Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2102809	10/31/2023
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 30-31, 2023. 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.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the 2023 internal LCMS proficiency testing laboratory records for analytes not included in an approved proficiency testing program, an interview with the laboratory supervisor, and a telephone conversation with the LCMS technologist, the laboratory failed to ensure that corrective action was taken and documented for unacceptable proficiency testing results for methylphenidate. Findings include: 1. A review of the 2023 internal LCMS proficiency testing document entitled, "Profienciency (sic) Testing for analytes not covered by CAP" dated 4/12/2023 revealed that Blind Sample number one of three produced an unacceptable result for methylphenidate, resulting in a score of 66% for that analyte. The summary conclusion for the event stated, "Differences between target values and LCMS results are less than 30%, excpet (sic) for methylphenidate Blind #1 sample. Will closely monitor any positive patient results and perform another blind spike study with new CCSS preparation." 2. There was no documentation of the performance of corrective action such as another blind spike study, as as stated in the summary of the blind sample analysis. 3. A review of the 2023 internal LCMS proficiency testing document entitled, "Profienciency (sic) Testing for analytes not covered by CAP" dated 9/27/2023 revealed that the laboratory did not include

	methylphenidate for test event number two during 2023. 4. The laboratory supervisor confirmed the findings during an interview conducted on October 30, 2023 at approximately 10:30 AM. 5. During a telephone conversation with the LCMS technologist on October 30, 2023 at approximately 11:00 AM, the technologist stated that the methylphenidate for test event one was retested, and the same results were obtained. It was further stated that the laboratory had decided to remove methylphenidate from the laboratory test menu. There was no documentation of the repeat analysis or documentation stating that the test had been removed from the test menu. The laboratory performs approximately 346,400 chemistry tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter DxC AU 700 operator's manual, the laboratory chemistry procedure manual, and an interview with the laboratory supervisor, the laboratory failed to ensure that a written procedure manual was available for all tests was available to the laboratory personnel. Findings include: 1. A review of the Beckman Coulter DxC AU 700 operator's manual revealed that the manual available to the personnel was incomplete. Chapters one through four were not in the operators manual, with the exception of pages 1-25 and 1-26 from chapter one. 2. A review of the chemistry procedure manual revealed that there was no procedure for the hemoglobin A1c test performed on the Beckman Coulter DxC AU 700 . 3. The findings were confirmed during an interview with the laboratory supervisor on October 31, 2023 at approximately 11:00 AM The laboratory performs approximately 346,400 chemistry tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the general chemistry procedure manual, a review of the LCMS procedures entitled, "Standard Solution Preparation for Pain Panel Analytes," "Extraction of Drugs of Abuse Analytes from Human Urine," and "Quantitation of Pain Panel Analytes by High Performance Liquid Chromatography Tandem Mass Spectrometry (LC/MS)", the laboratory failed to ensure that the methods in the procedure manuals were current, and that any modifications made were documented and approved by the laboratory director. Findings include: 1. A review of the chemistry procedure manual revealed that the procedures for the general chemistry tests were not current for the chemistry instrument in use. The procedures were written and approved for the Beckman Coulter AU 480. The procedures were originally written and approved in 2015. The general chemistry instrument currently in use in the laboratory is the Beckman Coulter DxC 700 AU. 2. The laboratory failed

	to update the LCMS procedures entitled, "Standard Solution Preparation for Pain Panel Analytes," "Extraction of Drugs of Abuse Analytes from Human Urine," and "Quantitation of Pain Panel Analytes by High Performance Liquid Chromatography Tandem Mass Spectrometry (LC/MS)", to reflect the removal of methylphenidate from the laboratory test menu. 3. The findings were confirmed during an interview with the laboratory supervisor on October 31, 2023 at approximately 12:00 PM. The laboratory performs approximately 346,400 chemistry tests annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, a review of the package insert for the hemoglobin A1c (HbA1c) quality control solutions, and an interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for the storage of the HbA1c quality control solutions that were in use. Findings include: 1. It was observed that the HbA1c control solutions that were currently in use were being stored refrigerated loosely capped in sample cups located in a sample rack for the Beckman Coulter DxC AU 700 analyzer. 