

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2262361	(X3) Date Survey Completed 02/21/2023
Name of Provider or Supplier Shreeven Llc	Street Address, City, State 1609 Sw 17th St, Ocala, FL	
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	An announced CLIA initial certification survey was conducted at Shreeven Llc on 2 /21/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. .
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with the Technical Consultant, the laboratory failed to document how it will monitor the pre-analytic testing process of the Sight OLO Complete Blood Count (CBC) analyzer, Abbott I-Stat analyzer, Abbott Afinion HbA1c (Hemoglobin A1C) analyzer, Abbott Piccolo analyzer, and the Qualigen FastPack System. The findings include: A review of the IQCP documentation showed that there was no assessment of the pre-analytic testing process and how problems will be corrected. The interview with the Technical Consultant on 2/21/23 at 11:35am confirmed the IQCP was incomplete. .</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the laboratory failed to document that the Laboratory Director approved, signed and dated the procedure manuals and Individualized Quality Control Plan (IQCP) for the Sight OLO Complete Blood Count (CBC) analyzer, Abbott I-Stat analyzer, Abbott Afinion HbA1c (Hemoglobin A1C) analyzer, Abbott Piccolo analyzer, and the Qualigen FastPack System. Findings include: Review of the procedure manual for each instrument showed that the the laboratory failed to document that the Laboratory Director approved, signed and dated the procedure manuals. Review of the IQCPs for the Sight OLO Complete Blood Count (CBC) analyzer, Abbott I-Stat analyzer, Abbott Afinion HbA1c (Hemoglobin A1C) analyzer, Abbott Piccolo analyzer, and the Qualigen FastPack System showed that the Laboratory Director had not approved and signed each IQCP before it was put in use. During an interview on 2/21/23 at 11:25 AM, the Technical Consultant confirmed the Laboratory Director had not signed the procedure manuals or the IQCPs. .

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to document the room temperature and humidity of the laboratory since May 2022. The findings include: At the time of survey, the laboratory was unable to provide documentation showing the room temperature and humidity of the laboratory was monitored since instruments were validated in May 2022. The interview with the Technical Consultant on 2/21/23 at 11:45am confirmed it was not being monitored. .

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with the Technical Consultant, the laboratory failed to document a complete

	<p>IQCP for the Sight OLO Complete Blood Count (CBC) analyzer, Abbott I-Stat analyzer, Abbott Afinion HbA1c (Hemoglobin A1C) analyzer, Abbott Piccolo analyzer, and the Qualigen FastPack System. Findings include: A review of the IQCP Quality Control Plan (QCP) documentation showed that there was no documentation of the number, type, frequency of testing, and criteria for acceptable quality control (QC) results. The interview with the Technical Consultant on 2/21/23 at 11:30am confirmed the IQCP was incomplete. .</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with the Technical Consultant, the laboratory failed to document how it will monitor the analytic testing process of the Sight OLO Complete Blood Count (CBC) analyzer, Abbott I-Stat analyzer, Abbott Afinion HbA1c (Hemoglobin A1C) analyzer, Abbott Piccolo analyzer, and the Qualigen FastPack System. The findings include: A review of the IQCP documentation showed that there was no assessment of the analytic testing process and how problems will be corrected. The interview with the Technical Consultant on 2/21/23 at 11:35am confirmed the IQCP was incomplete. .</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with the Technical Consultant, the laboratory failed to document how it will monitor the post-analytic testing process of the Sight OLO Complete Blood Count (CBC) analyzer, Abbott I-Stat analyzer, Abbott Afinion HbA1c (Hemoglobin A1C) analyzer, Abbott Piccolo analyzer, and the Qualigen FastPack System. The findings include: A review of the IQCP documentation showed that there was no assessment of the post-analytic testing process and how problems will be corrected. The interview with the Technical Consultant on 2/21/23 at 11:35am confirmed the IQCP was incomplete. .</p>