Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2003636	06/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Acute Patient Care Laboratory	1032 Mann St, Kissimmee, FL	

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 validation survey was conducted at Acute Patient Care Laboratory on May 3, 2024 to June 14, 2024. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The laboratory was found out of compliance with the following conditions: D5400- Analytic Systems-493.1250 D6076 - Laboratory Director - 493.1441
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the Florida Fire Prevention Code, observation and interview, the laboratory was not in compliance with the state of Florida regulations requiring a fire extinguisher from 03/18/2024 to 6/14/2024. Findings: Review of the Florida Fire Prevention Code 633.202 revealed the State Fire Marshall will adopt the edition of the Life Safety Code, National Fire Protection Association (NFPA)101. The Life Safety Code 39.3.5 Extinguishment Requirements noted, "Portable fire extinguishers shall be provided in every business occupancy in accordance with Section 9.9. Business occupancies are one of the few occupancies in the Code that mandates the presence of portable fire extinguishers. Subsection 38/39.3.5 requires portable fire extinguishers in every business occupancy in accordance with Section 9.9, which mandates that extinguishers be selected, installed and maintained in accordance with NFPA 10, Standard for Portable Fire Extinguishers." On 05/03/2024 at 9:30 AM, during a tour of the laboratory, there was no fire extinguisher observed in the laboratory. On 05/03 /2024 at 2:10 PM, the General Supervisor stated the laboratory did not have a fire extinguisher, and the laboratory was cited by the accreditation agency on 03/18/2024 for not having a fire extinguisher. On 06/14/2024 at 4:03 PM, the Laboratory Director stated they were working on getting a fire extinguisher for the laboratory.

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 review of proficiency testing (PT) records, and interview, the laboratory failed to verify and evaluate the accuracy of five toxicology analytes for 2022 and 2023 at least twice annually. Findings: The laboratory was enrolled in PT with American Proficiency Institute (API) for the following analytes: Barbiturates, Benzodiazepines, Buprenorphine, Opiates, and Oxycodone. Review of the API performance summary from the 2023 1st event listed the performance for the last three testing events (2022 1st and 2nd, 2023 1st) showed there were no proficiency testing scores for the first event in 2022. No other proficiency testing documentation for 2022 was available for review. Review of the API performance evaluation showed the laboratory received the following unsuccessful scores for 2023 2nd event for the analytes of Benzodiazepines 33%, Buprenorphine 33%, and Oxycodone 0 %. The performance review and corrective action signed on 04/24/2024 by the Laboratory Director and the General Supervisor read, "Analytes recalibrated and retested QC. QC passed." No other proficiency testing documentation except the unsigned performance review for the 2023 1st event for 2023 was available for review. Review of the API performance evaluation showed the performance evaluations for two (2022 2nd and 2023 1st) of three (2022 2nd, 2023 1st and 2nd) events were not signed by the Laboratory Director. On 05/032024 at 10:30 AM, the General Supervisor stated he had no other proficiency testing records and only 2023 2nd event's performance review was signed.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to record correct collection dates and times on the final report for 5 out of 5 patients (#1-#5) reviewed for Benzodiazepine, Opiate, Barbiturate and Oxycodone. Finding included: Review of test menu revealed drug screen test was Benzodiazepine, Opiate, Barbiturate and Oxycodone testing. On 5/3/2024 at 10:00 AM, a tour of the laboratory

