revealed the laboratory identified 4 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 2 of 4 testing personnel. They were (as listed on Form CMS 209): Testing personnel number 2 Testing personnel number 3 3. The laboratory was asked to provide documentation of education to quality the identified testing personnel. No documentation was provided. 4. An interview with the technical consultant on 03/08 /2018 at 1015 hours in the break room - after his review of the records- confirmed the findings.