Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2267342	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Anha	2328 Livernois Road, Troy, MI	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to ensure protection from chemically hazardous materials for 8 (June 2023 to January 2024) of 8 months since the laboratory started testing. Findings include: 1. An interview on 1/3/24 at 10: 36 am revealed the laboratory started urine toxicology testing in patients in June 2023. 2. A review of the laboratory's "Methanol" Safety Data Sheet (SDS) revealed a section stating "Provide eyewash stations, quick-drench showers and washing facilities accessible to areas of use and handling. Have supplies and equipment for neutralization and running water available." 3. The surveyor toured the laboratory on 1 /3/24 at 10:59 am and observed a lack of eyewash station, shower, or sink present. 4. An interview on 1/3/24 at 12:31 pm with the Laboratory Director confirmed the laboratory had not installed an eyewash, shower, or sink in the laboratory.
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 record review, observations, and interviews, the laboratory failed to establish a procedure for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer (refer to D5401), failed to ensure reagents and calibrators had not exceeded their expiration dates (refer to D5417), failed to verify performance specifications for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer (refer to D5421), failed to document its data used to establish performance specifications of its quantitative urine toxicology testing using the AB Sciex Triple Quad analyzer (refer to D5427), failed to establish criteria for acceptability for its urine toxicology screening controls (refer to D5469), and failed to perform corrective action for patient testing when calibrations were unacceptable (refer to D5783).
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 observation, record review, and interview with the General Supervisor, the laboratory failed to establish a procedure for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer for 3 (October 2023 to December 2023) of 3 months the laboratory was performing patient testing. Findings include: 1. An interview on 1/3/24 at 10:36 am with the General Supervisor revealed the laboratory had purchased a qualitative testing instrument and started patient testing in October 2023. 2. The surveyor observed the Thermo Fisher Scientific Indiko Plus analyzer on 1 /3/24 at 10:59 pm during a tour of the laboratory. 3. The surveyor requested the laboratory's procedure for the Thermo Fisher Scientific Indiko Plus analyzer qualitative urine toxicology testing on 1/3/24 at 2:18 pm. 4. An interview on 1/3/24 at 2:19 pm with the General Supervisor confirmed the laboratory had not established a procedure for its Thermo Fisher Scientific Indiko Plus analyzer urine qualitative toxicology testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the General Supervisor, the laboratory failed to include the preparation and expiration dates on its reagents for 7 reagents available for use. Findings include: 1. The surveyor observed the following reagents lacking labeling of the preparation or expiration dates on 1/3/24 at 10:59 am:

	a. Small, clear glass bottle labeled "MASTER MIX DOUBLE BLANK." b. Medium glass bottle with an orange cap labeled "MASTER MIX." c. Small, brown glass bottle labeled "ORASURE NEGATIVE CAL ORAL FLUID." d. Small, brown glass bottle labeled "ORASURE DILUENT." e. Two small, clear glass bottles labeled "MASTER MIX." f. One plastic squeeze bottle with clear fluid and no labeling. 2. A review of the laboratory's "QUALITY ASSURANCE GUIDELINES" revealed a section titled "Reagents" stating, "All laboratory prepared reagents/solutions will be clearly labeled to include at a minimum reagent identity, preparer's initials, storage and stability conditions and date of preparation or lot number" and lacked a process for including the expiration date. 3. An interview on 1/3/24 at 11:18 am with the General Supervisor confirmed the laboratory had not included the preparation and expiration dates on the reagents listed 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 observation, record review, and interview with the General Supervisor, the laboratory failed to ensure reagents and calibrators had not exceeded their expiration dates for 21 reagents and calibrators available for use. Findings include: 1. The surveyor observed the following reagents lacking labeling of the preparation or expiration dates on 1/3/24 at 10:59 am: a. Small clear glass bottle with an orange cap labeled "Psych Panel Step 1" with the expiration date of "1/1/24." b. Small clear glass bottle with an orange cap labeled "PAIN PANEL STEP 1" with the expiration date of "1/1/24." c. Three DRI Gravity Detect Low Calibrator bottles expired 9/30/23. d. DRI Multi-Drug Urine Calibrator 1 bottle expired 12/31/23. e. DRI Amphetamines Assay reagent expired 8/31/23. f. Two DRI Creatinine-Detect Calibrator Kits expired 1/31 /22. g. DRI Creatinine-Detect Calibrator Kit expired 8/31/23. h. DRI pH-Detect pH 10.0 Control expired 12/31/21. i. Three DRI pH-Detect pH 3.0 & 11.0 Calibrator Kits expired 4/30/22. j. DRI THC 50 ng/mL Urine Calibrator expired 4/30/22. k. DRI Creatinine-Detect 7.5 mg/dL Control Kit expired 4/30/22. l. DRI Creatinine-Detect 23.0 mg/dL Control Kit expired 12/31/23. m. Tubing Maintenance Solution expired 3 /31/23. n. DRI Benzodiazepine Assay reagent expired 8/31/23. o. DRI Benzodiazepine Assay reagent expired 12/31/23. p. DRI Cannabinoid Assay reagent expired 10/31/23. 2. A review of the laboratory's "QUALITY ASSURANCE GUIDELINES" revealed a section titled "Reagents" stating, "All chemicals and commercial reagents should be replaced when their stated expiration date or shelf life has expired and/or when they fail the quality check." 3. An interview on 1/3/24 at 11: 18 am with the General Supervisor confirmed the reagents and calibrators listed above had exceeded their expiration dates.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to verify performance specifications for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer for 3 (October 2023 to December 2023) of 3 months the laboratory was testing patient specimens. Findings include: 1. An interview on 1/3/24 at 10:36 am with the General Supervisor revealed the laboratory had purchased a qualitative testing instrument, a Thermo Fisher Scientific Indiko Plus analyzer, and had performed patient testing in October 2023 without verification of performance specifications performed. 