Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0988130	11/19/2021
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were 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.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from 2020-2021, and confirmed in interview, the laboratory failed to report 7162 SARS-CoV-2 negative Antigen test results as required by 400.200 for 13 of 13 months reviewed from 10/01/2020 to 10/31/2021. Findings were: 1. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 Antigen patient testing using Quidel Sofia2 Flu + SARS Antigen diagnostic test on 07/2020. 2. Review of the laboratory policies available revealed no documentation of a policy/procedure related to SARS-CoV-2 test reporting. 3. Review of the laboratory SARS-CoV-2 Antigen patient test records from 2020 and 2021 revealed no

	documentation the laboratory reported 7162 of 7162 patient negative test records for 13 of 13 months of testing. Refer to Covid Antigen Patient Alias list. 4. An interview with the technical consultant on 11/19/21 at 1140 hours in the office confirmed the above findings.
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: Based on review of the laboratory quality control and patient test records from 2020 and 2021 and confirmed in interview, the laboratory failed to document corrective actions taken when quality control was outside of the acceptable range for two of two tests: CBC (complete blood count) and bilirubin. Findings were: 1. Random review of the quality control records from April to October 2021 for CBC testing revealed four of twenty days with one quality control failure and no documentation of the corrective action. 4/1/21 QC lot 10550710, exp 6/2/21 PLT 77 (acceptable range 42-76) 8/14/21 QC lot 11390711, exp 8/25/21 NEUTROPHILS 4.9 (acceptable range 3.5-4.7) 8/27 /21 QC lot 12230710, exp 11/17/21 WBC 4.0 (acceptable range 2.7-3.7) 9/13/21 QC lot 12230710 exp 11/17/21 PLT 79 (acceptable range 42-76) 2. Random review of the above dates revealed the laboratory performed the following two CBC testing. 4/1/21 BRAJA018 9/13/21 1ZASL000 3. Random review of the quality control records from December 2020 to October 2021 for bilirubin testing revealed three of twenty days with one quality control failure and no documentation of the corrective action. 12/29 /20 QC out L2 (lot 44382): 18.3 (acceptable range 18.8-20.8) 6/30/21 QC out L2 (lot 44382): 17.5 (acceptable range 17.87 - 19.87) 9/2/21 QC out L2 (lot 44392): 15.6 (acceptable range 17.1-19.1) 4. Random review of the above dates revealed the laboratory performed the following three bilirubin testing. 12/29/20 VEGJ0001, QAME0009 6/30/21 AMILEU000, MEZLE000 9/2/21 LEU01 5. An interview with the technical consultant on 11/19/21 at 1100 hours in the break room confirmed the above findings.