Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503694	03/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Harlingen Pediatrics Associates	321 South 21st Street, Harlingen, 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.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Cell-Dyn Emerald hematology analyzer, review of the laboratory's policies, review of patient test records from January 2018, and staff interview, it was revealed the laboratory failed to have documentation of a protocol to follow to address flags on CBC (complete blood count) results. The findings were: 1. A review of the manufacturer's instructions for the Cell-Dyn Emerald hematology analyzer (9140847E June 2010) under the section titled "Table 3.4 WBC Flags" revealed the manufacturer identified the following flags and corrective actions to perform: a) L1 Action: Check specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required. b) L2 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. c) L3 Action: check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required. d) L5 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required. 2. A review of the laboratory policies revealed the facility failed to have a policy for testing personnel to follow to address the identified flags. The laboratory did not review stained smears either. 3. A review of patient test results from January 19, 2018 to January 25, 2018 identified the following patient results with flags which were reported to the provider: Date ID Flag 01/19 041228.03 L2 01/25 038289.02 L2 01/25 038289.01 L2 01/25 041181.03 L2 4. The laboratory was asked to provide documentation of a protocol which defined the laboratory's review criteria for results with flags. No documentation was provided. 5. An interview with the technical consultant on 03/14/2018 at 1130 hours in the break room - after his review of the records- confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's Temperature logs from October 2016 to December 2017, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when documented temperatures were outside the laboratory's defined acceptable ranges. The findings were: 1. A review of the laboratory's Temperature logs from October 2016 to December 2017 revealed the laboratory established the following ranges for temperature acceptability: Refrigerator: 36 - 46F Nurses Office: 59 - 77F Lab Room: 59 - 77F 2. Further review of the laboratory's Temperature logs from October 2016 to December 2017 revealed the following temperatures which were documented as being outside the laboratory's acceptable ranges: Date Area Temperature 10/25/16 Refrigerator 48 10/27/16

	Refrigerator 48 11/18/16 Refrigerator 48 11/25/16 Refrigerator 48 11/28/16 Refrigerator 48 01/10/17 Refrigerator 34 01/26/17 Refrigerator 34 03/01/17 Refrigerator 34 03/08/17 Refrigerator 34 04/11/17 Refrigerator 32 07/07/17 Nurses Office 79 11/14/17 Refrigerator 34 12/01/17 Refrigerator 35 12/19/17 Refrigerator 49 3. The laboratory was asked to provide documentation of performing corrective actions for the identified temperatures. No documentation was provided. 4. An interview with the technical consultant on 03/14/2018 at 1045 hours in the break room - after his review of the records- confirmed the findings.