2. A review of patient test reports revealed the laboratory had reported results from the urine toxicology Thermo Fisher Scientific Indiko Plus analyzer for the following analytes: a. Buprenorphine b. Amphetamine c. Benodiazepine d. Cocaine e. Ethanol f. Methadone g. Opiates h. Oxycodone i. THC j. pH k. Creatinine 3. A review of the laboratory's testing logs revealed a total of 605 patients received urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer between October 2023 and December 2023.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to document its data used to establish performance specifications of its quantitative urine toxicology testing using the AB Sciex Triple Quad analyzer for 8 (June 2023 to January 2024) of 8 months the laboratory has been performing patient testing using the test system. Findings include: 1. A review of the laboratory's "ANHA Lab Psych Panel Validation Report Summary Nov 2023, ANHA Lab Psych Panel Validation Report Summary January 2023, and ANHA Lab Main Panel Validation Report Summary January 2023" revealed data tables for the accuracy and precision studies that lacked the measured results for each of the analytes. 2. The surveyor requested the laboratory's establishment of performance specification data for the AB Sciex Triple Quad analyzer on 1/3/24 at 12:58 pm and it was not made available. 3. An interview on 1/3/24 at 2:52 pm with the General Supervisor confirmed the establishment of performance specification data for the AB Sciex Triple Quad analyzer was not available.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value

	of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to establish criteria for acceptability for its urine toxicology screening controls for 3 (October 2023 to December 2023) of 3 months the laboratory was performing patient urine toxicology screening. Findings include: 1. A review of the laboratory's urine toxicology screening quality control testing documentation for the Thermo Fisher Scientific Indiko Plus analyzer and revealed a lack of results, lack of acceptable ranges, and Levey-Jennings charts with several points outside of 3 standard deviations. 2. The surveyor requested the laboratory's acceptability criteria for its quality control testing for its urine toxicology screening controls on 1/3/24 at 12:10 pm and it was not made available. 3. An interview on 1/3/24 at 2:58 pm with the General Supervisor confirmed the laboratory did not establish quality control acceptability criteria for its for its urine toxicology screening controls.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to perform corrective action for patient testing when calibrations were unacceptable for 5 (7/29/23, 8/6/23, 10/5/23, 10/21/23, 11/5/23, and 12/17/23) of 8 patient testing runs reviewed. Findings include: 1. A review of laboratory's "Quality Control Guidelines" revealed a section titled "Calibration" stating, "Evaluate the correlation coefficient (r2) for the curve. For most applications a r2 value of 0.985 is acceptable (unless otherwise indicated in a specific method SOP)." 2. A review of 8 patient test runs revealed the following testing dates had a correlation coefficient of less than 0.985 for the following analytes: a. 7/29/23 i. Normeperidine 0.96028 b. 8/6 /23 i. Flurazepam 0.97522 c. 10/5/23 i. Flurazepam 0.97672 ii. Nicotine 0.97828 iii. Normeperidine 0.97515 iv. Oxymorphone 0.98143 v. Pregabalin 0.97902 vi. Ritalinic acid 0.97765 d. 10/21/23 i. Dihydrocodeine 0.97776 ii. Methyphenidate 0.97634 e. 11 /5/23 i. Selegiline 0.97088 f. 12/17/23 i. Codeine 0.98147 ii. Noroxycodone 0.97518 3. A review of the laboratory's patient testing logs revealed a total of 293 patients tested with the patient runs listed above with failed calibrations. 4. An interview on 1/3 /24 at 1:26 pm with the General Supervisor confirmed the calibration results were outside the laboratory's acceptable correlation coefficient.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the Laboratory Director failed to ensure performance specifications were verified for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer (refer to D6085 A), failed to ensure the laboratory documented its data used to establish performance specifications of its quantitative urine toxicology testing using the AB Sciex Triple Quad analyzer (refer to D6085 B), failed to ensure the laboratory established criteria for acceptability for its urine toxicology screening controls (refer to D6093), failed to ensure a quality assessment program was established (refer to D6094), failed to ensure the laboratory performed corrective action for patient testing when calibrations were unacceptable (refer to D6096), and failed to ensure the laboratory established a procedure for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer (refer to D6106).
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: . A. Based on record review and interview, the Laboratory Director failed to ensure performance specifications were verified for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer. Refer to D5421. B. Based on record review and interview, the Laboratory Director failed to ensure the laboratory documented its data used to establish performance specifications of its quantitative urine toxicology testing using the AB Sciex Triple Quad analyzer. Refer to D5427.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 record review and interview, the Laboratory Director failed to ensure the laboratory established criteria for acceptability for its urine toxicology screening controls. Refer to D5469.
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 record review and interview with the General Supervisor, the Laboratory Director failed to ensure a quality assessment program was established for 8 (June 2023 to January 2024) of 8 months the laboratory has been performing testing on patient specimens. Findings include: 1. A review of the laboratory records revealed a lack of quality assessment program policies and procedures to implement and monitor a quality system for all phases of the entire testing process. 2. The surveyor requested the laboratory's quality assessment documentation on 1/3/24 at 2:28 pm. 3. An interview on 1/3/24 at 2:29 pm with the General Supervisor revealed the laboratory had not established a quality assessment program.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure the laboratory performed corrective action for patient testing when calibrations were unacceptable. Refer to D5783.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview, the Laboratory Director failed to ensure the laboratory established a procedure for its urine toxicology testing using the Thermo Fisher Scientific Indiko Plus analyzer. Refer to D5401.