Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2082893	09/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ashley Pediatrices Day And Night Clinic	1200 E Ridge Road, Suite 2, Mcallen, 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.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, review of the laboratory's American Proficiency Institute's (API) proficiency testing (PT) records, and confirmed interview of facilicty personnel, the laboratory failed to have documentation that the laboratory director and testing personnel signed the attestation statement for 1 of 6 events. The findings were: 1. A review of the laboratory's policy "Proficiency Testing" approved by the laboratory director October 2016, stated, "PT samples shall be tested and results reported on a timely basis. The attestation statement shall be signed and dated by test personnel and the Lab Director at the time of testing." 2. A review of the laboratory's (API) proficiency testing records from 2017 (events 2 and 3), 2018

	(events 1, 2, and 3) and 2019 (events 1 and 2) revealed attestation statements were not signed. 2019 (event 2): attestation statement not signed by the laboratory director 2019 (event 2): attestation statement not signed by the testing person 3. An interview with the technical consultant on 09/11/2019 at 10:00 hours in the breakroom after his review of the records confirmed the findings.
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 direct observation, review of verification records, and confirmed in interview of facility personnel, the laboratory failed to have documentation of verifying patient normal ranges when it implemented a new hematology analyzer in April 2019. The findings were: 1. Direct observation made on September 11, 2019 at 09:05 hours in the laboratory revealed the laboratory uses the following patient normal ranges: 0 -2 years 2 - 10 years 11 - 18 years Adult female Adult male 2. Review of the laboratory's verification records for the Medonic M hematology analyzer from April 2019 revealed no patient normal range verification records were available to review. 3. The findings were confirmed in interview of the technical consultant on September 11, 2019 at 09:18 hours in the break room.
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 laboratory policy, review of environmental logs, and confirmed in interview of facility personnel, the laboratory failed to have documentation of corrective action when temperatures were documented out of range. The findings were: 1. Review of the laboratory's policy titled, "Daily Laboratory Duties" approved by the laboratory director October 2016, it stated, "Read and record temperatures for all Laboratory Temperature Control devise (incubators, heat blocks, water baths, refrigerators, freezers). Also note and record room temperature. Compare temperature readings with the proper operating temperature of each device to ensure proper operation." 2. Random review of environmental logs from October 2017 to August 2019 found the following temperatures documented out of range: a. December 2018 Control Refrigerator Range 36 - 46 degrees Fahrenheit December 21, 2019: 47 degrees Fahrenheit b. December 2018 Laboratory Room Temperature Range: 68 - 77 degrees Fahrenheit December 9, 2018: 78 degrees Fahrenheit c. November 2018 Control Refrigerator Range: 36 - 46 degrees Fahrenheit November 8, 2018: 47

	degrees Fahrenheit d. November 2018 Laboratory Room Temperature Range: 68 - 77 degrees Fahrenheit November 8, 2018: 78 degrees Fahrenheit e. October 2018 Laboratory Room Temperature Range: 68 - 77 degrees Fahrenheit October 23, 2018: 80 degrees Fahrenheit October 25, 2018: 81 degrees Fahrenheit f. September 2018 Control Refrigerator Range 36 - 46 degrees Fahrenheit September 26, 2018: 47 degrees Fahrenheit September 28, 2018: 47 degrees Fahrenheit g. August 2018 Control Refrigerator Range 36 - 46 degrees Fahrenheit August 16 2018: 46.4 degrees Fahrenheit August 17, 2018: 46.4 degrees Fahrenheit August 20, 2018: 46.5 degrees Fahrenheit August 21, 2018: 46.4 degrees Fahrenheit August 22, 2018: 46.5 degrees Fahrenheit August 24, 2018: 46.4 degrees Fahrenheit August 27, 2018: 47.1 degrees Fahrenheit August 28, 2019: 46.9 degrees Fahrenheit August 30, 2018: 46.2 degrees Fahrenheit h. June 2018 Laboratory Room Temperature Range: 68 - 77 degrees Fahrenheit June 15, 2018: 80 degrees Fahrenheit i. June 2018 Laboratory Room Temperature Range: 68 - 77 degrees Fahrenheit May 2, 2018: 67 degrees Fahrenheit j. May 2018 Laboratory Room Temperature Range: 68 - 77 degrees Fahrenheit May 24, 2018: 78 degrees Fahrenheit May 31, 2018: 80 degrees Fahrenheit k. April 2018 Laboratory Room Temperature Range: 65 - 75 degrees Fahrenheit April 2, 2018: 79 degrees Fahrenheit April 24, 2018: 76 degrees Fahrenheit 3. Interview with the technical consultant on September 11, 2019 at 11:24 hours in the break room confirmed the findings.