Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2191163	12/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Of The Northwest	14795 Sw Murray Scholls Drive, Ste121, Beaverton, OR	

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
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 discussion with staff and review of laboratory records for calibrating the Reichert Bilirubinometer, the laboratory failed to perform calibration before reporting patient test results. Findings include: 1. No written documentation of calibration for the Reichert Bilirubinometer could be produced since the clinic opened to patients 09/01/2020. 2. Interview with 2 staff members during survey 12/14/2020 at approximately 1230 pm confirmed that no written documentation for calibration of the instrument was available for review.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on inspection of the control materials used for Quality Control (QC) testing of the Reichert bilirubinometer and discussion with staff, the laboratory failed to choose control materials appropriate for this instrument. Findings include: 1. Upon inspection of the control materials for bilirubin from Thermo Scientific, it was noted that there were no reference ranges for these controls for this specific instrument. 2. Upon review of the daily QC log for the Reichert Bilirubinometer, there were no reference ranges for any of the three (3) controls used by staff. 3. During interview with one testing personnel (TP) on 12/14/2020 at approximately 1230 pm, she confirmed that she did not know what the reference ranges for the three (3) QC substances were.