	revealed urine specimen in a box and on the table ready for labeling. Patient #3's urine specimen was on the table with collection date of 5/1/2024. Patient #4's urine specimen was on the table with collection date of 5/2/2024. Review of 5 Final Drug Screen Reports revealed the following: 1. Patient #1 specimen was collected 4/1/2024 at 10:13 AM and received 4/1/2024 at 10:13 AM. 2. Patient #2 specimen was collected 5/3/2024 at 10:48 AM and received 5/3/2024 at 10:48 AM. 3. Patient #3 specimen was collected 5/3/2024 at 9:23 AM and received 5/3/2024 at 9:23 AM. 4. Patient #4 specimen was collected 5/3/2024 at 9:46 AM and received 5/3/2024 at 9:46 AM. 5. Patient #5 specimen was collected 5/3/2024 at 10:53 AM and received 5/3 /2024 at 10:53 AM. Review of electronic Clinical Work System patient drug screen testing revealed the following: 1. Patient #1 specimen was collected 3/29/2024 and no time recorded. 2. Patient #2 specimen was collected 5/1/2024 and no time recorded. 3. Patient #3 specimen was collected 5/2/2024 and no time recorded. 4. Patient #4 specimen was collected 5/1/2024 and no time recorded. Review of specimen collection policy revealed no policy for urine collections for drug screenings. Review of Patient report policy revealed no policy for patient reports. On 6/14/2024 at 4:01 PM, the General Supervisor confirmed incorrect collection dates and times on the final report for 5 out of 5 patients reviewed for Benzodiazepine, Opiate, Barbiturate and Oxycodone.
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, and interview, the laboratory failed to provide a specimen collection, storage and processing policy for urine specimens used for drug screen testing (D5403), failed to monitor temperature of refrigerator used in drug screening testing, failed to have performance verification for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay before testing patients reviewed from 11/3/2023 to 5/3/2024 (D5413), failed to establish positive and negative cutoff values with calibrators for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay from 11/3/2023 to 5/3/2024 (D5467) and failed to record correct collection dates and times on the final report for 5 out of 5 patients reviewed for Benzodiazepine, Opiate, Barbiturate and Oxycodone (D5805).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to provide specimen collection, storage and processing policy for urine specimens used for drug screen testing. Findings included: Review of test menu revealed drug screen test for benzodiazepine, opiate, barbiturate and oxycodone. On 5/3/2024 at 10:00 AM, tour of the laboratory revealed urine specimen in a box and on the table ready for labeling. Review of laboratory Drug Screen policies revealed there was no policy for urine specimen collection, storage and processing of urine specimens used for drug screen testing. On 6/14/2024 at 4:01 PM, the General Supervisor confirmed there was no policy for specimen collection, storage and processing of urine specimens used for drug screen testing.
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 observation, interview, and record review, the laboratory failed to monitor temperatures of refrigerator used in drug screen testing. Findings included: Observation of the nursing station on 5/3/2024 at 11:40 AM, revealed there was a black refrigerator used to store urine on the second shelf in a green box. There was no temperature gauge found in the refrigerator. Urine stored in the refrigerator was used in drug screen tests for buprenorphine, benzodiazepine, opiate, barbiturate and oxycodone. Review of the temperature log revealed no temperature monitoring of the refrigerator in the nursing station used to store urine specimens. Review of Oxycodone Enzyme Immunoassay package insert read, "Urine samples may be collected in plastic or glass containers. Use of plastics such as polyethylene is recommended (6). If the sample cannot be analyzed immediately, it may be refrigerated at 2-8 degrees Celsius (C) for up to seven days. For longer storage, keep sample frozen at -20 C and then thaw before use. Studies have shown oxycodone

	analytes in urine are stable at -20 degrees C for up to six months (7). Samples should be at room temperature (18-25 degrees C) for testing. Samples with high turbidity should be centrifuged before analysis. Adulteration may cause erroneous results. If sample adulteration is suspected, obtain a new sample and forward both samples to the laboratory for testing." On 5/3/2024 at 11:41 AM, Office Staff stated that refrigerator temperature was not monitored for urine storage.
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, the laboratory failed to have performance verification for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay before testing patients reviewed from 11/3/2023 to 5/3/2024. Findings included: Review of performance verification forms revealed the laboratory did not have any documentation of validation for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, or Oxycodone Enzyme Immunoassay. Observation of nursing station on 5/3/2024 at 11:40 AM revealed there was a black refrigerator used to store urine on the second shelf in a green box. Urine stored in the fridge was used in drug screen tests for Buprenorphine, Benzodiazepine, Opiate, Barbiturate and Oxycodone testing. Review of patient records revealed 38 patients reviewed from 11/3/2023 to 5/3/2024 were tested for Buprenorphine, Benzodiazepine, Opiate, Barbiturate and Oxycodone. During an interview on 06/14/2024 at 4:11 PM, the General Supervisor confirmed there was no performance verification for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay before testing patients reviewed from 11/3/2023 to 5/3/2024.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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--When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to establish positive and negative cutoff values with calibrators for Buprenorphine Enzyme Immunoassay,

	Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay from 11/3/2023 to 5/3/2024. Finding Included: Review of test menu revealed drug screen testing for benzodiazepine,opiate, barbiturate and oxycodone. Review of Drug Screen Quality Control (QC) worksheets provided by the General Supervisor revealed there were no cut off values for positive and negative controls from 11/3/2023 to 5/3/2024. QC reports noted positive and negative with no values present. Lin-Zhi International (LZI) Oxycodone Enzyme Immunoassay package insert read, "For qualitative analysis, use either the 100 ng/mL or 300 ng/mL cutoff calibrator. Qualitative: The cutoff calibrator, which contains 100 ng/mL or 300 ng/mL of oxycodone, is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Buprenorphine Enzyme Immunoassay package insert read, "For qualitative analysis, use the 5 ng/mL or 10 ng/mL as the cutoff calibrator. Qualitative: The cutoff calibrator, which contains 5 ng/mL or 10 ng/mL of norbuprenorphine, is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Benzodiazepine Enzyme Immunoassay package insert read, "For qualitative analysis, use the 200 ng/mL or 300 ng/mL as the cutoff calibrator. Qualitative: The cutoff calibrator, which contains 200 ng/mL or 300 ng/mL of oxazepam, is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (mA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (mA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Barbiturate Enzyme Immunoassay package insert read, "For qualitative analysis, use the 200 ng/mL or 300 ng/mL as the cutoff calibrator. Qualitative: The cutoff calibrator which contains 200 ng/mL or 300 ng/mL of secobarbital is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Opiate 2000 Enzyme Immunoassay package insert read, "For qualitative analysis use the 2000 ng/mL as the cutoff calibrator. Qualitative: The cutoff calibrator which contains 2000 ng/mL of morphine is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." Review of patient records revealed 38 out of 38 patients reviewed from 11/3/2023 to 5/3/2024 were tested for Buprenorphine, Benzodiazepine, Opiate, Barbiturate and Oxycodone with no values to determine positive or negative results. During an interview on 06/14/2024 at 4:11 PM, the General Supervisor confirmed they failed to establish positive and negative cutoff values with calibrators for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay from 11/3/2023 to 5/3/2024.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to record correct collection dates and times on the final report for 5 out of 5 patients (#1-#5) reviewed for benzodiazepine, opiate, barbiturate and oxycodone. Finding included: Review of test menu revealed drug screen test was for benzodiazepine, opiate, barbiturate and oxycodone testing. On 5/3/2024 at 10:00 AM, a tour of the laboratory revealed urine specimen in a box and on the table ready for labeling. Patient #3's urine specimen was on the table with collection date of 5/1/2024. Patient #4's urine specimen was on the table with collection date of 5/2/2024. Review of 5 Final Drug Screen Reports revealed the following: 1. Patient #1 was collected 4/1/2024 at 10:13 AM and received 4/1/2024 at 10:13 AM. 2. Patient #2 was collected 5/3/2024 at 10:48 AM and received 5/3/2024 at 10:48 AM. 3. Patient #3 was collected 5/3/2024 at 9:23 AM and received 5/3/2024 at 9:23 AM. 4. Patient #4 was collected 5/3/2024 at 9:46 AM and received 5/3/2024 at 9:46 AM. 5. Patient #5 was collected 5/3/2024 at 10:53 AM and received 5/3/2024 at 10:53 AM. Review of Electronic Clinical Work System patient drug screen testing revealed the following: 1. Patient #1 was collected 3/29 /2024 and no time recorded. 2. Patient #2 was collected 5/1/2024 and no time recorded. 3. Patient #3 was collected 5/2/2024 and no time recorded. 4. Patient #4 was collected 5/1/2024 and no time recorded. Review of specimen collection policy revealed no policy for urine collections for drug screenings. Review of polices revealed there was no policy for patient reports. On 6/14/2024 at 4:01 PM, the General Supervisor confirmed incorrect collection dates and times on the final report for 5 out of 5 patients reviewed for benzodiazepine, opiate, barbiturate and oxycodone testing.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory director failed to have performance verifications for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay before testing patients reviewed from 11/3/2023 to 5/3/2024(D6013), failed to establish positive and negative cutoff values with calibration for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay,

	Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay from 11/3 /2023 to 5/3/2024(D6020), failed to provide safe environment by not being in compliance with the state of Florida regulations requiring a fire extinguisher from 03 /18/2024 to 6/14/2024(D6084) and failed to evaluate the performance of Proficiency Testing for two (2022 2nd and 2023 1st) of three (2022 2nd, 2023 1st and 2nd) events (D6091).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to have performance verifications for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay before testing patients reviewed from 11/3/2023 to 5/3/2024. Findings included: Review of performance verification forms revealed the laboratory did not have any documentation of validation for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, or Oxycodone Enzyme Immunoassay. Findings: Observation of the nursing station on 5/3 /2024 at 11:40 AM, revealed a black refrigerator used to store urine on the second shelf in a green box. Urine stored in the fridge was used in drug screen tests for Buprenorphine, Benzodiazepine, Opiate, Barbiturate and Oxycodone. Review of patient records revealed 38 patients reviewed from 11/3/2023 to 5/3/2024 were tested for Buprenorphine, Benzodiazepine, Opiate, Barbiturate and Oxycodone. During an interview on 06/14/2024 at 4:11 PM, the Laboratory Director confirmed there was no performance verification for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay before testing patients reviewed from 11/3/2023 to 5/3/2024.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to establish

