Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0699412	10/06/2020
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.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and confirmed in interview of facility personnel, the laboratory failed to ensure proficiency testing samples were handled the same as patient samples. The findings included: 1. Review of proficiency testing records from 2018 and 2019 found that the 2019 attestation

	statement for Microbiology (event 2) was signed by two testing persons. The attestation statement did not include which samples were tested by which testing persons. 2. An interview with the primary testing person on October 6, 2020 at 13:30 hours in the break room confirmed the findings. She stated that she was the only testing person now, but before they would look at the results together.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview with facility personnel, the laboratory failed to ensure reagents were labeled with identification of contents, lot number, and expiration date. The findings were: 1. Surveyor observation on October 6, 2020 at 13:05 hours in the laboratory found two green top containers with clear contents sitting on the countertop next the Sysmex analyzer. The containers were not labeled with content identification, lot number, or expiration date. 2. An interview with the primary testing person on October 6, 2020 at 13:05 hours in the laboratory confirmed the findings. She revealed the reagents were cleansers for the analyzer.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's IQCP (Individualized Quality Control Plan), review of laboratory policies, and confirmed in interview with facility personnel, the laboratory failed to have a policy for ongoing review of its IQCP for Rotavirus. The findings included: 1. An IQCP is composed of three parts: a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) Plan. 2. Review of the laboratory's IQCP for Rotavirus found the laboratory failed to establish written policies and procedures for the ongoing effectiveness of its IQCP for Rotavirus. There was no ongoing documentation of review of the IQCP since the original document was put into use. 4. The findings were confirmed in interview with the technical consultant on October 6, 2020 at 14:45 hours in the break room.
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. This is a repeat deficiency from the survey conducted March 8, 2018. 2. A review of the laboratory's personnel records revealed testing personnel number 1 (as listed on Form CMS 209) was employed by the laboratory from September 2018 to October 6, 2020 (the date of the survey). Thus, two competency assessments were required by September 2019. 3. A review of the personal records for testing personnel number 1 revealed no documentation of two competency assessments from September 2018 to September 2019. 4. The laboratory was asked to provide documentation of the technical consultant performing two competency assessments within the testing person's first year of patient testing. No documentation was provided. 5. An interview with the technical consultant on October 6, 2020 at 13:30 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 each testing person performing moderate complexity testing (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 laboratory records, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 1 testing personnel to perform moderate complexity testing

	prior to testing patient samples. The findings were: 1. This is a repeat deficiency from the survey conducted March 3, 2018. 2. Random review of laboratory records, found the following patient samples for moderate complexity testing performed by an employee who was no longer employed by the facility: Sample ID: 11706 Test: CBC (complete blood count) was performed on the Sysmex analyzer and finalized in the patient's medical record Date Performed: 08-30-2019 3. Review of the personnel records for the testing person found no documentation of education prior to patient testing that would qualify them to perform moderate complexity testing. The records available for review were for a certificate in medical assisting. 4. The laboratory was asked to provide documentation of education to quality the identified testing personnel. No documentation was provided. 5. An interview with the technical consultant on October 6, 2020 at 13:20 hours confirmed the findings.