

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2149533	(X3) Date Survey Completed 10/25/2018
Name of Provider or Supplier Nevada Stat Laboratory	Street Address, City, State 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 initial CLIA survey conducted at your facility on October 25, 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.
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) results for the second event 2018 for Hematology and Coagulation, a review of the documents of corrective action for failed analytes and an interview with the laboratory testing personnel, the laboratory failed take and document corrective action necessary to correct any problems associated with the proficiency testing failure. Findings include: 1. The laboratory failed to take and document the corrective action for the API second event 2018 for Hematology and Coagulation for blood cell identification. The laboratory received a 60% score for this event and the corrective action states, "No corrective action done but discussed and reviewed with the lab director." 2. The laboratory failed to take and document the corrective action for the API second event 2018 for Hematology and Coagulation for MPV. The laboratory received a 60% score for this</p>

	<p>event and the corrective action states, "Samples re-run but too old. Results unacceptable. No corrective action taken." This was confirmed by the laboratory testing personnel on October 25, 2018 at approximately 11:00 am. The laboratory performs approximately 25,000 patient Hematology tests annually.</p>
<p>D5213</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the API second event 2018 for Hematology and Coagulation and an interview with the laboratory testing personnel, the laboratory failed to verify the accuracy of all analytes that were evaluated by the proficiency testing program. Findings include: 1. The laboratory failed to evaluate the results of the API second event 2018 for Hematology and Coagulation for the educational blood cell identification. The laboratory reported results did not match the expected results from the proficiency testing agency for samples BCI-13 and BCI-14. 2. For sample BCI-13, the API expected result was Blast and the laboratory reported result was Lymph, reactive (atyp,variant). 3. For sample BCI-14, the API expected result was Auer rod and the laboratory reported result was Lymph, reactive (atyp, variant). This was confirmed by the laboratory testing personnel on October 25, 2018 at approximately 11:00 am. The laboratory performs approximately 25,000 patient Hematology tests annually.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the validation/verification results for the Beckman Coulter Access 2 chemistry analyzer, there were eight analytes that did not meet the director approved policy for acceptability to indicate accuracy (refer to D5421) and a review of the quality control results from July 16, 2018 through October 25, 2018 for hematology and chemistry revealed that patient test results were reported when the quality control performed did not meet the criteria of acceptability indicated in the director approved policy and procedure manual for quality control (refer to D5481).</p>
<p>D5421</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it</p>

can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of the performance verification data and reports of the Beckman Coulter Access 2 chemistry analyzer, a review of the director approved policy and procedure manual which represents the validation or verification of new instruments and an interview with the laboratory testing personnel, the laboratory failed to demonstrate that it can obtain performance specifications comparable to the manufacturer for accuracy before patient testing is performed. Findings include: 1. The laboratory failed to meet the director approved acceptable criteria to determine accuracy for all chemistry tests performed on the Beckman Coulter Access 2 analyzer before patient testing was performed. The acceptable criteria for accuracy that is stated in the director approved policy and procedure manual states that "The linear regression of the correlated data must demonstrate a slope $r > 0.95$ or $r^2 > 0.90$." 2. The accuracy report for T Uptake found the correlation r value to be 0.7028 which does not meet the criteria for acceptability. 3. The accuracy report for CA 15-3 found the correlation r value to be 0.7874 which does not meet the criteria for acceptability. 4. The accuracy report for Calcium found the correlation r value to be 0.7757 which does not meet the criteria for acceptability. 5. The accuracy report for Sodium found the correlation r value to be 0.7419 which does not meet the criteria for acceptability. 6. The accuracy report for Magnesium found the correlation r value to be 0.7498 which does not meet the criteria for acceptability. 7. The accuracy report for CA 125 found that the evaluation of the results indicated that the test for accuracy comparison failed. There was no further evaluation performed to meet the criteria for acceptability for accuracy. 8. The accuracy report for CA 19-9 found that the evaluation of the results indicated that the test for accuracy comparison failed. There was no further evaluation performed to meet the criteria for acceptability for accuracy. 9. The accuracy report for CEA found that the evaluation of the results indicated that the test for accuracy comparison failed. There was no further evaluation performed to meet the criteria for acceptability for accuracy. This was confirmed with the laboratory testing personnel on October 25 2018 at approximately 1:30 pm. The laboratory performs approximately 25,000 patient chemistry tests annually.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the quality control results for chemistry from July 16, 2018 to October 25, 2018, a review of the director approved policy and procedure representing quality control and an interview with the laboratory testing personnel, the laboratory failed to meet the laboratory's criteria for quality control acceptability before patient test results were reported. Findings include: 1. The laboratory failed to meet the director approved policy for acceptable quality control results which states, "All

controls must be within +/- 2 SDs of the established mean value before patient results can be reported." 2. The Levey-Jennings report for the dates 9/04/18 through 9/28/18 for Sodium revealed that on 9/06/18 that level one and level two controls were run. The level one control indicated a control value greater than 3 SD and level two control greater than 2 SD. There were 23 patient Sodium results reported on 9/06/18. The quality controls for Sodium were not repeated and there was no corrective action taken. This was confirmed by the laboratory testing personnel on October 25, 2018 at approximately 2:30 pm. The laboratory performs approximately 25,000 patient chemistry tests annually.

