Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0864215	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Alere Toxicology Services, Inc	450 Southlake Blvd, Richmond, 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 Alere Toxicology Services on April 27 & 28, 2022 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 -42 C.F.R. 493-1250 Condition: Analytic Systems *Repeat Deficiencies*. D6108- 42 C.F. R. 493-1447 Condition: Laboratory Technical Supervisor *Repeat Deficiencies*.
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 policies, maintenance/temperature records, lack of documentation, and interviews, the laboratory failed to: 1. follow their established water quality policy of monthly microbial content checks during seventeen of twenty-six (26) months reviewed (timeframe January 2020 to the date of the inspection April 27-28, 2022); 2. document the monitoring for acceptable storage temperature of negative urine specimens for 26 of 26 months reviewed; 3. follow established policies for required maintenance protocols for two (2) of 2 toxicology micro-plate enzyme immunoassay platforms, thirteen of seventeen liquid chromatography mass spectrometry toxicology instruments and five of eight gas chromatography mass spectrometry toxicology instrument platforms during the 26 month review timeframe. See D5401(*repeat deficiency), D5413 (*repeat deficiency), and D5429.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a tour, review of policies and maintenance records, lack of documentation, and interviews, the laboratory failed to follow their established water quality policy of monthly microbial content checks during seventeen (17) of twenty-six (26) months reviewed (timeframe January 2020 to the date of the inspection April 27-28, 2022). **REPEAT DEFICIENCY Findings include: 1. During a tour of the laboratory on 4 /27/22 at approximately 2:00 PM, the inspectors noted a Siemens Vantage PTC Water System (Serial Number 0162125187, service installer Evoqua Water Technologies) in use to provide Type 1 deionized water for all laboratory applications. 2. Review of the laboratory's Standard Operating Procedure Manual revealed an "Ancillary Equipment" section policy (titled: Water Quality) that stated "water quality is monitored with microbial content checked monthly, and both 1 and 10 mOhm resistivity lights to be recorded on a daily basis. If the count is greater than 10 cfu/mL notify your supervisor immediately. If either daily reading is unacceptable, the Evoqua vendor will be notified immediately for remedial action. Corrective action documentation is required on the logs." 3. Review of the laboratory's available two (2) Water Quality DI System Heterotrophic Plate Count logs (LCMS and Screening lab) revealed no monthly microbial check documentation for the following months during the 26 month review timeframe: LCMS 2020: January, February, April, May, September, October; LCMS 2021: September, October, December; LCMS 2022: January, February, March; Screening 2021: March, April, May, June, July. Six (6) months in 2020, eight (8) in 2021, and three (3) in 2022 lacked monthly microbial check records. A total of 17 months lacked the required documentation. The inspectors requested to review the missing maintenance documentation noted above. No records were available for review. 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager, and accessioning manager on April 28, 2022 at approximately 6:00 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 tour, review of policies and available temperature records, lack of documentation, and interviews, the toxicology laboratory failed to document (per their

	established policy) monitoring of acceptable storage temperature for negative urine specimens for twenty-six (26) of 26 months reviewed (January 2020 to the time of the inspection April 27-28, 2022). *REPEAT DEFICIENCY Findings include: 1. During a tour of the laboratory on 4/27/22 at approximately 2:30 PM, the inspectors noted approximately five thousand (5,000) negative urine samples stored in bins. The accessioning manager stated "our negative screened samples are stored here at room temperature for seven days before we discard them". 2. Review of the laboratory's Standard Operating Procedure Manual revealed the following two policies: "Specimen Disposal Long Term Storage" that stated, "After initial testing, negative specimens will be discarded after 7 days. After initial testing is complete negative specimens are stored at room temperature (15-25 C). "Environmental Monitoring" that stated, "The purpose of procedure is to ensure a method of monitoring and documenting thermostatic temperatures and or relative humidity for all storage, equipment, and controlled areas. Procedure for monitoring: Primary temperature readings from a digital thermometer (min/max device) are recorded daily by trained and designated personnel; all logs have documented acceptable temperature requirements." 