Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2054066	11/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bootin & Savrick Pediatric Associates	10970 Shadow Creek Pkwy, Suite # 350, Pearland, 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(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 the review of the laboratory's policy, proficiency testing record, and confirmed in an interview, the laboratory failed to have documentation of attestation statement for 1 of 1 proficiency testing event: Nonchemistry M3 2024. The findings were: 1. Review of the laboratory's policy titled Proficiency Testing Guidelines under Procedure revealed "8. Attestation statements are signed by each individual performing the testing and by the laboratory Director or designee." 2. Review of the laboratory proficiency testing from AAB MLE revealed no documentation of attestation statement for 1 of 1 proficiency testing event. Nonchemistry M3 2024 3. An interview on 11/07/24 at 11:30 am in the lab, the technical consultant confirmed the above findings. Key: AAB MLE=American Association of Bioanalysts Medical Laboratory Evaluation
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 the review of the laboratory's validation records, policies, and confirmed in an interview, the laboratory failed to establish a written policy for verification study of acceptability for accuracy and precision for 1 of 1 new test systems put in used in 2024: Sysmex XN-330. The findings were: 1. Review of the laboratory's validation records revealed the laboratory director signed off the new test system Sysmex XN-330 in May, 2024. 2. Review of the laboratory's policies revealed no written policy for verification study of acceptability for accuracy and precision for one of one new test systems put in used in 2024. Sysmex XN-330 SN:16307 3. An interview on 11/07/24 at 12:30 pm in the lab, the technical consultant confirmed the above 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 the review of the laboratory's method verification records and confirmed in an interview, the laboratory failed to document verification of the laboratory's reference ranges for 1 of 1 new hematology instrument implemented in 2024. The findings were: 1. An interview on 11/07/2024 at 12:15 pm in the lab, the testing personnel confirmed the new hematology instrument started the patient testing on 07/02/2024. Sysmex XN-330 SN: 16307 2. Review of the laboratory's method verification records reveal no documentation of the laboratory's reference ranges for 1 of 1 new hematology instrument: Sysmex XN-330 (SN: 13706). 3. An interview on 11/07/24 at 12:30 pm in the lab, the technical consultant confirmed the above findings.
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 the review of the laboratory's policy, the laboratory's record from 07/02 /2024 to 11/07/2024, and confirmed in an interview, the laboratory failed to follow the laboratory's own policy to have documentation for 1 of 1 lot to lot verification. The findings were: 1. Review the laboratory's policy titled Quality Control Policy under XV. NEW LOT QUALITY CONTROL revealed "1. Analyze the old lot and the new lot simultaneously for ten consecutive days if possible. Establish a new lot range and mean using the following guidelines." 2. Review of the laboratory's records from 07 /02/2024 to 11/07/2024 revealed the laboratory had no documentation for 1 of 1 lot to lot verification. Lot #: 4181140 Exp: 2024-10-08 Opened date: 07/30/2024 Lot #: 4265140 Exp: 2024-12-31 Opened date: 10/10/2024 3. An interview on 11/07/24 at 2: 20 pm in the lab, the technical consultant confirmed the above findings.