Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0931690	10/22/2020
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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: 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: Based on review of manufacturer's instructions for the Sysmex XN-330 hematology analyzer, review of laboratory policies, review of patient test records, and confirmed in staff interview, it was revealed that the laboratory failed to provide documentation of following its own policy to ensure CBC (complete blood count) samples with flags are verified prior to release to the healthcare provider for 4 of 10 patient test records reviewed. The findings were: 1. Review of the laboratory's policy titled, "Policy for Handling Flagged Differentials" approved by the laboratory director on February 6, 2016, it stated: "It will be the policy of this laboratory to rerun flagged results. If the

	second run still shows flags, then the lab will evaluate flagged differentials according to the 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 persist, 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 XN-330 (Code No. BW212660, Revised, June 2017) under, "5.2 List of IP messages" it stated: "Messages Atypical Lympho?: Possibility of atypical lymphocytes, Judged from the distribution of the upper area of LYMPH in the WDF Scattergram. Blasts /Abn Lympho?: Possibility that blasts are present/Possibility of abnormal lymphocytes, Judged from the presence of Blasts/Abn Lympho of the WDF scattergram. NRBC?: Possibility of nucleated red blood cells, Judged from the presence of NRBC in the WDF scattergram." 3. Random review of patient records from October 1, 2020 to October 20, 2020 found the following 4 patient results were resulted without resolving the flags prior to their release to the healthcare provider. Last 3 Digits of Sample #: 620 Date: 10-19-2020 WBC IP Message: Blasts/Abnormal Lymphocytes? Neutrophils: 27.8 * Lymphocytes: 56.7 * Monocytes: 10.1 * Immature Granulocytes: 0.9* Last 3 Digits of Sample #: 617 WBC IP Message: Blasts/Abn Lympho? Neutrophils: 30.5* Lymphocytes: 44.7* Monocytes: 16.6* IG: 2.0* Last 3 Digits of Sample #: 891 Date: 10-20-2020 WBC IP Message: Blasts/Abn Lympho?, Atypical Lympho? Neutrophils: 33.2* Lymphocytes: 55.1* Monocytes: 11.1* IG: 0.0 * Last 3 Digits of Sample #: 623 Date: 10-20-2020 WBC IP Message: Blasts/Abn Lympho? Neutrophils: 36.4* Lymphocytes: 44.8* Monocytes: 13.0* IG: 1.7* 4. The laboratory was asked to provide documentation of following its own policy to invalidate flags or send the abnormal results out for analysis. No documentation was provided. 5. An interview with the primary testing person on October 22, 2020 at 12: 30 hours in the laboratory confirmed the findings. Key: IP - interpretive program IG - immature granulocytes Abn - abnormal WBC - white blood cell
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of the laboratory's verification records for the Sysmex XN-330 and confirmed in staff interview, it was revealed the laboratory failed to complete a patient normal range study prior to patient testing when it implemented an FDA approved analyzer in January 2019. The findings were: 1. Review of 10 patient final reports revealed that the laboratory utilizes three sets of patient normal values: 2 years old to 6 years old 6 years old to 12 years old 12 years old to 18 years old 2. Review of the laboratory's policy titled, "Pre-Use Test System Validation Performance" approved by the laboratory director on February 26, 1998, it stated, "This laboratory will perform pre-use test system validation and will document the comparison of patient test results with an alternate method or comparison of split samples with an established method. Comparisons will be made to determine,

	accuracy, precision, reportable range." The laboratory's policy failed to include that a patient normal range study must be included as part of the verification study. 3. A review of the laboratory's verification records revealed the laboratory failed to complete the patient normal range verification study for the Sysmex XN-330. 4. An interview with the primary testing person on October 22, 2020 at 12:45 hours in the hallway confirmed the findings. Key: FDA - Food and Drug Administration
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the review of manufacturer's instructions for the XN-330 Sysmex hematology analyzer, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of a corrective action policy for testing patient specimens in a manner that ensures accurate and reliable results and reports for 3 of 10 patient samples reviewed that were positive for Interpretive Program messages. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XN-330 (Code No. BW212660, Revised, June 2017) under "5.1 Overview of IP messages" stated: "Caution! - A Positive or Error judgement indicates the possibility of an abnormality. It is not a diagnosis of the patient. If a Positive or Error judgement occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of your laboratory. - IP messages are only intended for use in the clinical laboratory and are not for patient diagnosis. IP messages provide notification of the possibility of a specific sample abnormality based on examination of the analysis data." and under "Positive/Negative judgement": "[Positive] Indicates that a blood cell analysis value or cell morphology exceeds the preset criteria for the IP message (abnormal sample). Displayed on a red background. A positive judgment is classified into 3 types shown below. Touch [Positive] to display a dialog box. [Diff. Abnormal]: Indicates an abnormal blood cell differentiation value. [Morph. Abnormal]: Indicates an abnormal cell morphology. [Count Abnormal]: Indicates an abnormal blood cell count." 2. Random review of patient records from October 1, 2020 to October 20, 2020 found the following 3 of 10 patients were resulted with positive morphology error judgements: Last 3 Digits of Sample #: 953 Date: 10-16-2020 IP Judgement: Positive PLT IP Message: PLT Clumps? Last 3 Digits of Sample #:617 Date: 10-19-2020 IP Judgement: Positive PLT IP Message: PLT Clumps? Last 3 Digits of Sample #: 623 Date: 10-20-2020 IP Judgement: Positive PLT IP Message: PLT Clumps? 3. The laboratory was asked to provide documentation of corrective action policy for resolution of the positive IP messages. No documentation was provided. 4. An interview with the primary testing person and the technical consultant on October 22, 2020 at 12:00 hours in the hallway confirmed the findings. Key: PLT - platelet
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification studies for the Sysmex XN-330 and staff interview, it was revealed the laboratory director failed to ensure the verification studies were complete prior to patient testing (refer to D5421).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification studies for the Sysmex XN-330 and staff interview, it was revealed the technical consultant failed to ensure the verification studies were complete prior to patient testing (refer to D5421).
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 CMS 209 Form, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training prior to patient testing to qualify 2 of 8 testing personnel (refer to D6066).
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 Form, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training to qualify 2 of 8 testing personnel (refer to D6066). The findings were: 1. A review of the laboratory's CMS 209 Form revealed the laboratory identified 8 personnel who performed moderate-complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training on the new Sysmex XN-330 hematology analyzer

	implemented in January 2019 prior to patient testing for 2 of 8 testing personnel. They were (as listed on Form CMS 209): Testing Personnel #1 Testing Personnel #4 Testing Personnel #5 Testing Personnel #6 Testing Personnel #7 Testing Personnel #8 3. The laboratory was asked to provide documentation of training on the new analyzer prior to patient testing. No documentation was provided. 4. An interview with the primary testing person on October 22, 2020 at 11:30 hours in the hallway confirmed the findings. She revealed that she and another person were trained by the company and then they trained the rest of the testing persons, but they did not document the training. This confirmed the findings.