

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0988130	<b>(X3) Date Survey Completed</b>  12/10/2024
<b>Name of Provider or Supplier</b>  Bootin And Savrick Pediatric Associates	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The facility was found to be out of compliance with the conditions of the CLIA program. The following <b>CONDITION LEVEL DEFICIENCIES</b> were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This <b>CONDITION</b> is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the proficiency testing company American</p>

Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events in the specialty of Hematology for a regulated analyte of Cell ID or WBC Diff for two of three proficiency testing events in 2024. (Refer to D2130 and D2131). Key: CMS=Center for Medicare and Medicaid Services I.D. =Identification WBC=White Blood Cell Diff=Differential

**D2130**

**HEMATOLOGY**

CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the proficiency testing company American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events in the specialty of Hematology for two of three proficiency testing events in 2024. The findings were: 1. Review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile revealed the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events in the specialty of Hematology for a regulated analyte of Cell ID or WBC Diff for two of three proficiency testing events in 2024. Cell ID or WBC Diff 2024 Event 2 Score: 0% 2024 Event 3 Score: 24% 2. Review of the proficiency testing company American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) CMS Cumulative Scores-Regulated Analyte, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events in the specialty of Hematology for two of three proficiency testing events in 2024. 2024 Event 2 WBC Differential: 0% 2024 Event 3 WBC Differential: 24% Key: PT=Proficiency Testing AAB-MLE= American Association of Bioanalysts Medical Laboratory Evaluation CMS=Center for Medicare and Medicaid Services I.D. =Identification WBC=White Blood Cell Diff=Differential

**D2131**

**HEMATOLOGY**

CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 153 Unsatisfactory (failed) and Unsuccessful (2 of 3) PT Report and Report 155 Individual Laboratory Profile, the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events in the specialty of Hematology for two of three proficiency testing events in 2024. The findings were: 1. Review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 153

Unsatisfactory (failed) and Unsuccessful (2 of 3) PT Report revealed the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events for two of three proficiency testing events in 2024. 2024 Event: 2 Score: 66 Event: 3 Score: 74 2. Review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile revealed the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events in the specialty of Hematology for two of three proficiency testing events in 2024. Hematology 2024 Event 2 Score: 66% 2024 Event 3 Score: 74% Key: PT=Proficiency Testing AAB-MLE= American Association of Bioanalysts Medical Laboratory Evaluation CMS=Center for Medicare and Medicaid Services

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the proficiency testing company American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory director failed to provide overall management and direction of the laboratory services. (Refer to D6016)

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on a desk review of proficiency testing records obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and verified with the proficiency testing company American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), the laboratory director failed to ensure successful testing performances in a HHS improved proficiency testing program for two of two consecutive testing events for the overall testing events in the specialty of Hematology and the analyte Cell ID, resulting in an initial unsuccessful performance. (Refer to D2130 and D2131). Key: ID= Identification