Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2044859	06/22/2018
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 June 21 and 22, 2018. 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.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing results for hematology for testing years 2016, 2017 and 2018 and an interview with the medical assistant, the laboratory failed to test proficiency testing samples in the same manner that the laboratory tests patient specimens. Findings include: 1. The laboratory failed to perform the API first event hematology proficiency testing in the same manner that the laboratory performs patient hematology testing. 2. The laboratory had ceased patient hematology testing from 10/31/17 through 5/04/18 due to the hematology reagents having expired. The laboratory performed the API hematology first event 2018 on 3/22/18 using expired hematology reagents. 3. The laboratory's API proficiency test results revealed that the RDW was 0% with no

	corrective action investigation performed. This was confirmed by the medical assistant on June 22, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,000 patient hematology tests annually.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing results for hematology for testing years 2016, 2017 and 2018 and an interview with the medical assistant, the laboratory failed to take the appropriate actions necessary to correct problems associated with unacceptable proficiency testing results. Findings include: 1. The laboratory failed to perform corrective action investigation for the API first event hematology of 2017 proficiency test which indicated results of 80% for lymph and 80% for MPV. 2. The laboratory failed to perform corrective action investigation for the API second event hematology of 2017 proficiency test which indicated results of 80% for mono. 3. The laboratory failed to perform corrective action investigation for the API first event hematology of 2018 proficiency test which indicated results of 0% for RDW. This was confirmed by the medical assistant on June 22, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,000 patient hematology tests annually.
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 a review of patient hematology test records, a review of the API proficiency testing records and an interview with the medical assistant, the laboratory failed to refrain from using expired reagents when performing hematology testing. Findings include: The laboratory performed API hematology proficiency testing on March 22, 2018 using reagents that were expired. This was confirmed by the medical assistant on June 22, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,000 patient hematology tests annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that 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 a review of the American Proficiency Institute (API) proficiency testing results for hematology for testing years 2016, 2017 and 2018 and an interview with the medical assistant, the laboratory director failed to ensure that all proficiency testing reports that are received are evaluated to determine the laboratory's performance and to identify problems that require corrective action. Findings include: 1. The laboratory failed to perform corrective action investigation for the API first event hematology of 2017 proficiency test which indicated results of 80% for lymph and 80% for MPV. 2. The laboratory failed to perform corrective action investigation for the API second event hematology of 2017 proficiency test which indicated results of 80% for mono. 3. The laboratory failed to perform corrective action investigation for the API first event hematology of 2018 proficiency test which indicated results of 0% for RDW. 4. The laboratory failed to review the API second event 2017 hematology proficiency testing results to determine if there were any problems that require corrective action. This was confirmed by the medical assistant on June 22, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,000 patient hematology 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 director approved quality assessment policy and procedure, a review or the documentation of laboratory quality assessment from August 2016 to June 2018 and an interview with the medical assistant, the laboratory director failed to ensure that laboratory quality assessment is maintained to assure the quality of the laboratory services provided. Findings include: 1. The laboratory director failed to ensure that quality assessment was performed and documented according to the director approved policy. 2. The policy for quality assessment states that there will be monthly audits, bi-monthly quality assessment and bi-weekly quality control check. 3. The last time that quality assessment was performed and documented was for July 2017. 4. The last time that bi-monthly quality assessment was performed and documented was for June 2017. 5. The last time that bi-weekly quality control check was performed and documented was on June 28, 2017. This was confirmed by the medical assistant on June 22, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,000 patient hematology tests annually.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the testing personnel training and competency records in the performance of hematology patient laboratory testing and an interview with the medical assistant, the laboratory technical consultant failed to evaluate and document the performance of individuals performing moderate complexity hematology testing at least semiannually during the first year of patient testing. Findings include: There was no documentation of semiannual competency in the performance of moderately complex hematology patient testing for two of two testing personnel. This was confirmed by the medical assistant on June 22, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,000 patient hematology tests annually.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the testing personnel training and competency records in the performance of hematology patient laboratory testing and an interview with the medical assistant, the laboratory technical consultant failed to evaluate and document the performance of individuals performing moderate complexity hematology testing at least annually after the first year of patient testing. Findings include: There was no documentation of annual competency in the performance of moderately complex hematology patient testing for two of two testing personnel for testing year 2017. This was confirmed by the medical assistant on June 22, 2018 at approximately 1:30 PM. The laboratory performs approximately 1,000 patient hematology tests annually.