3. Review of the laboratory's temperature logs revealed no documentation of monitoring the 15-25 C limit for the negative specimen storage area during the 26 months reviewed. The inspectors requested the temperature records. The senior quality manager stated on 4 /28/22 at approximately 12:00: "We do not monitor/record the temperatures in that storage area." 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager, and accessioning manager on April 28, 2022 at approximately 6:00 PM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 laboratory tour, review of procedures, equipment maintenance records, lack of documentation, and interviews, the laboratory failed to follow established policies for required maintenance protocols for two (2) of 2 toxicology micro-plate enzyme immunoassay platforms for sixteen (16) months during the twenty-seven (27) month review timeframe (January 2020 to the time of the inspection April 27-28, 2022). Findings include: 1. During a tour of the laboratory on 4/27/22 at approximately 2:30 PM, the inspectors noted the following 2 toxicology micro-plate enzyme immunoassay platforms in use: Tecan Analyzer with Biotek Elisa Plate Washers PW 01 and PW 02 2. Review of the laboratory's Standard Operating Procedure Manual and maintenance guidelines revealed a procedure (Oral Screening ELISA Tecan) outlined: "Perform the manufacturer's required maintenance and record in maintenance log for each instrument. Daily and other required maintenance are described in the Tecan instrument manual". 3. Review of the analyzer manual revealed a Tecan Analyzer with Biotek Elisa Plate Washer Log detailing required protocols: Daily (Flush Syringe and Washer at end of shift, wipe down instrument and work area), Weekly (Replace DH2O with fresh DI water, Clean Biostack and Washer Plate Carrier and Stacks), Monthly (Replace Dispense Manifold O-rings, Replace Cylinder Retainer O-rings, Replace Check Valves, Inspect Tubing). 4. Review of the laboratory's Tecan/Plate Washer maintenance log records from January 2020 to April

2022 revealed lack of documentation for the following required maintenance tasks: Calendar year 2020: Analyzer PW 01: No daily, weekly, or monthly maintenance logs for January, February, March, April, May, June, July, August, September, October; Analyzer PW 02: No daily, weekly, or monthly maintenance logs for January, February, March, April, May, June, July, August, September, October; Calendar year 2021: Analyzer PW 01: no monthly maintenance recorded in September, November, December; Analyzer PW 02: no monthly maintenance recorded in September, November, December; Calendar year 2022 year to date: Analyzer PW 01: No daily, weekly, or monthly maintenance logs for January, February, March; Analyzer PW 02: No daily, weekly, or monthly maintenance logs for January, February, March; A total of ten (10) of twelve (12) months reviewed in 2020, three (3) of 12 months reviewed in 2021, and 3 of 3 months reviewed in 2022 lacked maintenance documentation as outlined above. 5. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager, and accessioning manager on April 28, 2022 at approximately 6:00 PM confirmed the above findings. B. Based on a laboratory tour, review of procedures, equipment maintenance records, lack of documentation, and interviews, the laboratory failed to follow established policies for required maintenance protocols for thirteen (13) of seventeen (17) liquid chromatography mass spectrometry (LC-MS) toxicology instruments for five (5) months in calendar year 2021. Findings include: 1. During a tour of the laboratory on 4/27/22 at approximately 2:30 PM, the inspectors noted the following 17 LC-MS instruments in use for client toxicology testing: LCMS 01, LCMS 02, LCMS 03, LCMS 04, LCMS 06, LCMS 07, LCMS 08, LCMS 09, LCMS 10, LCMS 11, LCMS 12, LCMS 13, LCMS 14, LCMS 15, LCMS 16, LCMS 17, LCMS 18. 2. Review of the laboratory's Standard Operating Procedure Manual and maintenance guidelines revealed a procedure (LC-MSMS Instrument Operation) that outlined-"Perform daily, weekly, monthly, semiannual and as needed per specific instructions of instrument manual. Document Frequently (Verify Mobile Phase Full, Syringe Wash Bottles Full, Syringe Checked for Leaks), Weekly (Curtain Plate Cleaned, Syringe Plunger Checked, Filter Frit Replaced), Monthly (Front End Cleaned, Oil Level Checked, Cooling Fans Vacuumed)". 