Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2150952	01/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Starting Point Of Virginia, Pc	301 Falls Drive, Suite 353, Abingdon, VA	

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 recertification survey was conducted at Starting Point of Virginia PC (Abingdon) on January 14-15, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The inspection also included an offsite follow up interview with the compliance specialist on 1/16/25. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D5400 -42 CFR. 493.1250 Analytic Systems .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour, review of standard operating procedures, manufacturer's operation manual, Dirui CS (IR-1200) chemistry analyzer maintenance logs, chemistry calibration records, lack of documentation, and interviews, the laboratory failed to: 1. document performance of monthly chemistry analyzer water supply inlet filter maintenance in twenty-two (22) of twenty-three (23) months reviewed (timeframe: February 9, 2023 to January 15, 2025) - Cross Reference D5429 A; 2. document every three month analyzer maintenance protocols in two (2) of 2 years reviewed (2023 and 2024) - Cross Reference D5429 B; 3. document weekly chemistry analyzer maintenance protocols in 2 of fifty-two (52) weeks in calendar year 2024 - Cross Reference D5429 C; 4. document performance of annual preventative maintenance (PM) for one Dirui CS (IR-1200) chemistry analyzer in 2024 - Cross Reference

	D5429 D; 5. document annual function checks of revolutions per minute verification for 2 of 2 centrifuges per their policy in calendar years 2023 and 2024 - Cross Reference D5435 A; 6. document thermometer calibration verification for six (6) of 6 thermometers annually per policy in calendar year 2023 (review timeframe 2/9/23 to 1 /15/25) - Cross Reference D5435 B; 7. document annual calibration verification for one analytic balance per policy in 2 of 2 calendar years reviewed (2023 and 2024) - Cross Reference D5435 C; 8. document annual timer calibration verification for three (3) of 3 timers per policy in calendar years 2023 and 2024 - Cross Reference D5435 D; 9. document weekly Fentanyl assay calibration procedures according to established criteria for twenty (20) of ninety-eight (98) weeks reviewed (timeframe: 2/9/23 to 1/15 /25) - Cross Reference D5437.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on a tour, review of standard operating procedures (SOP), manufacturer's operation manual, maintenance logs, lack of documentation, and interviews, the laboratory failed to document performance of monthly chemistry analyzer water supply inlet filter maintenance in twenty-two (22) of twenty-three (23) months reviewed (timeframe: February 9, 2023 to January 15, 2025). Findings include: 1. During a laboratory tour on 1/14/25 at 1:00 PM, the inspector noted one Dirui CS (IR-1200) chemistry analyzer (Serial number S1901200CS0138) in use for urine drug screen testing with onboard chemistry reagents for Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Ethyl Glucuronide, Fentanyl, Methadone, Methadone Metabolite, Opiates, Oxycodone, Urine Creatinine and pH. 2. Review of the laboratory's online SOP revealed a protocol (title: TOX-IR1200 Standard Operating Procedures Dirui CS Series 1200 Maintenance Schedule) that outlined task "Clean Water Supply Inlet Filter" as a required monthly maintenance procedure. 3. Review of the manufacturer's operation manual (Section: CS Series Auto-Chemistry Analyzer Maintenance Procedures) revealed instructions that stated, "It is necessary to maintain the analyzer in strict accordance with the requirements of the user manual". The inspector noted manufacturer instructions under Section 4-Monthly Procedure that outlined, "Rinse Filter - Rinse the filter net with pure water at the water supply port monthly". 4. Review of the Dirui CS (IR-1200) chemistry analyzer maintenance logs for February 2023 to the date of the inspection on 1/15/25, revealed that the monthly procedure outlined above was recorded as performed once on 10/9/23. The inspector requested to review additional records that the monthly task "Clean Water Supply Inlet Filter" was performed during the 23 months of review. No documentation was available. 5. An interview with the lab director and compliance specialist on 1/15/25 at 2 PM confirmed the above findings. B. Based on a review of SOP, maintenance logs, lack of documentation, and interviews, the laboratory failed to document required every three (3) month chemistry analyzer maintenance protocols in two (2) of 2 years reviewed (calendar year 2023 and 2024). Findings include: 1. Review of the laboratory's SOP revealed a protocol (title: TOX-IR1200 Standard Operating Procedures Dirui CS Series 1200 Maintenance Schedule) that outlined the task "Run Rinse Water Tank" as required every 3 months. 2. Review of the laboratory's monthly maintenance logs for calendar years 2023 and 2024 revealed no documentation that the required maintenance outlined above was performed. The

