Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2149533	05/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nevada Stat Laboratory	2675 S Jones Blvd Ste 111, 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 May 28, 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.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory Quality Assurance Plan, a random patient audit between the dates of December 12, 2018 and November 20, 2019, and an interview with the Laboratory Director, and Laboratory Supervisor, the laboratory failed to maintain the quality control records for the Sysmex XS1000i hematology analyzer, Beckman Coulter AU400 chemistry analyzer, and the Beckman Coulter Access 2 immunoassay analyzer, and failed to maintain the maintenance records for the Beckman Coulter Access 2 immunoassay analyzer for a minimum of two years. Findings include: 1. A random audit of patient records tested between the dates of December 12, 2018 and November 20, 2019 revealed that there were no quality control records available for review for five of six dates of testing performed on the Beckman Coulter Access 2 immunoassay analyzer. There were no control records available for the following dates: December, 12, 2018, May 29, 2019, July 31, 2019, October 15, 2019, and November 20, 2019. 2. A random audit of patient records tested between the dates of December 12, 2018 and November 20, 2019 revealed that there were no quality control records available for review for two of six dates of

	testing performed on the Beckman Coulter AU400 chemistry analyzer. There were no control records available for the following dates: May 29, 2019, and July 31, 2019. 3. A random audit of patient records tested between the dates of December 12, 2018 and November 20, 2019 revealed that there were no quality control records available for review for two of six dates of testing performed on the Sysmex XS1000i analyzer. There were no control records available for review for the following dates: July 31, 2019, and November 20, 2019. 4. A random audit of patient records tested between the dates of December 12, 2018 and November 20, 2019 revealed that there were no instrument maintenance records available for review for five of six dates of testing performed on the Beckman Coulter Access 2 immunoassay analyzer. There were no maintenance records available for the following dates: March 11, 2019, May 29, 2019, July 31, 2019, October 15, 2019, and November 20, 2019. 5. The director approved policy number QA 100.0 entitled "Quality Assurance Plan (QMP)," section II. "Analytical Quality Assurance Areas," sub-section E. "Test Specific Quality Control" stated in step 4, "Retain QC and patient test records, including instrument print-outs if applicable, for 2 years." 6. An interview conducted with the Laboratory Director on May 28, 2021 at approximately 4:00 PM revealed that there were 49 patients tested on December 12, 2018, 34 patients tests on March 11, 2019, seven patients tested on May 29, 2019, six patients tested on July 31, 2019, 13 patients tested on October 15, 2019, and eight patients tested on November 20, 2019 that were potentially affected. 7. The Laboratory Director and the Laboratory Supervisor confirmed that the records were not available for review during an interview conducted on May 28, 2021 at approximately 3:45 PM. The laboratory performs approximately 4500 chemistry tests, and 1300 hematology tests annually.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the director approved Quality Assurance Plan, and an interview with the Laboratory Director, and the Laboratory Supervisor, the laboratory failed to retain all laboratory quality assessment records for a minimum of 2 years. Findings include: 1. The director approved policy number QA 100.0 entitled "Quality Assurance Plan (QMP)," in the section entitled "Quality Assurance Procedure" stated in step 5, "Retain quality assessment records for a minimum of two years." 2. The Laboratory Director and the Laboratory Supervisor confirmed that there were no records of quality assessment available for review at the time of the survey during an interview conducted on May 28, 2021 at approximately 3:30 PM. The laboratory performs approximately 4500 chemistry tests, and 1300 hematology tests annually.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) 2020 and 2021

