

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0264907	<b>(X3) Date Survey Completed</b>  10/21/2020
<b>Name of Provider or Supplier</b>  Savannah Pediatrics Pc	<b>Street Address, City, State</b>  1000 Town Center Boulevard Suite 301, Pooler, GA	
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>	On December 28,2020, an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interview the lab director and/or testing personnel failed to attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of PT records revealed attestation signatures of the lab director and/or testing personnel were missing on the 2019 Events 2 and 3; and on 2020 Events 1 and 2. 2. Interview with staff #4 (CMS 209) on 10/21/20 at approximately 11:00 AM in a back patient exam room, confirmed the missing signatures.</p>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two</p>

years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of proficiency test (PT) records and staff interview the lab failed to maintain copies ( analyzer printouts) of all test results reported to the PT provider.

Findings include: 1. Review of proficiency test (PT) records revealed the lack of analyzer print offs/results for PT 2019 event #2; 2020 events #1 and #2. 2. Interview with staff #4 (CMS 209) on 10/21/20 at approximately 11:00 AM in a back patient exam room, confirmed the PT result printouts were not available.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of proficiency test (PT) records and staff interview the lab failed to review and evaluate the results obtained on proficiency testing. Findings include: 1. Review of proficiency test (PT) records revealed the lab failed to review/evaluate PT results for 2019 events #1, #2, #3. 2. Interview with staff #4 (CMS 209) on 10/21/20 at approximately 11:00 AM in a back patient exam room, confirmed the PT results were not signed as reviewed/evaluated.

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of proficiency test (PT) records and staff interview the lab failed to document corrective action taken for unsatisfactory score obtained on proficiency testing. Findings include: 1. Review of proficiency test (PT) records revealed the lab failed to document corrective actions taken for 2019 event #2 missed differential monocyte analyte for score of 80%. 2. Interview with staff #4 (CMS 209) on 10/21/20 at approximately 11:00 AM in a back patient exam room, confirmed the monocyte PT result did not have documented corrective action..

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:  
Based on calibration document review and staff interview, the lab failed to calibrate or perform calibration verification on the Sysmex XP300 analyzer every six (6) months as required by the manufacturer. Findings include: 1. Review of calibration data revealed the Sysmex XP300 was calibrated or calibration verification performed on : 7/23/18, 1/14/19, 6/18/19, and 6/9/20. The calibration or calibration verification was not performed in December 2019. 2. Interview with staff #4 (CMS 209 form) on 10/21/20 at approximately 12 PM in a back patient exam room, confirmed the time spans.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:  
Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to monitor, assess, and correct problems as required. Findings include: 1. SOP review revealed the laboratory director failed to review the quarterly quality assurance (QA) checklist for July 2018 or October 2018 per the SOP. 2. Interview with staff #4 (CMS 209 form) on 10/21/20 at approximately 12 PM in a back patient exam room, confirmed the aforementioned QA checklists were not reviewed by the laboratory director.