	inspector requested to review records that the every 3 month maintenance task "Run Rinse Water Tank" was performed during the 2 years of review. No documentation was available. 3. An interview with the lab director and compliance specialist on 1/15 /25 at confirmed the above findings. C. Based on a review of SOP, manufacturer's operation manual, maintenance logs, lack of documentation, and interviews, the laboratory failed to document required weekly chemistry analyzer maintenance protocols in two (2) of fifty-two (52) weeks in calendar year 2024. Findings include: 1. Review of the laboratory's SOP revealed a protocol (title: TOX-IR1200 Standard Operating Procedures Dirui CS Series 1200 Maintenance Schedule) that outlined the following three required tasks to be performed weekly: Run Rinse All Cuvettes Cycle, Run Cuvettes Blank Test, Run Rinse Sample Probe. 2. Review of the operations manual revealed maintenance protocols (Section: CS Series Auto-Chemistry Analyzer Maintenance Procedures) that stated, "It is necessary to maintain the analyzer in strict accordance with the requirements of the user manual". The inspector noted manufacturer instructions under Section 3-Weekly Maintenance Procedures that outlined, "Place the reagent bottle with CS-Alkaline Detergent inside the position 45 of reagent disk. Ensure detergent is sufficient, if not add some. Run system maintenance under Rinse for cuvettes and probe. Run system maintenance under Cuvette Blank Test". 3. Review of monthly Dirui CS (IR-1200) chemistry analyzer maintenance logs revealed no documentation that the three weekly maintenance tasks outlined above were performed during the last weeks of February and April in 2024. The inspector requested to review documentation that the required weekly maintenance tasks were performed in the week of 2/26/24 -3/1/24 and 4/22/24-4/27 /24. No documentation was available. 4. An interview with the lab director and compliance specialist on 1/15/25 at confirmed the above findings. D. Based on a review of SOP, Dirui CS (IR-1200) chemistry analyzer maintenance logs, lack of documentation, and interviews, the laboratory failed to document performance of one (1) of two (2) annual preventative maintenance (PM) required during the review timeframe of February 9, 2023 to January 15, 2025. Findings include: 1. Review of the laboratory's SOP revealed a protocol (title: TOX-IR1200 Standard Operating Procedures Dirui CS Series 1200 Maintenance Schedule) that outlined Select Laboratory Partners' to perform service preventative maintenance annually. 2. Review of monthly Dirui CS (IR-1200) chemistry analyzer maintenance logs revealed one (1) PM that included the following twelve (12) tasks: Drain/clean incubation bath, clean rinsing bath for sample and reagents' probe, clean rinsing baths of mixers, clean water supply filter, clean reagent and sample cooling holding units, clean two detergent containers, clean cooling fans and screen on back of analyzer, clean sample barcode windows, remove water from vacuum tank using discharge tubing, replace water in the storage tank for cooling system, check if reagent cuvettes need replacing, check if lamp needs replacing. The Select Laboratory Partners field service performed the PM on 10/9/23. The inspector requested to review PM documentation completed in calendar year 2024. No documentation was available. 3. An interview with the lab director and compliance specialist on 1/15/25 at confirmed the above findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
A. Based on a tour, review of standard operating procedures (SOP), maintenance logs, lack of documentation, and interviews, the laboratory failed to document annual function checks of revolutions per minute (RPM) verification for two (2) of 2 centrifuges per their policy in calendar years 2023 and 2024. Findings include: 1. During a tour on 01/14/25 at 1:00 PM, the inspector noted 2 centrifuges (Serial Numbers JG828955, 480406-67) in use for toxicology and liquid chromatography mass spectrometry (LCMS) specimen processing. 2. Review of the laboratory's SOP revealed: Equipment Calibration Procedure that stated under section 4.5, "Centrifuges should be verified annually to ensure they are operating at the desired RPM speeds. Centrifuges will be verified using a digital laser photo tachometer." LCMS Sample Prep Procedure stated under step 3, "viscous samples or samples with visible particulates should be centrifuged at 3380 rpm" and under extraction step 9, "centrifuge aliquot at 10,000 rpm". 3. Review of the laboratory's 2023 and 2024 equipment maintenance logs revealed no record of RPM checks for the 2 centrifuges outlined above. The inspector requested to review annual centrifuge calibrations for the survey timeframe of 2/9/23 to 1/15/25. No documentation was available for review. 