Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0988130	06/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bootin And Savrick Pediatric Associates	7501 Fannin Suite #850, Houston, 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	A recertified onsite survey was completed on 06/20/2025. 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) (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 events for 2024 and 2025, and confirmed in an interview, the laboratory failed to have documentation of signed attestation statement for 3 of 7 proficiency testing events. 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 events from AAB-MLE for 2024 and 2025 revealed no documentation of signed attestation statement for 3 of 7 proficiency testing events. Chemistry M1 2024- Testing personnel did not sign Chemistry M2 2024- Both testing personnel and Laboratory Director or designee did not sign AAB-MLE M1 2025- Testing personnel did not sign 3. An interview on 06/20/25 at 12:13 pm in the lab, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings. Key: AAB-MLE=American Association of Bioanalysts Medical Laboratory Evaluation CMS=Center for Medicare and Medicaid Services
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g)

	(d)(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the laboratory's reagent replacement logs from 02/05/2025 to 05/10/2025, QC logs, patient records, and confirmed in an interview, the laboratory failed to document a quality control run after a change in a reagent for 3 of 3 days reviewed on one of one Sysmex XN-330 hematology instrument. The findings were: 1. The surveyor's direct observation on 06/20/2025 at 10:15 am revealed the laboratory used the following 4 reagents for Sysmex XN-330 hematology instrument (SN: 16317). Cellpack DCL Lysercell WDF Fluorocell DCL Sulfolyser 2. Random review of the reagent replacement logs from 02/05/2025 to 05 /10/2025 revealed 3 of 3 days reviewed had no documentation of a quality control run after the following reagent change on the Sysmex XN-330 hematology analyzer. 02/05 /2025 Changed Cellpack DCL at 11:34 am Changed Fluorocell WDF at 12:19 pm 04 /17/2025 Changed Fluorocell WDF at 10:32 am 05/10/2025 Changed Sulfolyser at 10: 33 am 3. Review of the laboratory's QC logs for the above dates revealed the QC was performed for the day and failed to perform a level of QC run after reagent changes until QC was performed the next day. 02/05/2025 Changed Cellpack DCL at 11:34 am Changed Fluorocell WDF at 12:19 pm QC Level 1 was run at 9:30 am QC Level 2 was run at 9:32 am QC Level 3 was run at 9:34 am 04/17/2025 Changed Fluorocell WDF at 10:32 am QC Level 1 was run at 9:55 am QC Level 2 was run at 9:57 am QC Level 3 was run at 9:59 am 05/10/2025 Changed Sulfolyser at 10:33 am QC Level 1 was run at 9:27 am QC Level 2 was run at 9:31 am QC Level 3 was run at 9:33 am 4. Review of the patient records for the above dates revealed the laboratory performed 6 patient CBC testing after the reagent change with no documentation of a quality control run after reagent change. 02/05/2025 at 2:41 pm Sample ID: MARJA056 02/05 /2025 at 2:59 pm Sample ID: MAREN003 04/17/2025 at 2:31 pm Sample ID: SCHWA004 04/17/2025 at 2:49 pm Sample ID: SMIT0001 04/17/2025 at 5:02 pm Sample ID: APOER000 05/10/2025 at 10:40 am Sample ID: BROWA 5. An interview on 06/20/25 at 1:08 pm in the lab, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings. Key: QC=Quality Control CBC=Complete Blood Count CMS=Center for Medicare and Medicaid Services
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on the review of the laboratory's SN-330 hematology instrument validation records, testing personnel's training records, and confirmed in an interview, the technical consultant failed to have training documentation for 9 of 10 testing personnel prior to performing CBC testing on XN-330 hematology instrument. The findings were: 1. Review of the laboratory's XN-330 (SN: 16317) hematology instrument validation records revealed the laboratory director signed the validation

	data in December, 2024. An interview on 06/20/25 at 12:50 pm in the lab, the technical consultant (as indicated on the CMS 209 form) confirmed the laboratory started using XN-330 hematology instrument in December, 2024. The technical consultant also confirmed the laboratory was using Sysmex XP-300 and K-series prior to XN-330. 2. Review of the laboratory's testing personnel training records revealed no documentation of training records for 9 of 10 testing personnel prior to use XN-330 hematology instrument. Testing personnel #2 Hired Date: 12/24/2014 Testing personnel #3 Hired Date: 11/18/2022 Testing personnel #4 Hired Date: 09/15/2021 Testing personnel #5 Hired Date: 08/05/2024 Testing personnel #6 Hired Date: 05/13 /2024 Testing personnel #7 Hired Date: 01/02/2024 Testing personnel #8 Hired Date: 08/26/2024 Testing personnel #9 Hired Date: 12/16/2024 Testing personnel #10 Hired Date: 05/23/2016 3. An interview on 06/20/25 at 12:55 pm in the lab, the technical consultant (as indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services