3. Review of the laboratory's LC-MS maintenance log records revealed lack of documentation for the following required maintenance tasks in calendar year 2021: LCMS 01- no frequently/daily recorded in April, weekly maintenance performed one of four (4) weeks in June (on 6 /21/21), no monthly maintenance recorded in August, September, December; LCMS 02- no monthly maintenance recorded in December; LCMS 03- weekly maintenance performed two of 4 weeks in August (8/4, 8/12) and September (9/15, 9/28), no monthly maintenance recorded in December; LCMS 04- weekly maintenance performed two of 4 weeks in September (9/15, 9/28), no monthly maintenance recorded in December; LCMS 07 - no monthly maintenance recorded in December; LCMS 08 - frequently/daily recorded once December (12/13) with no monthly recorded; LCMS 09 - frequently/daily recorded once (12/15) with weekly maintenance performed 2 of 4 weeks (12/15, 12/27) and no monthly in December; LCMS 10 - no monthly maintenance recorded in August with weekly maintenance 2 of 4 weeks (8/6, 8/11), no monthly recorded in December; LCMS 11 - no monthly maintenance recorded in September with weekly maintenance recorded 2 of 4 weeks (9/15, 9/24); LCMS 12 - frequently/daily recorded twice December (12/13, 12/17) with no monthly recorded; LCMS 15 - no monthly maintenance recorded in August; LCMS 17 - no frequently/daily or monthly maintenance recorded in September, no monthly maintenance recorded in December; LCMS 18 - no monthly recorded in August, no frequently/daily or monthly in September; A total of 13 LCMS platforms lacked required maintenance as outlined above for 5 of 12 months reviewed in 2021. The inspectors requested to review documentation for the maintenance. No records

	were available for review. The senior quality manager stated on 4/28/22 at approximately 3 PM: "We had staffing turnover in 2021 and recording maintenance as performed was overlooked at times". 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager, and accessioning manager on April 28, 2022 at approximately 6:00 PM confirmed the above findings. C. Based on a laboratory tour, review of procedures, equipment maintenance records, lack of documentation, and interviews, the laboratory failed to follow established policies for required monthly maintenance protocols for five (5) of eight (8) gas chromatography mass spectrometry (GS-MS) toxicology confirmation platforms in September and December of calendar year 2021. Findings include: 1. During a tour of the laboratory on 4/27/22 at approximately 2:30 PM, the inspectors noted the following 8 GC-MS instruments in use for client toxicology drug confirmation testing: GC 01, GC 02, GC 03, GC 05, GC 06, GC 07, GC 08, and GC 09. 2. Review of the laboratory's Standard Operating Procedure Manual and maintenance guidelines revealed a procedure GC/MS Operation which stated: "Perform maintenance per schedule log in procedure as appendix B". The inspectors noted that the Appendix B outlined column to be changed monthly. 3. Review of the laboratory's GC-MS maintenance log records revealed lack of documentation for the following required maintenance tasks in calendar year 2021: GC 01 - no monthly maintenance documented in September; GC 02 - no monthly maintenance documented in September; GC 07 - no monthly maintenance documented in September; GC 08 - no monthly maintenance documented in September, GC 09 - no monthly maintenance documented in September, December; A total of 5 GC-MS platforms lacked required monthly maintenance as outlined above for 2 of 12 months reviewed in 2021. The inspectors requested to review documentation for the maintenance. No records were available for review. The senior quality manager stated on 4/28/22 at approximately 3 PM: "We had staffing turnover in 2021 and recording maintenance as performed was overlooked at times". 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager, and accessioning manager on April 28, 2022 at approximately 6:00 PM confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of procedures, daily temperature logs, lack of documentation, and interviews, the toxicology laboratory failed to document corrective action when recorded temperatures were outside of acceptable limits for the storage of non negative urine specimens in Long Term Freezer Serial Number 2803C2350A000 for four (4) consecutive days in November 2021. Findings include: 1. Review of the laboratory's Standard Operating Procedure Manual revealed the following policy "Environmental Monitoring": that stated: "The purpose of procedure is to ensure a method of monitoring and documenting thermostatic temperatures and or relative humidity for all storage, equipment, and controlled areas. Procedure for monitoring: Primary temperature readings from a digital thermometer (min/max device) are recorded daily by trained and designated personnel; all logs have documented

	acceptable temperature requirements. Non-negative specimens are transferred to Long-Term Freezer Storage and stored at less than or equal to -20 C when confirmation testing is completed. Signed/ Completed Daily monitoring log and weekly reports (including supporting documentation) are stored in a controlled location." 2. The inspectors selected six (6) random monthly temperature monitoring charts for the twenty-five monitored areas. The inspectors noted the toxicology laboratory's walk in Long Term Freezer (Device ID 134908123) for November 2021 revealed no corrective action documented when the sample storage freezer failed to meet protocol criteria on the following dates: 11/20 (3.1 C); 11/21 (1.1 C); 11/22 (-2.6 C); 11/23 (-7.3); A total of 4 consecutive days for the identified device in November 2021. 