| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0988130 | 05/11/2023 |
| **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 |
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| **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. |
| **D5437** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies, the laboratory's calibration records from 2022 and 2023, and staff interview, it was revealed that the laboratory failed to have documentation of performing a calibration every six months on the: a) Sysmex XP-300 hematology analyzer in 2022 and 2023 b) Reichert Unistat bilirubinometer in 2022. Findings include: 1. A review of the laboratory's policies revealed the following: a) The laboratory's policy titled 'Sysmex XP-300' revealed the following: "Initial calibration is preformed during installation. Calibration is also required if one or more of the following occur: - Critical parts, such as manometers, apertures or detector circuit boards are replaced. - Controls show an unusual trend or are outside of acceptable limits and cannot be corrected by maintenance or troubleshooting. - When advised by Sysmex Field Service Representative. - Every six months." b) The |

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| | laboratory's policy titled 'Reichert Unistat Bilirubin' revealed the following: "Calibration frequency The Reichert Unistat bilirubinometer requires calibration upon installation and then at least at six-month intervals, unless quality control data indicate the need for earlier calibration." 2. A review of the laboratory's calibration records from 2022 and 2023 revealed the following: a) Sysmex SP-300 hematology analyzer was calibrated in April 2022 b) Reichert Unistat bilirubinometer was calibrated in November 2022 3. Further review of the laboratory's calibration records revealed no documentation of the laboratory performing the following calibrations: a) Sysmex SP-300 hematology analyzer-- October 2022 and April 2023 b) Reichert Unistat bilirubinometer-- May 2022 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 5/11/23 at 9:45 a.m. in the break room, after review of the records, confirmed the above findings. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's quality control and calibration records, calibration verification records for the Reichert Unistat bilirubinometer from 2022, and staff interview, it was revealed that the laboratory failed to have documentation of performing one of two calibration verification procedures in 2022 for bilirubin testing on the Reichert Unistat bilirubinometer. Findings include: 1. A review of the laboratory's quality control and calibration records for the Reichert Unistat bilirubinometer revealed bilirubin was calibrated using 1 calibrator and the laboratory tested 2 levels of quality control once a day, thus calibration verification was required at least every 6 months. 2. A review of the calibration verification records from 2022 revealed the laboratory performed calibration verification procedures for bilirubin on the Reichert Unistat in November 2022. 3. Further review of the calibration verification records revealed the laboratory failed to have documentation of performing calibration verification procedures for bilirubin, six months prior, in May |

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| | 2022. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 5/11/23 at 11:15 a.m. in the break room, after review of the records, confirmed the above findings. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies, the laboratory's quality control records for the Sysmex SP-300 hematology analyzer from October and November 2022, a review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running two levels of quality control material each day of patient testing for two of sixty one days on the Sysmex XP-300 hematology analyzer. Findings include: 1. A review of the laboratory's policy titled 'Sysmex XP-300' revealed the following: "Frequency of Control Use and QC Data Review - Three levels of controls are analyzed each day of patient testing." 2. A review of the laboratory's quality control records for the Sysmex XP-300 hematology analyzer from October and November 2022 revealed the laboratory failed to have documentation of running two levels of quality control material each day of patient testing for following two days: 10/21/22 11/4/22 3. A review of patient test records revealed the following 12 patient's samples were resulted on the days when there was no documentation that quality controls were run: Date: 10/21/22 Patient Accession #s: 11139, 11140, 11134, 11136, 11141, 11144, 11145, 11147 Date: 11/4/22 Patient Accession #s: 11215, 11216, 11219, 11220, 11221, 11222, 11223, 11224, 11225, 11226, 11229, 11230 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 5 /11/23 at 10:05 a.m. in the break room, after review of the records, confirmed the above findings. Key: QC = Quality Control |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of the technical consultant performing a competency assessment, at least semiannually during the first year of testing, for two of four testing personnel in 2022 for all moderate complexity testing performed in the laboratory. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified four testing person performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed the following testing personnel, their hire date, and date(s) a competency assessment was performed by the technical |

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| | consultant for Complete Blood Count (CBC) testing on the Sysmex XP-300 hematology analyzer and Bilirubin testing on the Reichert Unistat bilirubinometer: a) Testing person #3 Hire date: 2/18/22 Competency assessment: 2/18/22 Based on the hire date, testing person #3 should have had at least 2 competency assessments performed prior to 2/2023. b) Testing person #4 Hire date: 2/8/22 Competency assessment: 2/8/22 Based on the hire date, testing person #4 should have had at least 2 competency assessments performed prior to 2/2023. 3. Further review of the personnel records revealed the laboratory failed to have documentation of the technical consultant performing a competency assessment for the following testing: a) Testing person #3 - No documentation of a second competency assessment prior to 2 /2023 for CBC testing on the Sysmex XP-300 hematology analyzer b) Testing person #4 - No documentation of a second competency assessment prior to 2/2023 for CBC testing on the Sysmex XP-300 hematology analyzer and Bilirubin testing on the Reichert Unistat bilirubinometer 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 5/11/23 at 11:09 a.m. in the break room, after review of the records, confirmed the above findings. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the technical consultant failed to perform a competency assessment on two of four testing personnel in 2022 for Complete Blood Count (CBC) testing on the Sysmex SP-300 hematology analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 4 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed no documentation of the technical consultant performing a competency assessment for CBC testing on the Sysmex SP-300 hematology analyzer for the following personnel: - Testing person #1 in 2022 - Testing person #2 in 2022 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 5/11/23 at 11:09 a.m. in the break room, after review of the records, confirmed the above findings. |