4. An exit interview with the lab director and compliance specialist on 1/15/25 at 2 PM confirmed the above findings. B. Based on a tour, review of SOP, maintenance logs, lack of documentation, and interviews, the laboratory failed to document thermometer calibration verification for six (6) of 6 thermometers annually per policy in calendar year 2023 (review timeframe 2/9/23 to 1/15/25). Findings include: 1. During a tour of the laboratory on 01/14/25 at 1:00 PM, the inspector noted the following thermometers in use to monitor toxicology and LCMS specimen/reagent storage: Refrigerator 1 (Serial Number (SN) 200323686) Refrigerator 2 (SN 210723411 Refrigerator 3 (SN 200323684) Freezer 1 (SN 200323685) Freezer 2 (SN 200323686) Incubator (SN 210723411) 2. Review of the laboratory's SOP revealed an Equipment Calibration Procedure that stated under section 4.2 "Thermometers are to be calibrated annually to ensure accuracy is maintained. Acceptance criteria, temperature reached is within 1 degree C of NIST thermometer reading. Calibration should be documented on the annual calibration log." 3. Review of the laboratory's 2023 and 2024 equipment maintenance logs revealed no record of thermometer calibrations for the 6 thermometers outlined above documented in calendar year 2023. The inspector noted that on the calendar year 2024 log the thermometers' calibration task was documented as completed on "2024". The inspector requested to review annual thermometer calibrations completed in calendar year 2023 and for the specific date that the calibration was completed in 2024. No additional documentation was available for review. 4. An exit interview with the lab director and compliance specialist on 7/15/25 at 2 PM confirmed the above findings. C. Based on a tour, review of SOP, maintenance logs, lack of documentation, and interviews, the laboratory failed to document annual calibration verification for one analytic balance per their policy in two (2) of 2 calendar years reviewed (2023 and 2024). Findings include: 1. During a tour of the laboratory on 01/14/25 at 1:00 PM, the inspector noted one analytic balance (SN B944501894) in use in the toxicology/LCMS laboratory. 2. Review of the laboratory's SOP revealed an Equipment Calibration Procedure that stated under section 4.3 "Balances should be calibrated annually to ensure accuracy and precision are within the acceptable tolerance. Acceptance criteria, weight measured using a Troemner Traceable Certified weight set is within 0.05 grams of the nominal mass value." 3. Review of the laboratory's 2023 and 2024 equipment maintenance logs revealed no record of the analytic balance calibrations for the unit outlined above. The inspector requested to review annual balance calibrations during

	the survey timeframe of 2/9/23 to 1/15/25. No documentation was available for review. 4. An exit interview with the lab director and compliance specialist on 7/15/25 at 2 PM confirmed the above findings. D. Based on a tour, review of SOP, maintenance logs, lack of documentation, and interviews, the laboratory failed to document annual timer calibration verification for three (3) of 3 timers per policy in calendar years 2023 and 2024. Findings include: 1. During a tour of the laboratory on 01/14/25 at 1:00 PM, the inspector noted the following timers in use in the toxicology / LCMS laboratory: LCMS Counter Timer #1 (SN 200401747) Black Incubator Timer #2 (SN 200313530) LCMS Counter Timer #3 (SN 200319209) 2. Review of the laboratory's procedures revealed an Equipment Calibration Procedure that stated under section 4.4, "Laboratory timers should be verified annually to ensure accuracy is maintained for timed laboratory procedures. Timers will be verified using atomic clock or computer timer that is NIST verified." 3. Review of the laboratory's 2023 and 2024 equipment maintenance logs revealed no record of timer verification for 3 of 3 timers outlined above. The inspector requested to review annual timer verifications during the survey timeframe of 2/9/23 to 1/15/25. No documentation was available for review. 4. An exit interview with the lab director and compliance specialist on 7/15/25 at 2 PM confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of standard operation procedures (SOP), chemistry calibration records, lack of documentation, test logs, and interviews, the laboratory failed to document weekly Fentanyl assay calibration procedures according to the laboratory's established criteria for twenty (20) of ninety-eight (98) weeks reviewed while reporting six thousand seven hundred twenty-nine (6,729) client drug screen results during the calibration lapses (timeframe: 2/9/23 to 1/15/25). Findings include: 1. Review of the laboratory's SOP revealed a policy document (TOX-IR 1200-104 Standard Operating Procedure Reagent Calibration Log) that outlined Fentanyl calibrations to be performed weekly. 2. Review of the IR 1200 calibration records, during the review timeframe of 2/9/23 to 1/15/25, revealed no documentation that the laboratory calibrated Fentanyl reagents per established protocol during the following weeks: Calendar year 2023: 4/17-4/21, 4/24-4/28, 9/25-9/29, 11/20-11/24; Calendar year 2024: 1/8-1/12, 1/22-1/26, 3/11-3/15, 3/18-3/22, 4/1-4/5, 6/3-6/7, 6/10-6/14, 6/17-6/21, 6/24-6/28, 9/16-9/20, 9/30-10/4, 10/21-10/25, 10/28-11/1,11/18-11/22, 12/2-12/6, 12/9-12/13; --a total of 20 of 98 weeks reviewed lacked records for required Fentanyl calibrations. 3. The inspector requested to review calibration records for the 20 weeks outlined above. No additional calibration documentation was available. 4.

