Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0467679	11/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of West Memphis	108 West Tyler, West Memphis, AR	

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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of Horiba Micros 60 manufacturer's calibration instructions, calibration documentation for 2018 and 2019 and interviews with laboratory staff, it was determined the laboratory failed to take and document corrective actions for failure of one of four calibrations performed in 2018 and 2019. Survey findings include: A. Manufacturer's instructions for calibration of the Horiba Micros 60 hematology analyzer includes a step titled "Verify Calibration". The instructions for verifying calibration are as follows: "Once calibration has passed for all parameters, verify by running the Minocal calibrator 3 more times as a patient sample (mix between each run). Calculate the mean of WBC, RBC, Hgb, HCT, and Plt for the 3 runs and ensure each mean falls within the Assay ranges in the Minocal package insert." B. Through a review of the documentation of calibration dated 3/28/2018 it was determined the laboratory ran the calibrators 3 times for verification. The results for PLT were documented as 273, 249, and 286. The mean value documented for these three runs was 257, which is incorrect (correct calculated mean of 273, 249, and 286 is 269.3). The assay ranges on the Minocal package insert for the lot used (CX421) is listed as 245+/-12 (233 - 257). The correctly calculated mean (269.3) is

	outside of the assay range. C. In an interview at 11:12 on 11/27/19, the technical consultant confirmed there were no corrective actions for this failure and that the laboratory had no documentation of identifying the calibration failure.