2. A review of the package insert for the extendSURE Hemoglobin A1c liquid controls revealed that the instructions stated, "Once the controls are opened; they can be used for 30 days when stored tightly capped." 3. The findings were confirmed during an interview conducted on October 31, 2023 at approximately 11:30 AM. The laboratory performs approximately 346,400 chemistry tests annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random patient audit of two patients tested for hemoglobin A1c (HbA1c) the on dates of November , 2022 and October 10, 2023, a review of the HbA1c quality control records, a review of the HbA1c quality control reference ranges established by the manufacturer of the control, and an interview with the laboratory supervisor and

	office manager, the laboratory failed to ensure that the stated reference ranges for the methodology and instrumentation employed by the laboratory were consistently in use for the duration of use of the quality control solution, and that the quality control solution manufacturer's expiration date was correctly recorded in the laboratory information system. Findings include: 1. A random patient audit of two patients tested for HbA1c on the dates of November 18, 2022 and October 10, 2023 revealed that the quality control ranges for the HbA1c in use for the extendSURE control lot number 4247, initially placed into use on April 7, 2022, were changed on March 27, 2023 in the laboratory information system from the ranges for use with the Beckman Coulter DxC AU chemistry systems (currently used by the laboratory) to perform the testing. The range entered for level one control was indicated for use with the Beckman Coulter AU chemistry systems. The range entered for level two was indicated for use with the Beckman Coulter DxC chemistry systems. 2. The level one control range for the Beckman Coulter AU chemistry systems entered into the system on March 27, 2023 was 4.8-6.8%. The appropriate reference range for the Beckman Coulter DxC AU chemistry system was 4.6-6.6%. 3. The level two control range for the Beckman Coulter DxC chemistry systems entered into the system on March 27, 2023 was 9.1-12.7%. The appropriate reference range for the Beckman Coulter DxC AU chemistry system was 8.3-11.7%. 4. The extendSURE quality control solution lot number 4247 had a manufacturer's expiration date of 02/29/2024. The expiration date recorded in the laboratory information system was 04/29/2024. 5. The findings were confirmed during an interview with the laboratory supervisor and the office manager on October 31, 2023 at approximately 12:00 PM. The laboratory performs approximately 346,400 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 the laboratory temperature and humidity logs between the dates of January 1, 2022 and March 31, 2023, a review of the laboratory policy ASL /QM009 entitled, "Verification and Maintenance of Equipment," and an interview with the laboratory supervisor and the office manager, the laboratory failed to ensure that corrective action was taken when temperature and humidity values exceeded the acceptable ranges established by the laboratory. Findings include: 1. A review of the laboratory temperature and humidity logs between the dates of January 1, 2022 and March 31, 2023 revealed that the laboratory failed to ensure that corrective action was taken and documented for temperature and humidity excursions in the following situations: A. The minimum and maximum temperatures recorded on the log entitled "COVID Lab" for the Norlake freezer exceeded the established acceptable range of -70 degrees C to -10 degrees C on 293 of 293 days between the dates of February 1, 2022 and March 31, 2023. B. The minimum and maximum humidity recorded on the log entitled "COVID Lab" exceeded the established acceptable range of 20% to 80% on 191 of 191 days between the dates of July 1, 2022 and March 31, 2023. C. The minimum and maximum temperatures recorded on the log entitled "Access/DXC AU700" for the Norlake freezer exceeded the established acceptable range of -70 degrees C to -10 degrees C on 239 of 256 days between the dates of January 3, 2022 and March 31, 2023. D. The maximum temperature recorded on the log entitled,

