Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2116958	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Brightview Va	101 North Lynnhaven Road Suite 100, Virginia Beach, 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 Right Path Addiction Clinic on October 24, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on a tour, review of instrument user manual, manufacturer's site planning guide, reagent manufacturer's safety instructions, and an interview, the laboratory failed to ensure adequate space and ventilation related to patient urine drug confirmation testing on the Sciex Triple Quad 4500 MD analyzer from the installation date of January 19, 2018 to October 24, 2018. Findings include: 1. During a tour of the laboratory at approximately 11:00 AM on 10/24/18, the inspector noted: four (4) working reagents stored on top of a cabinet adjacent to the Sciex analyzer (acetonitrile, methanol, formic acid, and isopropyl alcohol). The inspector asked the primary testing personnel (TP) to describe how the 4 working reagents were prepared. The TP stated: "We use the reagents for the Sciex 4500 LC Mass Spec. We struggle with finding room for all of the materials while we are preparing our solutions. We do not have a ventilation hood work space so we use the top of the cabinet and we hold our breath as we prepare the solutions." The inspector also noted small wall clearances on three (3) of the four (4) sides of the Sciex analyzer. The inspector and TP measured the clearances from the back wall to the analyzer as twenty (20) inches, the clearance from the analyzer to the wall on left as twenty-eight (28) inches, and clearance from the front of the analyzer as thirty-one (31) inches. 2. Review of the

	Sciex 4500 User Manual revealed installation specification requirement instructions of forty (40) inch clearances on each side of the analyzer. 3. Review of the Sciex 4500 (serial number CP20071708) manufacturer's Site Planning Guide revealed a required site check list that included ventilation and waste-collection requirements and site clearances for the laboratory layout. The inspector requested to review the completed installation check list for site clearances for the laboratory layout. The documentation was not available for review. 4. Review of the VWR Life Science acetonitrile, methanol, formic acid, and isopropyl alcohol reagent safety label instructions revealed the manufacturer's statement: "use ventilating equipment, do not breathe fumes". 5. In an interview with the general supervisor and primary testing personnel at approximately 3:00 PM, it was confirmed that the laboratory failed to ensure adequate space and ventilation according to manufacturer's instructions for performing patient urine drug confirmation testing on the Sciex analyzer for nine (9) months reviewed as outlined above.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, available proficiency testing records, patient test logs, and an interview, the laboratory failed to perform accuracy verification for thirty-three (33) urine toxicology confirmation (non regulated) tests reported on the Sciex Triple Quad 4500 analyzer from January 19, 2018 to October 24, 2018. Findings include: 1. Review of the laboratory's QA policies revealed a Proficiency Testing (PT) policy that stated: "The lab will enroll in proficiency testing for all urine drug screen testing to ensure accuracy". 2. Review of the laboratory's American Proficiency Institute (API) PT documentation for 2017 to the date of survey on 10/24/18, a total of four (4) events, revealed: Urine Drug Screen Module PT documentation for 2018 2nd Event, 2018 1st Event, 2017 2nd Event, and 2017 1st Event recorded for the laboratory's Diatron P500 instrument analytes. The inspector requested documentation of PT or accuracy verification for the drug confirmation panel testing performed on the Sciex 4500 analyzer. No documentation was available for review. The general supervisor and TP stated that they "had not enrolled for the second analyzer but we have discussed with our lab director". 3. Review of the patient test logs revealed that the laboratory's Drug Confirmation Report assayed on the Sciex 4500 analyzer included a panel result of the following 33 analytes: 6-Acetlymorphine, 7-Aminoclonazepam, Hydroxyalprazolam, Amphetamine, Benzoylecgonine, Buprennorphine, Codeine, EDDP, Fentanyl, Gabpentin, Hydrocodone, Hydromorphone, Ketamine, Lorazapam, MDA, MDMA, Methadone, Methamphetamine, Morphine, Naloxine, Naltrexone, Norbuprenorphine, Nordiazepam, Norfentanyl, Oxazepam, Oxycodone, Oxymorphone, PCP, Pregabalin, Temazepam, Tramadol, Zolpidem, and Carboxy-THC. 4. In an interview with the general supervisor and primary testing personnel at approximately 3:00 PM, it was confirmed that the laboratory failed to verify the accuracy of the 33 Sciex 4500 analyzer toxicology tests performed on their drug confirmation panel through split sampling or participation with a PT program for the timeframe as outlined above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of policy and procedure manual, manufacturer's package insert, and interview, the laboratory failed to ensure that two (2) of 2 bottles of Biorad Urine Toxicology quality control (QC) material stored in the refrigerator were within the stated expiration dates during the timeframe of July 5, 2018 to October 24, 2018. Findings include: 1. During a laboratory tour at approximately 11: 30 AM on 10/24/18, the inspector noted the following 2 QC reagent bottles stored in the laboratory refrigerator: One (1) bottle of Biorad Urine Toxicology QC Level C3, Lot Number 68840 with open date of 6/5/2018; One (1) bottle of Biorad Urine Toxicology QC Level C4, Lot Number 68850 with open date of 6/5/2018. The laboratory inspector asked if the 2 QC reagents were being used for verifying patient testing and the general supervisor stated: "Yes, they are being used on our Sciex Triple Quad 4500MD LC Mass Spec." 2. Review of the laboratory's policy and procedure manual revealed a quality assurance (QA) policy that included a protocol that stated: "Handling and storing of reagents and quality control will be according to manufacturer's recommendations". 3. Review of the BioRad QC manufacturer's package insert revealed Storage and Stability instructions: "once the control is opened, all analytes will be stable for 30 days when stored tightly capped at 2-8 degrees Celsius." 4. During an interview with the general supervisor and primary testing personnel at approximately 3:00 PM, it was confirmed that the laboratory failed to ensure that the 2 urine toxicology QC reagents, listed above, were not used beyond the expiration date from 7/5/18 to 10/24/18.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 policies and procedures, proficiency testing records, patient test logs, manufacturer's package insert, a laboratory tour, and interviews, the laboratory director failed to ensure quality assurance (QA) policies were maintained and followed to document accuracy verification for urine toxicology confirmation panel tests and failed to ensure the laboratory followed QA protocols for handling and storing of quality control material in calendar year 2018. Findings include: 1. The laboratory director failed to ensure the accuracy of thirty-three (33) Sciex 4500 analyzer toxicology tests performed on their drug confirmation panel through split sampling or participation with a PT program for the timeframe of January 19, 2018 to October 24, 2018. (Cross Reference D 5217.) 2. The laboratory director failed to ensure that two (2) urine toxicology QC reagents were not used beyond the open expiration date from 7/5/18 to 10/24/18. (Cross Reference D 5417)