

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0971833	(X3) Date Survey Completed 05/14/2024
Name of Provider or Supplier Arroyo Oaks Medical Associates Inc	Street Address, City, State 2230 Lynn Rd, Ste 200, Thousand Oaks, CA	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, instrument print out, final report and interview with the laboratory staff on May 14, 2024, at 2 pm, the laboratory failed to follow its procedure to verify the critical value by repeating the test run for 1 patient out of 10 patients, reviewed. The findings include: 1. The laboratory obtained a critical high result of potassium, 6.3 mmol/L, for the patient acc# 24050338 on the Vitros 5600 chemistry analyzer. The laboratory reported this result without verifying it by repeat analysis though its procedure instructed to repeat. Therefore, the accuracy of the laboratory's reported critical results cannot be assured and may have potentially harmed patients. 2. The laboratory staff on May 14, 2024, at 2 pm, affirmed that the sample, # 24050338, was not repeated to verify the result as per the laboratory's policy. 3. The laboratory's testing declaration form signed by the laboratory director on 5/8/2024, stated that the laboratory performed approximately 165,797 tests in routine chemistry, annually.</p>
D5813	<p>TEST REPORT CFR(s): 493.1291(g)</p> <p>The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.</p>

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's critical value reporting records and interview with the laboratory staff on May 14, 2024, at 2 pm, the laboratory failed to immediately alert the test ordering physician after obtaining critical or panic values. The findings include: 1. The laboratory recorded the date of the critical value reported to the ordering physician, however, it did not record the reporting time. Therefore, it cannot be assured that the laboratory had reported the critical value to the ordering physician immediately after obtaining the results and may have potentially harmed patients. 2. The laboratory staff on May 14, 2024, at 2 pm, affirmed that the laboratory failed to record the reporting time. 3. The laboratory's testing declaration form signed by the laboratory director on 5/8/2024, stated that the laboratory performed approximately 254,011 tests, annually.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final test report, proficiency testing records and interview with the laboratory staff on May 14, 2024, at 2 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and may have potentially harmed patients. The findings include: See D5401 and D5813.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, test requisition, instrument print out, final report and interview with the laboratory staff on May 14, 2024, at 2 pm, the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: The laboratory personnel did not verify the potassium test results by repeat analysis. See D5401.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, instrument print out, final report and interview with the laboratory staff on May 14, 2024, at 2 pm, the laboratory testing personnel failed to follow the laboratory's procedures for test analyses. The findings include: The laboratory testing person #1 did not verify the potassium test results by repeat analysis. See D5401.