Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2100814	09/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Adams Medical Center	23850 Van Born Road, Dearborn Heights, 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
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 record review and interview with the Laboratory Consultant, the laboratory failed to verify the accuracy of its toxicology testing at least twice annually for 2 (September 2018 to September 2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed one testing event was performed in 2019. 2. A review of the laboratory's established "Proficiency Testing (PT) and Split-Specimen Testing" revealed a section stating, "Split-Specimen testing is required on five specimens twice each year for all unregulated analytes not enrolled in PT. This is a quality assurance external comparison, as well. Our yearly QA review should consider enrolling unregulated analytes in PT instead of performing split-sample testing. The annual QA review of split-specimen testing should also verify that: Split-specimen testing is performed for all unregulated analytes not enrolled in PT (five specimens twice a year). Split-specimen testing results are reviewed by staff. Split-specimen testing results are reviewed by the laboratory director or technical consultant. Corrective action is taken if results fall outside acceptable limits. Accuracy of back-up instruments or methods is verified every six months by split-sample testing." 2. The surveyor requested additional verification of accuracy documentation between September 2018 and September 2020 on 9/28/20 at 9:09 and it was not made available for the following toxicology analytes: a. Benzodiazepine b. Cocaine c. Opiates d. Oxycodone 3. An interview on 9/28/20 at 9:09 am with the Laboratory Consultant confirmed the laboratory did not perform verification at least twice annually.
D5301	TEST REQUEST

	CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to have test requests for toxicology testing for 13 (Patients 1-13) of 13 patients reviewed. Findings include: 1. A review of patient test records revealed a lack of test requests for patients with test reports for toxicology testing for the following patients: a. Patient 1 performed on 2/1/19 b. Patient 2 performed on 1/25/19 c. Patient 3 performed on 12/20/18 d. Patient 4 performed on 11/29/18 e. Patient 5 performed on 10/30/18 f. Patient 6 performed on 7/11/20 g. Patient 7 performed on 8/2/20 h. Patient 8 performed on 9/22/20 i. Patient 9 performed on 2/24/20 j. Patient 10 performed on 10/1/19 k. Patient 11 performed on 8/8/19 l. Patient 12 performed on 6/27/19 m. Patient 13 performed on 5/17/19 2. An interview on 9/28/20 at 10:36 am with the Office Manager confirmed the laboratory did not have test requests for the patients listed above. ***This is a repeat deficiency from the 11/8/17 and 6/9/16 surveys.***
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 record review and interview with the Laboratory Consultant, the laboratory failed to establish control procedures for 2 (September 2018 to September 2020) of 2 years reviewed. Findings include: 1. A review of the laboratory-established procedure manual revealed a lack of control procedures for toxicology testing. 2. An interview on 9/28/20 at 11:15 am with the Laboratory Consultant revealed the laboratory did not establish control procedures.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 Laboratory Consultant, the laboratory failed to perform control procedures each day of patient testing for 1 (2/24/20) of 13 patient testing days reviewed. Findings include: 1. A review of patient testing records revealed Patient 5 received toxicology testing on 2/24/20. 2. A review of quality control documentation revealed a lack of a negative control tested for Oxycodone. 3. The surveyor requested corrective action records on 9/28/20 at 10:28 am and they were not made available. 4. An interview on 9/28/20 at 11:15 am with the Laboratory Consultant confirmed the laboratory did not perform control procedures.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to ensure test results were reliably sent to the patients' charts for 5 (Patients 1, 4, 5, 6, 7, and 8) of 13 patient charts audited. Findings include: 1. A review of patient test records revealed the following patients received toxicology testing: a. Patient 1 on 2/1 /19 b. Patient 4 on 11/29/18 c. Patient 5 on 10/30/18 d. Patient 6 on 7/11/20 e. Patient 7 on 8/2/20 f. Patient 8 on 9/22/20 2. A review of the patients' charts revealed the laboratory had a lack of test reports for the patients and test dates listed above. 3. An interview on 9/28/20 at 10:36 am with the Office Manager confirmed the laboratory did not ensure test results reached the patients' charts.
D6021	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 quality assessment programs are 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 with the Laboratory Consultant, the Laboratory Director failed to maintain quality assessment programs for 2 (September 2018 to September 2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's established "Patient Test Management System" procedure revealed a section stating,"Purpose of review: To verify the integrity of the communication path from physician order to patient test record. To verify that all policies and procedures governing this process meet the needs of the facility and accrediting body, and are being followed. To verify that each test ordered was performed and billed under appropriate codes. Relevant Policies, Procedures, and Forms to Review: Requisitions and reports, Accession logs and worksheets, Alert value list, reporting policy and documentation of alert values reported since the last review, Error correction policy and reporting documentation, Policy and process for obtaining a written request if a verbal request was accepted, confidentiality of patient information policy and process, Turn-around time from order to report to physician, billing practices and codes. Frequency of Review: Each element of the Patient Test Management (PTM) system should be evaluated annually." 2. A review of the laboratory's established "Quality Assurance" procedure revealed a section stating, "Purpose of Review: The purpose of this review is to verify that the scope of the Quality Assurance Plan reflects our actual processes, that the plan is complete, and meets the needs of our facility and our staff. Relevant Policies, procedures, and forms to review: Quality Assurance Plan, All quality assurance documentation acquired since the last review of the plan, all forms used to document QA activities. Frequency of review: Once a year." 3. A review of the laboratory's established "Magnacare" procedure revealed a section stating, "Our lab is committed to following the established appropriate performance standard for the entire laboratory process as set forward by COLA. Quality Assurance Objectives: The quality assurance program is a viable, on-going program that is intended to fulfill the following objectives: To achieve the goal of quality patient care by issuing accurate and timely reports, to monitor, evaluate, and document performance, to identify and correct problems, to assure laboratory and staff competency, to communicate effectively with staff and physicians, to make quality assurance everyone's responsibility by providing management leadership, commitment, and participation. Responsibility for the Quality Assurance Program: The Laboratory Director has overall responsibility for the Quality Assurance Program. The Laboratory Director will act to implement the Quality Assurance policies as part of the all-encompassing Risk Management Program." 4. The surveyor requested the laboratory's quality assessment documentation on 9/28/20 at 10:57 am and it was not made available. 5. An interview on 9/28/20 at 11:15 am with the Laboratory Consultant confirmed the Laboratory Director did not maintain the laboratory's established quality assessment program.