

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2116958	(X3) Date Survey Completed 01/24/2023
Name of Provider or Supplier Brightview Va	Street Address, City, State 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 Brightview VA on January 23-24, 2023 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:
D2015	<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's toxicology proficiency testing (PT) documentation, lack of documentation, and interviews, the laboratory failed to retain PT attestation statements signed by the laboratory director (LD) for two (2) of four (4) events reviewed (timeframe February 2021 to date of inspection January 24, 2023). Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) Drug Monitoring for Pain Management Toxicology module PT records (2021 Events A-B, 2022 Events A-B) revealed no signed LD attestation statements for 2022</p>

Events A and B. The inspector requested the attestation statements. No records were available. 2. Interviews with the Quality Assurance Manager and Compliance Consultant on 1/24/23 at approximately 3:30 PM confirmed the above findings.

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 a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to document review/evaluation for three of four toxicology PT modules reviewed (timeframe calendar years 2021 and 2022). Findings include: 1. Review of the laboratory's College of American Pathologists (CAP) PT records (2021 Events A-B, 2022 Events A-B) revealed no documentation of review /evaluation for the following Drug Monitoring for Pain Management Toxicology modules: 2021 DMPM-B: noted- challenge samples #05, #06, #08 resulted as unacceptable; 2022 DMPM-A; 2022 DMPM-B: noted - module scored as zero, reported by CAP as "test results not received". The inspector requested the review /evaluation documentation for the 3 toxicology module events outlined above. No documentation was available for review. 2. Interviews with the Quality Assurance Manager and Compliance Consultant on 1/24/23 at approximately 3:30 PM confirmed the above findings.

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 a review of quality assessment (QA) procedures, manufacturer's user guides /package inserts, daily temperature/environment logs, lack of documentation, and interviews, the laboratory failed to monitor daily room/refrigerator/freezer temperatures and relative humidity percent (%) per approved QA policy for thirteen (13) of twenty-three (23) months reviewed (review timeframe: February 2021 to 1/24 /23). Findings include: 1. Review of the laboratory's procedures revealed a Quality Assurance protocol that outlined daily monitoring of environmental conditions that included laboratory room temperature/ humidity and refrigerator/freezer temperatures. The protocol stated, "The laboratory has defined criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. Temperatures for the following will be recorded every day of testing: room, refrigerators, freezers; the humidity in the laboratory will also be monitored and recorded. Corrective action will be taken and annotated if it exceeds the manufacturer or laboratory acceptable limits." 2. Review of

manufacturer's user guides and package inserts utilized for patient urine drug toxicology analysis during the review timeframe of February 2021 to 1/24/23 revealed: Shimaozu 8040 LCMS User Guide - "Environmental Specifications: Room temperature 64-82 degrees Fahrenheit. Operating outside this range could compromise the reliability of the Mass Spectrometer unit. Ensure that the temperature is kept within this range day and night. It is important to accommodate the potential heat load generated by the LCMS and the accessory components. If the heat load is not accounted for the room temperature may rise above the accepted range risking compromise to data quality or damage to the unit. Please advise facility management about heat generation in order to keep laboratory temperature within proper environmental conditions. Relative humidity range is 20-70% (No condensation. No static electricity)". Lin-Zhi International, Inc. (LZI) Drug Enzyme Immunoassay Package Inserts for Synermed IR 500: Reagent and Quality Control Preparation and Storage - "All assay components should be refrigerated at 2-8C when not in use." Specimen Collection and Handling - "If the urine sample cannot be analyzed immediately, it may be refrigerated at 2-8C for up to seven days. For longer storage, keep sample frozen at -20C and then thaw before use. Samples should be at a room temperature of 18-25C for testing." AB SCIEX 4500 LCMS System User Guide- "Environmental Specifications: An ambient temperature of 15 to 30C 2 per hour (46 to 86F 3.6)". BioRad Urine QC manufacturer's package insert - "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." 3. Review of the available laboratory records from February 2021 to the date of the inspection on 1/24/23 revealed no record of daily monitoring for the toxicology laboratory room temperature/humidity, five (5) of 5 patient refrigerators, 5 of 5 reagent refrigerators, four (4) of 4 patient sample freezers, and one (1) of 1 reagent freezer from February 2021 to April 2022. The inspector requested to review environmental temperature log/documentation for the 13 months outlined above. No records were available for review. 4. Interviews with the Quality Assurance Manager and Compliance Consultant on 1/24/23 at approximately 3:30 PM confirmed the above findings.