	positive and negative cutoff values with calibration for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay from 11/3/2023 to 5/3/2024. Finding Included: Review of test menu revealed drug screen testing for Benzodiazepine, Opiate, Barbiturate and Oxycodone. Review of Drug Screen Quality Control (QC) worksheets provided by the General Supervisor revealed there were no cut off values for positive and negative controls from 11/3/2023 to 5/3/2024. QC reports noted positive and negative with no values present. Lin-Zhi International (LZI) Oxycodone Enzyme Immunoassay package insert read, "For qualitative analysis, use either the 100 ng/mL or 300 ng/mL cutoff calibrator. Qualitative: The cutoff calibrator, which contains 100 ng/mL or 300 ng/mL of oxycodone, is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Buprenorphine Enzyme Immunoassay package insert read, "For qualitative analysis, use the 5 ng/mL or 10 ng /mL as the cutoff calibrator. Qualitative: The cutoff calibrator, which contains 5 ng /mL or 10 ng/mL of norbuprenorphine, is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Benzodiazepine Enzyme Immunoassay package insert read, "For qualitative analysis, use the 200 ng/mL or 300 ng/mL as the cutoff calibrator. Qualitative: The cutoff calibrator, which contains 200 ng/mL or 300 ng/mL of oxazepam, is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (mA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (mA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Barbiturate Enzyme Immunoassay package insert read, "For qualitative analysis, use the 200 ng/mL or 300 ng/mL as the cutoff calibrator. Qualitative: The cutoff calibrator which contains 200 ng/mL or 300 ng/mL of secobarbital is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." LZI Opiate 2000 Enzyme Immunoassay package insert read, "For qualitative analysis use the 2000 ng/mL as the cutoff calibrator. Qualitative: The cutoff calibrator which contains 2000 ng/mL of morphine is used as a reference for distinguishing a preliminary positive from negative samples. A sample with a change in absorbance (fmA/min) equal to or greater than that obtained with the cutoff calibrator is considered a preliminary positive. A sample with a change in absorbance (fmA/min) lower than that obtained with the cutoff calibrator is considered negative." Review of patient records revealed 38 out of 38 patients reviewed from 11/3/2023 to 5 /3/2024 were tested for Buprenorphine, Benzodiazepine, Opiate, Barbiturate and Oxycodone with no values to determine positive or negative results. During an interview on 06/14/2024 at 4:11 PM, the Laboratory Director confirmed they failed to establish positive and negative cutoff values with calibrators for Buprenorphine Enzyme Immunoassay, Opiate 2000 Enzyme Immunoassay, Barbiturate Enzyme Immunoassay, Benzodiazepine Enzyme Immunoassay, Oxycodone Enzyme Immunoassay from 11/3/2023 to 5/3/2024.

D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on review of the Florida Fire Prevention Code, observation and interview, the Laboratory Director failed to provide a safe environment by not being in compliance with the state of Florida regulations requiring a fire extinguisher from 03/18/2024 to 6 /14/2024. Findings: On 05/03/2024 at 9:30 AM during a tour of the laboratory, no fire extinguisher was present in the laboratory as required by Life Safety Code, National Fire Protection Association (NFPA)101. (See D3009). On 06/14/2024 at 4:03 PM, the Laboratory Director stated they were working on getting a fire extinguisher for the laboratory.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, and interview, the Laboratory Director failed to identify the proficiency testing for five toxicology analytes was not performed at least twice annually for 2022 and 2023, and failed to evaluate the performance of PT for two (2022 2nd and 2023 1st) of three (2022 2nd, 2023 1st and 2nd) events. Findings: The laboratory was enrolled in PT with American Proficiency Institute for the following analytes: Barbiturates, Benzodiazepines, Buprenorphine, Opiates, and Oxycodone. The laboratory failed to successfully perform PT at least twice annually in 2022 and 2023, and the Laboratory Director failed to sign the performance reviews for two (2022 2nd and 2023 1st) of three (2022 2nd, 2023 1st and 2nd) events. (See D5217) On 05/03/2024 at 10:30 AM the General Supervisor stated he had no other proficiency testing records and only 2023 2nd event's performance review was signed. On 06/14/2024 at 4:00 PM, the Laboratory Director acknowledged the PT problems.