Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0931690	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Abc Pediatrics	3675 Boca Chica Blvd Suite E, 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. 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209 approved by the laboratory director on July 09, 2018, review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2016 (event 3), 2017 (events 1, 2, and 3), 2018 (event 1), and confirmed in interview of facility personnel, the laboratory failed to ensure proficiency testing was rotated among all testing persons. The findings were: 1. Review of the laboratory's submitted CMS Form-209, approved by the laboratory director on July 19, 2018 revealed the laboratory identified nine testing persons. Testing person one Hire date: 07-20-02 Testing person two Hire date: 06-17-12 Testing person three Hire date: 07-04-12 Testing person four Hire date: 02-06-13

	Testing person five Hire date: 06-06-13 Testing person six Hire date: 12-23-14 Testing person seven Hire date: 07-26-17 Testing person eight Hire date: 08-05-15 Testing person nine Hire date: 10-02-15 2. Based on these hire dates each testing person should have participated in proficiency testing in 2017. 3. Review of the laboratory's proficiency testing attestation sheets and proficiency testing records from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (event 1) revealed proficiency testing was performed by the following testing persons in 2017: Hematology 2017 (event 1) Performed by testing personnel six Hematology 2017 (event 2) Performed by testing personnel five Hematology 2017 (event 3) Performed by testing personnel three 4. An interview with the technical consultant on 07/25/2018 in the hallway at 09: 30 hours confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of instrument manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of semi-annual instrument maintenance on the Abbott Cell-Dyn Emerald. The findings included: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on February 26, 1998, stated, "Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacturer's recommendations. Document all maintenance performed on the test system in use ..." 2. Review of the manufacturer's instructions for the maintenance on the Abbott Cell-Dyn Emerald (9410861E-August 2012) under the Maintenance section it stated, "Semi-Annually: Lubricate the pistons." 3. Review of the laboratory's maintenance logs for the Abbott Cell-Dyn Emerald hematology analyzer revealed there was a section to document semi-annual maintenance. However, from January 2016 to July 2018 there was no documentation on the logs that would indicate semi-annual maintenance was performed. 4. An interview with testing personnel one (as listed on Form CMS-209) on July 25, 2018 at 11:00 hours confirmed the findings. She revealed the service engineer has done it in the past, but the last time was in 2015.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on laboratory policy, review of manufacturer's instructions, review of the laboratory's instrument calibration records, and confirmed in interview of facility personnel, it was revealed the laboratory failed to have documentation of performing calibrations on the Abbott Cell-Dyn Emerald every 6 months. The findings were: 1. Review of the laboratory's policy, "Instrument Operation and Maintenance" approved by the laboratory director on February 26, 1998, stated, "Calibration of all laboratory instruments will be every six months, every time there is a complete change in lot numbers, or when controls don't give desired results ..." 2. Review of the manufacturer's instructions for the Abbott Cell-Dyn Emerald (9140861E, August 2012) under the section "Calibration" it stated, "Calibration should be confirmed on a regular basis according to your laboratory's protocols." 3. A review of the laboratory's calibration records for the Abbott Cell-Dyn Emerald hematology analyzer revealed the laboratory performed calibrations as follows: 01-14-2017 11-03-2017 (10 months, 20 days later) 05-18-2018 4. An interview with the technical consultant on July 25, 2018 at 11:30 hours in the hallway confirmed the findings. He confirmed he saw a record for a precision study in April of 2017, but agreed the calibration records were not there.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and confirmed in interview of facility personnel, the technical consultant failed to perform an annual competency assessment for each testing person in 2017 who required one. The findings were: 1. Review of the laboratory's personnel files revealed each current testing person who required an annual competency assessment had one on file for 2018. 2. Further review of the laboratory's personnel files revealed no 2017 annual competency assessments were available for review to evaluate each testing person on their moderate complexity testing responsibilities. 3. In an interview with the technical consultant on July 25, 2018 at 09:30 hours in the hallway confirmed the findings. He revealed they were done, but he did not maintain copies and they could not be located.