	proficiency testing (PT) reports, a review of the director approved Quality Assurance Policy, and an interview with the Laboratory Director, and the Laboratory Supervisor, the laboratory failed to ensure that the PT results were evaluated, and that corrective action was taken when required. Findings include: 1. There was no documentation of corrective action for the 2020 API Hematology/Coagulation Event 1 for the Monocytes % result reported on sample XE-01 that was unacceptable. The reported result was 7.1%. The acceptable range was 7.3% - 12.9%. 2. The 2020 third API Hematology testing event, specimen US-06 result for urine sediment was not graded. The expected result area stated to "See Data Summary." The laboratory reported the result as a renal tubular epithelial cell. According to the Participant Summary, the laboratory was in consensus with 2757 of 5497 laboratories reporting results. There was no documentation of review of the data summary to evaluate the response reported by the laboratory according to the performance of the peer group for the same specimen. 3. The laboratory policy number QA 100.0 entitled "Quality Assurance Policy (QMP)," section II. "Analytical Quality Assurance Areas," sub-section G. "Proficiency Testing" stated under "Indications and Monitoring" in step 2, "Corrective action for incorrect results will be documented for each department." Step 3 went on to state, "For performance on PT challenges that were not graded because of lack of consensus, because the results were submitted after the cut-off date, not submitted, or an error was made completing the form, these must be addressed by the department supervisor and/or Laboratory Director, and notation made on the result report form." 4. The Laboratory Director and the Laboratory Supervisor confirmed the findings during an interview conducted on May 28, 2021 at approximately 2:00 PM. The laboratory performs approximately 4500 chemistry tests, and 1300 hematology tests 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 a review of the laboratory Quality Assurance Plan, a random patient audit between the dates of December 12, 2018 and November 20, 2019, and an interview with the Laboratory Director, and Laboratory Supervisor, the laboratory failed to ensure that the test request was ordered by an authorized provider. Findings include: 1. A random audit of patient laboratory test records between the dates of December 12, 2018 and November 20, 2019 revealed that one of six patient requisitions did not include the name of a person authorized to order tests or receive test results. A patient that had laboratory testing performed on March 11, 2019 did not have an authorized provider name represented on the laboratory order. The requisition indicated that the order was a 'self-request.' 2. The director approved policy number QA 100.0 entitled "Quality Assurance Plan (QMP)," Section II. "Analytical Quality Assurance Areas," sub-section B. "Laboratory Requisitions" stated in step 2 that "Each Requisition must bear the name of the requesting physician." 3. The Laboratory Director and the Laboratory Supervisor confirmed the finding during an interview conducted on May 28, 2021 at approximately 11:30 AM. The laboratory performs approximately 4500 chemistry tests, and 1300 hematology tests annually.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the 2021 American Proficiency Institute (API) proficiency testing (PT) records, the 2021 API order confirmation and shipping schedule, and an interview with the Laboratory Director, and the Laboratory Supervisor, the director failed to ensure that the specimen shipment for the Sex Hormone Binding Globulin (SHBG) and Testosterone first event were received, performed, and submitted within the timeframe established by the PT program. Findings include: 1. A review of the 2021 API PT records revealed that no records of that the SHBG and Testosterone the first event specimens were received by the laboratory and that results were returned to API for evaluation. 2. A review of the 2021 Order Confirmation, and the complete 2021 API schedule revealed that the samples for the first event for SHBG and Testosterone were scheduled to be shipped on April 19, 2021. The schedule also revealed that the cut-off to request replacement specimens was April 27, 2021, and the results were due to be submitted by May 12, 2021. 3. The Laboratory Supervisor stated during an interview conducted on May 28, 2021 at approximately 1:30 PM that the laboratory was unaware that the shipment was scheduled for April 19, 2021. The laboratory failed to contact API to find out what happened to the specimens until the day of the survey. An investigation by the laboratory at the time of the survey revealed that the specimens had not been delivered. The laboratory performs approximately 4500 chemistry tests, and 1300 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 assurance plan and an interview with the Laboratory Director and Laboratory Supervisor, the director failed to ensure that the records of quality assessment were performed and maintained to assure the quality of the laboratory services. Findings include: 1. There were no records of quality assessment available for review at the time of the survey. 2. The policy number QA 100.0 entitled "Quality Assurance Policy (QMP)" in the section entitled "Quality Assurance Procedure" stated, "1. Document problems or events on a daily basis using the facility incident forms. 2. Schedule reviews and conduct them accordingly to the schedule...3. Evaluate the review to determine if any corrective actions is needed...4. Document all reviews, corrective action and follow-up activities...5. Retain quality assessment records for a minimum of 2 years." The same

	policy states that the "Director(s) and Administrator(s) have overall responsibility for the Quality Assurance Program." 3. The Laboratory Director and the Laboratory Supervisor confirmed the findings during an interview conducted on May 28, 2021 at approximately 3:00 PM. The laboratory performs approximately 4500 chemistry tests, and 1300 hematology tests annually.