Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2044859	03/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Osteopathic Medical Associates Of Nevada	5410 W Sahara Ave, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on March 3, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Testing Institute (API) proficiency testing records for testing years 2018, 2019, and 2020, and an interview with testing personnel #1 on the CMS 209 form, the director failed to ensure that the proficiency testing samples were tested by all personnel who routinely perform the testing in the laboratory. Findings include: The laboratory failed to rotate the proficiency testing specimens for the Hematology 2018 testing events two and three, the 2019 testing event equivalent number one, and API testing events two, and three, and the 2020 testing events one, two and three among all testing personnel in the laboratory. The specimens were tested by the same testing personnel for each event. The testing personnel #1 confirmed the finding during an interview conducted on 3/3/21 at approximately 10:30 am. The laboratory performs approximately 1000 hematology patient tests annually.
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: Based on a review of laboratory maintenance logs for the Sysmex XP-300 Hematology analyzer for testing years 2018, 2019, 2020 and 2021, and an interview with testing personnel #1 from the CMS 209 form, the director failed to ensure that all maintenance was performed and documented with the frequency specified by the manufacturer of the instrument. Findings include: The laboratory failed to record the weekly maintenance for the Sysmex XP-300 Hematology instrument during the months of July, 2018, and May, 2019. Testing personnel #1 confirmed the finding during an interview conducted on 3/3/21 at approximately 10:00 am. The laboratory performs approximately 1000 hematology patient tests annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a random review of daily background check and quality controls performed during testing years 2018, 2019, and 2020 and an interview with testing personnel #1 from the CMS 209 form, the director failed to ensure that the function checks defined by the manufacturer were performed and documented with the frequency specified by the manufacturer. Findings include: A random review of eight patient testing dates from 7/3/2018 through 12/15/2020 revealed that six of eight patient testing dates had no evidence of the required daily background check for the Sysmex XP-300. The finding was confirmed during an interview with the testing personnel #1 on 3/3/21 at approximately 10:45 am. The laboratory performs approximately 1000 hematology patient tests annually.
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 a review of the laboratory quality assessment program documentation from May, 2018 through February, 2021, and an interview with testing personnel #1, the director failed to ensure that the established quality assessment program was

	maintained to assure the quality of laboratory services provided. Findings include: The laboratory failed to complete the monthly quality assessment as described in the director approved policy and procedure manual for the months of July, 2018, August, 2018, October, 2018, December, 2018, May, 2019 through December 2019, April, 2020, May 2020, and August, 2020 through February 2021. Testing personnel #1 confirmed the findings during an interview conducted on 3/3/21 at approximately 10: 45 am. The laboratory performs approximately 1000 hematology patient tests annually.