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:
A. Based on a review of quality assessment (QA) policies/procedures, available proficiency testing (PT) records, patient test logs, lack of documentation, and interviews, the laboratory director (LD) failed to verify twice annual mass spectrometer (MS) analyzer accuracy of fifty-five (55) of 55 urine toxicology (non regulated) tests per approved QA policy (from August 2021 to 1/24/23). Findings include: 1. Review of the laboratory's QA policies revealed a PT policy (titled: Proficiency Testing) that stated, "For analytes that are not regulated, the laboratory will verify the accuracy of the test twice annually through external assessment programs or split sample comparisons with another laboratory's instrument/method. When testing is performed on analytes that are not regulated, an alternate proficiency must be performed twice a year to validate the accuracy of the testing procedure. All results are to be documented and signed by the performing Technologist and Laboratory Director." 2. Review of the laboratory's College of American Pathologists

(CAP) Urine Toxicology PT documentation for calendar year 2021 to the date of survey on 1/24/23, a total of four (4) events, revealed participation for eleven analytes included on the laboratory's Synermed IR 500 urine toxicology panels. The PT events did not include the 55 analytes assayed by the laboratory on their MS instrument platform. 3. Review of the patient test logs revealed toxicology panels with the following additional 55 analytes on the MS instrument platform: 6-Acetylmorphine, Amphetamine, Benzoyllecgonine, Buprenorphine, Codeine/Morphine/Oxycodone, Meperidine, Normeperidine, Methamphetamine, PCP, Hydrocodone, Norhydrocodone, Hydromorphone, Methadone, Oxycodone, Tramadol, Ritalinic Acid, N-desmethyl-Tapentadol, Propoxyphene, Cannabinoids (THC), Fentanyl, Carisoprodol, Meprobamate, 3,4-Methylenedioxy-N-ethylamphetamine (MDEA), Barbiturates, Naloxone, Norfentanyl Oxalate, Norbuprenorphine, Tricyclic Antidepressants, Gabapentin, Pregabalin, MDMA, Methylenedioxypropylone (MDPV), Ethyl-Sulfate, Norpropoxyphene, Mitragynine alkaloids, Serotonin Specific Reuptake Inhibitor Antidepressants (SSRIs), Pentazocine, Zolpidem, Amitriptyline, a-PVP, Zaleplon, 7-Aminoclonazepam, Hydroxyalprazolam, Clonazepam, Nordiazepam, Nortriptyline, Oxazepam, Temazepam, Lorazepam, Citalopram, Fluoxetine, Noroxycodone, EDDP, Sertraline, Zolpidem-P4CA, Ethylglucuronide /Ethylsulfate, Alprozolam. 4. The inspector requested proficiency documentation or twice annual accuracy verification for the additional 55 drug confirmation panel test analytes outlined above in calendar year 2021, 2022, and up to the date of the survey on 1/24/23. One split panel accuracy verification report was available for review (evaluated/verified by the LD July 2021). A repeat split analysis was performed August 2021 (but was not evaluated/reviewed by the LD). No additional accuracy verification was available for review. 5. Interviews with the Quality Assurance Manager and Compliance Consultant on 1/24/23 at approximately 3:30 PM confirmed the above findings. B. Based on a review of quality assessment (QA) procedures, daily temperature/environment logs, lack of documentation, and interviews, the laboratory director failed to ensure that daily room/refrigerator/freezer temperatures and relative humidity percent (%) were monitored per approved QA policy for thirteen of twenty-two months reviewed (March 2021 to 1/24/23). Cross Reference D5413.