Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2102809	10/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
American Specialty Lab Llc	7251 W Charleston Blvd, 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 October 14 and 18, 2019. 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.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a random audit of patient laboratory testing requisitions and final reports from 10/24/17 through 9/05/19 and an interview with the laboratory manager, the laboratory failed to follow director approved policy to ensure positive identification of information from the time of the sample collection through the completion of testing and the reporting of the results. Findings include: 1. A random audit of patient test requisitions and patient final test reports from 10/24/17 through 9/05/19, revealed that the laboratory failed to ensure that the patient and sample information that was recorded on the patient requisition matched the information that was on the patient final test report. 2. A random patient on 5/7/18 had a recorded collection time of 12 noon on the test requisition and a collection time of 8:00 AM on the patient final test report. 3. A random patient on 10/03/18 had a recorded collection time of 12:56 PM on the test requisition and a collection time of 5:16 PM on the patient final test report.

	This was confirmed by the laboratory manager on October 18, 2019 at approximately 2:30 PM. The laboratory performs approximately 346,400 patient laboratory tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing reports for all non-waived tests performed by the laboratory from July 2017 through October 2019 and an interview with the laboratory manager, the laboratory failed to verify the accuracy, at least twice a year, for non-regulated non-waived laboratory tests that were not included in a Health and Human Services (HHS) approved proficiency testing program. Findings include: 1. The laboratory failed to verify the accuracy of 15 toxicology confirmation analytes, at least twice a year, for testing years 2018 and 2019. 2. The laboratory failed to verify the accuracy, at least twice a year during testing years 2018 and 2019, for the following toxicology confirmation analytes in which patient testing was performed: 2-Hydroxyethylflurazepam, 4-Hydroxyalprazolam, 4-Hydroxymidazolam, 7-Aminoflunitrazepam, Chlordiazepoxide, Desipramine, Estazolam, MDEA, Methylphenidate, Naloxone, Naltrexol, Naltrexone, Norhydrocodone and PCP. This was confirmed by the laboratory manager on October 14, 2019 at approximately 1:30 PM. The laboratory performs approximately 340,000 patient Chemistry tests annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of temperature recording logs from July 2017 through October 2019 and an interview with the laboratory manager, the laboratory failed to take and document, corrective actions for the storage of reagents and specimens that were found to be outside of the acceptable storage criteria. Findings include: 1. The laboratory failed to take and document, corrective action for reagents and specimens that were stored in the laboratory according to the storage criteria stipulated by the manufacturer and established by the laboratory. 2. The temperature recording logs from July 2017 through December 2017 revealed that the Norlake refrigerator had 28 of 125 temperature recordings that were outside of the acceptable range of 36 to 46 degrees Fahrenheit (F) and the Spartan refrigerator temperature recordings were outside of the same acceptable range 36 of 125 times with no corrective action taken and documented for either refrigerator. 3. The humidity recording logs from October 2017 through December 2017 revealed that the storage area humidity was outside of the acceptable range of 20 to 60%, 36 of 63 times with no corrective action taken and documented. 4. In March 2018, the temperature logs indicates that the Norlake refrigerator had temperature recordings outside of the 36 to 46 degree F range 7 of 25 times and the humidity for the storage area was outside of the acceptable range of 20

	to 60%, 9 of 25 times with no corrective action taken and documented. 5. The temperature recording logs from January 2019 through April 2019 revealed that the G. E. refrigerator had temperature recordings outside of the acceptable range of 2 to 8 degrees Centigrade (C) 47 of 83 times with no corrective action taken and documented. This was confirmed by the laboratory manager on October 18, 2019 at approximately 2:30 PM. The laboratory performs approximately 346,400 patient laboratory tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory proficiency testing results from July 2017 through October 2019, a review of the temperature recording logs from the same time period, a random audit of patient test requisitions and patient final test reports from 10/24/17 through 9/05/19 and an interview with the laboratory manager, the laboratory director failed to ensure that the quality assessment system in place, could assure the quality of the laboratory services provided and identify failures in quality as they occur. Findings include: 1. The laboratory director failed to have a quality assessment system that could identify and correct areas of proficiency testing for non-regulated non-waived analytes not included in an HHS approved proficiency testing program, failures in taking and documenting corrective actions necessary for the storage of reagents and specimens, failures in ensuring that information on patient test requisitions were accurately transcribed to be correctly found on the patient final report and the failure for the documentation of training and competency for all testing personnel performing patient laboratory testing. 2. There were multiple dates from July 2017 through April 2019 that temperature and humidity recordings were found to be outside of the acceptable storage criteria established by the laboratory with no corrective action taken and documented (see D5785). 3. There were no twice a year verification of accuracy for 15 toxicology confirmation analytes for testing years 2018 and 2019 (see D5217). 4. A review of the training and competency records found that personnel performing patient laboratory testing did not all have documentation of initial training and semi-annual competency (see D6102 and D6127). 5. A random audit of ten patient requisitions and patient final reports between 10/24/17 and 9/05/19 revealed that two of ten patient requisitions did not indicate the correct time of specimen collection on the patient final report (see D5203). This was confirmed by the laboratory manager on October 18, 2019 at approximately 4:00 PM. The laboratory performs approximately 346,400 patient laboratory tests annually.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on a review of training records for patient laboratory testing personnel and an interview with the laboratory manager, the laboratory director failed to ensure that all testing personnel had the appropriate training for the types and complexity of testing offered. Findings include: 1. The laboratory director failed to have documentation of training for two of five laboratory testing personnel. 2. Testing personnel number three from the Centers for Medicare & Medicaid Services (CMS)-209 form was found to have no documentation of initial training for the AU480 Chemistry analyzer. 3. Testing personnel number five from the CMS-209 form was found to have no documentation of initial training for the Architect Chemistry analyzer. This was confirmed by the laboratory manager on October 14, 2019 at approximately 11:00 AM. The laboratory performs approximately 346,400 patient laboratory tests annually.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 training records for patient laboratory testing personnel and an interview with the laboratory manager, the laboratory technical supervisor failed to ensure that all testing personnel had semiannual competency documentation during the first year of patient testing for the types and complexity of testing offered. Findings include: 1. The laboratory technical supervisor failed to have documentation of semiannual competency for two of five laboratory testing personnel. 2. Testing personnel number one from the CMS-209 form was found to have no documentation of semiannual competency for the Sysmex XN-550 Hematology analyzer and the Architect Chemistry analyzer. 3. Testing personnel number five from the CMS-209 form was found to have no documentation of semiannual competency for the AU 480 Chemistry analyzer. This was confirmed by the laboratory manager on October 14, 2019 at approximately 11:00 AM. The laboratory performs approximately 346,400 patient laboratory tests annually.