	Review of test logs revealed the following number of client Fentanyl drug screen results reported during the weeks outlined above: 4/17/23-4/21/23 - 252 4/24/23-4/28 /23 - 304 9/25/23-9/29/23 - 296 11/20/23-11/24/23 - 229 1/8/24-1/12/24 - 350 1/22/24-1/26/24 - 305 3/11/24-3/15/24 - 355 3/18/24-3/22/24 - 344 4/1/24-4/5/24 - 326 6/3/24-6/7/24 - 373 6/10/24-6/14/24 - 350 6/17/24-6/21/24 - 332 6/24/24-6/28/24 - 324 9/16 /24-9/20/24- 359 9/30/24-10/4/24 - 366 10/21/24-10/25/24 - 361 10/28/24-11/1/24 - 305 11/18/24-11/22/24 - 397 12/2/24-12/6/24 - 385 12/9/24-12/13/24 - 416 a total of 6,729 client Fentanyl results were reported during the calibration lapses (timeframe: 2 /9/23 to 1/15/25). 5. An exit interview with the lab director and compliance specialist on 7/15/25 at 2 PM and an offsite follow up interview with the compliance specialist on 7/16/25 at 9:30 AM confirmed the above findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedures, equipment maintenance and calibration documentation, quality assurance records, and interviews, the laboratory director (LD) failed to ensure that the laboratory's monthly Quality Assessment Review (QA) identified failures and corrective action as they occurred in two (2) of 2 calendar years reviewed (timeframe: 2/9/23 to 1/15/25). 1. Review of the laboratory's General Policies and Procedures (CMP-001) under Section 3- Quality Systems 3.2.5 Quality Assessment Review revealed the following protocols that outlined, "All quality assessment activities are documented and reviewed on monthly basis signed off by the Laboratory Director/Designee and the Compliance Team. Identified problems should be thoroughly investigated by the General Supervisor and all contributing factors explored. Based on the findings, the identified problem can be assessed as behavior, knowledge or process, in which the appropriate corrective action is implemented. The identified problem is monitored over time to ensure permanent resolution and prevent recurrences. Follow-up reviews are scheduled as needed to evaluate the effectiveness of the corrective action implemented. A new corrective action plan should be developed if the current plan is deemed ineffective. Acquired knowledge from the QA reviews must be shared amongst laboratory personnel and any affected parties." 2. Review of the laboratory's QA records revealed no documentation by the LD of follow-up reviews that evaluated or documented corrective action was implemented when the following Dirui CS (IR-1200) chemistry analyzer maintenance failures occurred in calendar years 2023 and 2024: monthly water supply inlet filter maintenance was not performed in twenty-two (22) of twenty-three (23) months reviewed, every three month maintenance protocols were not documented in two (2) of 2 years reviewed (2023 and 2024), weekly chemistry analyzer maintenance protocols were not performed in 2 of fifty-two (52) weeks in calendar year 2024, and annual preventative maintenance (PM) was missed in 2024. CROSS REFERENCE D5429. 3. Review of the laboratory's QA records revealed no documentation by the LD of follow-up reviews that evaluated or documented corrective action was implemented when the following toxicology and liquid chromatography mass spectrometry (LCMS) chemistry equipment maintenance failures occurred: Annual function checks were not performed for 2 of 2 centrifuges, calibration of one analytic balance, three (3) of 3 timers in calendar years 2023 and

	2024, and thermometer calibration verification for six (6) of 6 thermometers in calendar year 2023. CROSS REFERENCE D5435. 4. Review of the laboratory's QA records revealed no documentation by the LD of follow-up reviews that documented corrective action was implemented when the following toxicology calibration protocol failed: Fentanyl assay weekly calibration procedures were not performed for twenty (20) of ninety-eight (98) weeks reviewed (timeframe: 2/9/23 to 1/15/25). CROSS REFERENCE D5437. 5. An exit interview with the lab director and compliance specialist on 7/15/25 at 2 PM and an offsite follow up interview with the compliance specialist on 7/16/25 at 9:30 AM confirmed the above findings