3. Review of the available corrective action logs revealed a lack of documentation of the corrective actions taken when the freezer temperature was not within the acceptable range for the above listed days. The surveyor requested documentation of the corrective actions taken. The laboratory provided no documentation to review. The senior quality manager stated on 4/28/22 at approximately 4 PM: "I do not have the daily log or documentation of corrective action for the specimens stored in that freezer. I have an invoice from our refrigeration service. We had them come in 11/29 /21". 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager, and accessioning manager on April 28, 2022 at approximately 6:00 PM confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policies, testing personnel records, lack of documentation, and interviews, the lab director failed to ensure new testing personnel (TP) had training and competency assessment documentation prior to patient testing for four of the 13 testing personnel (TP) reviewed. Findings include: 1. Review of the CMS 209 form revealed three personnel performed the duties of TS and 46 TP. 2. Review of the laboratory's Standard Operating Procedure Manual revealed a Quality Management policy that stated "all new personnel will be trained and competency documented via training documentation forms. New personnel are evaluated at 6 months and 12 months. All technical personnel will be evaluated at least annually thereafter with six competency elements". 3. Review of 13 randomly selected TP records revealed the following TP lacked documentation of training and competency assessment: TP D (date of hire 07 /06/21), TP E (date of hire 03/01/21), TP G (date of hire 08/17/21), and TP G (date of hire 11/01/21). (See Personnel Code Sheet.) The inspector requested to review the documentation. No records were available. 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager and accessioning managers on 04/28/22 at approximately 6:00 PM, confirmed the above findings.
D6108	LABORATORY TECHNICAL SUPERVISOR

	CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: **REPEAT DEFICIENCY** Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&P), testing personnel records, lack of documentation, and interviews, the technical supervisors (TS) failed to perform annual competency assessment evaluations for four of the 13 testing personnel (TP) reviewed. See D6128.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policies, testing personnel records, lack of documentation, and interviews, the technical supervisor(s) failed to perform semi-annual competency assessment evaluations for one of the 13 testing personnel (TP) reviewed. Findings include: 1. Review of the CMS 209 form revealed three personnel performed the duties of technical supervisor (TS) and 46 TP. 2. Review of the laboratory's Standard Operating Procedure Manual revealed a Quality Management policy that stated "all new personnel will be trained and competency documented via training documentation forms. New personnel are evaluated at 6 months and 12 months. All technical personnel will be evaluated at least annually thereafter with six competency elements". 3. Review of 13 randomly selected TP records revealed the following TP lacked documentation of of a semi-annual competency assessment: TP E (date of hire 03/01/21). (See Personnel Code Sheet.) The inspector requested to review the documentation. No records were available. 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager and accessioning managers on 04/28/22 at approximately 6:00 PM confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: ** REPEAT DEFICIENCY** Based on a review of the Laboratory Personnel Report

	Form (CLIA) (CMS-209 Form), policies, testing personnel records, lack of documentation, and interviews, the technical supervisors (TS) failed to perform annual competency assessment evaluations in calendar year 2021 for four of the 13 testing personnel (TP) reviewed. Findings include: 1. Review of the CMS 209 form revealed three personnel performed the duties of TS and 46 TP. 2. Review of the laboratory's Standard Operating Procedure Manual revealed a Quality Management policy that stated "all new personnel will be trained and competency documented via training documentation forms. New personnel are evaluated at 6 months and 12 months. All technical personnel will be evaluated at least annually thereafter with six competency elements". 3. Review of 13 randomly selected TP records revealed the following TP lacked a 2021 annual competency assessment: TP A, TP B, TP C, and TP F. (See Personnel Code Sheet.) The inspector requested to review the documentation. No records were available. 4. An exit interview with the laboratory director, operation director, senior quality manager, technical supervisors, general supervisors, biomedical resource manager and accessioning managers on 04/28/22 at approximately 6:00 PM confirmed the above findings.