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 a random review of patient final test reports from July 16, 2018 through October 25, 2018, a review of patient final test reports sent to outside reference laboratories during the same time period and an interview with the laboratory testing personnel, the laboratory failed to ensure that test results are accurately and reliably sent from the point of data entry to the final report. Findings include: 1. The laboratory failed to ensure that patient laboratory results performed by an outside reference laboratory were correctly entered into the laboratory information system (LIS). 2. A random patient test sample collected on 10/12/18 that was sent to Primex Clinical Laboratory for a PTH, INTACT test, found that Primex issued a patient final test result of 26 pg/ml on 10/13/18. The patient final test report that was sent to the provider from Nevada Stat Laboratory revealed a test result for PTH, INTACT of 52 pg/ml. This was confirmed by the laboratory testing personnel on October 25, 2018 at approximately 2:30 pm. The laboratory performs approximately 50,000 patient laboratory tests annually.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of the API proficiency testing results for hematology and chemistry for testing year 2018, the laboratory director failed to take and document corrective action necessary to correct any problems associated with the proficiency testing failures (refer to D6019), the laboratory director failed to ensure that all controls performed daily met the criteria for acceptability before patient laboratory results

were reported (refer to D6020) and the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of the laboratory tests provided (refer to D6021).

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) results for the second event 2018 for Hematology and Coagulation, a review of the documents of corrective action for failed analytes and an interview with the testing personnel, the laboratory director failed take and document corrective action necessary to correct any problems associated with the proficiency testing failure. Findings include: 1. The laboratory director failed to take and document the corrective action for the API second event 2018 for Hematology and Coagulation for blood cell identification. The laboratory received a 60% score for this event and the corrective action states, "No corrective action done but discussed and reviewed with the lab director." 2. The laboratory director failed to take and document the corrective action for the API second event 2018 for Hematology and Coagulation for blood cell identification. The laboratory received a 60% score for this event and the corrective action states, "Samples re-run but too old. Results unacceptable. No corrective action taken." 3. The laboratory director failed to evaluate the results of the API second event 2018 for Hematology and Coagulation for the educational blood cell identification. The laboratory reported results did not match the expected results from the proficiency testing agency for samples BCI-13 and BCI-14. 4. For sample BCI-13, the API expected result was Blast and the laboratory reported result was Lymph, reactive (atyp,variant). 5. For sample BCI-14, the API expected result was Auer rod and the laboratory reported result was Lymph, reactive (atyp, variant). This was confirmed by the laboratory testing personnel on October 25, 2018 at approximately 11:00 am. The laboratory performs approximately 25,000 patient Hematology tests annually.

D6020

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 the quality control program is 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 quality control results for chemistry from July 16, 2018 to October 25, 2018, a review of the director approved policy and procedure representing

quality control and an interview with the laboratory testing personnel, the laboratory director failed to meet the laboratory's criteria for quality control acceptability before patient test results were reported. Findings include: 1. The laboratory director failed to meet the director approved policy for acceptable quality control results which states, "All controls must be within +/- 2 SDs of the established mean value before patient results can be reported. 2. The Levey-Jennings report for the dates 9/04/18 through 9/28/18 for Sodium revealed that on 9/06/18 that a level one and a level two controls were run. The level one control indicated a control value greater than 3 SD and a level two control greater than 2 SD. There were 23 patient Sodium results reported on 9/06/18. This was confirmed by the laboratory testing personnel on October 25, 2018 at approximately 2:30 pm. The laboratory performs approximately 25,000 patient chemistry 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 random review of the quality control performed by the laboratory from July 16, 2018 through October 25, 2018, a random review of laboratory data entry during the same time period, a review of the laboratory quality assessment program, a review of the laboratory validation/verification results for the Beckman Coulter Access 2 chemistry analyzer, a review of the results of the API proficiency testing for 2018 and an interview with the laboratory testing personnel, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of the laboratory tests provided. Findings include: 1. The laboratory director failed to evaluate the results of the API second event 2018 for Hematology and Coagulation for the educational blood cell identification. The laboratory reported results did not match the expected results from the proficiency testing agency for samples BCI-13 and BCI-14. 2. The laboratory director failed to take and document the corrective action for the API second event 2018 for Hematology and Coagulation for blood cell identification. The laboratory received a 60% score for this event and the corrective action states, "No corrective action done but discussed and reviewed with the lab director." 3. The laboratory director failed to take and document the corrective action for the API second event 2018 for Hematology and Coagulation for blood cell identification. The laboratory received a 60% score for this event and the corrective action states, "Samples re-run but too old. Results unacceptable. No corrective action taken." 4. The laboratory director failed to meet the director approved acceptable criteria to determine accuracy for all chemistry tests performed on the Beckman Coulter Access 2 analyzer before patient testing was performed. The following analytes failed to meet the criteria for acceptability for accuracy: T Uptake, CA 15-3, Calcium, Sodium, Magnesium, CA 125, CA 19-9 and CEA. 5. The laboratory failed to meet the director approved policy for acceptable quality control results which states, "All controls must be within +/- 2 SDs of the established mean value before patient results can be reported. The Levey-Jennings report for the dates 9/04/18 through 9/28/18 for Sodium revealed that on 9/06/18 that level one and level

two controls were run. The level one control indicated a control value greater than 3 SD and level two control greater than 2 SD. There were 23 patient Sodium results reported on 9/06/18. 6. The laboratory failed to ensure that patient laboratory results performed by an outside reference laboratory were correctly entered into the laboratory information system (LIS). A random patient test sample collected on 10/12/18 that was sent to Primex Clinical Laboratory for a PTH, INTACT test, found that Primex issued a patient final test result of 26 pg/ml on 10/13/18. The patient final test report that was sent to the provider from Nevada Stat Laboratory revealed a test result for PTH, INTACT of 52 pg/ml. 7. There was no documented review of quality assessment in accordance with the director approved policy and procedure manual. This was confirmed by the laboratory testing personnel on October 25, 2018 at approximately 3:30 pm. The laboratory performs approximately 50,000 patient chemistry and hematology tests annually.