	"Main Lab" for refrigerator number 1 exceeded the established acceptable value of 8 degrees C on 100 of 173 days between the dates of February 1, 2022 and September 30, 2022. On August 13, 2022 the maximum temperature was not recorded. E. The minimum temperature recorded on the log entitled, "Main Lab" for refrigerator number 1 exceeded the established acceptable value of 2 degrees C on eight of 23 days between the dates of March 1, 2022 and March 31, 2022. F. The minimum temperature recorded on the log entitled, "Main Lab" for refrigerator number 2 exceeded the established acceptable value of 2 degrees C on 29 of 68 days between the dates of January 1, 2022 and March 31, 2022. G. The maximum temperature recorded on the log entitled, "Main Lab" for refrigerator number 2 exceeded the established acceptable value of 8 degrees C on 251 of 252 days between the dates of April 1, 2022 and March 31, 2023. On August 13, 2022 the minimum and maximum temperatures were not recorded. H. The minimum temperature recorded on the log entitled, "Storeroom/Phleb Drawing Area" for the room temperature exceeded the established acceptable value of 18 degrees C on 15 of 20 days between the dates of February 1, 2022 and February 28, 2022. 2. The laboratory policy ASL/QM009, entitled, "Verification and Maintenance of Equipment" stated "If any recorded temperatures are not within the expected range, it may be necessary to rearrange the contents of the refrigerator or freezers to facilitate more even cooling. Adjust and check in one hour." It goes on to state, "For room temperature and humidity monitoring, adjust temperature on thermostat and recheck in one hour. If humidity falls outside the expected range of 20-80%, additional equipment may need to be utilized to adjust the humidity levels." 3. An interview with the office manager and the laboratory supervisor on October 31, 2023 at approximately 10:00 AM confirmed the findings. This is a repeat deficiency that was previously cited during the CLIA recertification survey conducted on October 18, 2019. The laboratory performs approximately 346,400 chemistry tests and 5000 hematology tests annually.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Post-analytic systems was not met. The laboratory failed to have a mechanism to ensure that results from reference laboratories Quest Diagnostics (CLIA ID 29D0652720), and Biological Laboratory Inc., (CLIA ID 05D0930143) that were manually transcribed to the laboratory's LIS were accurate and reliable (Refer to D5801), the laboratory failed to ensure that test reports from reference laboratories indicated the name and address of the laboratory where the tests were performed (Refer to D5805), and the laboratory failed to ensure that the send out test reports included pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, were available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. (Refer to D5807)
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 audit of four patient final test reports between the dates of February, 2022 and October, 2023 reviewed as part of the laboratory quality assessment process, and an interview with the laboratory supervisor and office manager, the laboratory failed to ensure that the laboratory had an adequate system in place to ensure that test results and other patient-specific data were accurately and reliably sent from the point of data entry to the final report. Findings include: 1. A review of one random patient final report that had been audited by the laboratory as part of the February, 2022 quality assessment revealed that the specimen for a patient with the accession number 125897 dated February 15, 2022 that was sent to a reference laboratory for a urine culture had the following errors: A. The Urine Culture and Sensitivity report was indicated as a Preliminary Urine Culture, despite the label on the report designating the report as the "Final Copy" in the upper right corner of the laboratory report. B. The name of the organism identified by the reference laboratory on the culture was misspelled. The organism name was identified as "proteus Mirablis" (sic) on the report issued by the laboratory. The correct spelling of the organism is Proteus mirabilis. C. The antimicrobial sensitivity results on the reference laboratory report did not match the antibiotics results transcribed by the laboratory for the final report. The final report issued by the laboratory did not include the results for the ceftriaxone, ertapenem, gentamicin, imipenem, tobramycin, or trimethoprim/sulfa sensitivities reported by the reference laboratory. D. The laboratory failed to transcribe the interpretive comment from the reference laboratory report onto the final laboratory report issued to the provider. The interpretive comment stated, "This organism may show imipenem resistance by mechanisms other than a carbapenemase." The laboratory also failed to transcribe the additional comment from the reference laboratory report onto the final report issued, which stated, "Additional non-predominating organism(s) isolated. These organisms, commonly found on external and internal genitalia, are considered colonizers. No further testing performed." 2. A review of one random patient final report that had been audited by the laboratory as part of the April, 2022 quality assessment revealed that the specimen for a patient with the accession number 131054 dated April 28, 2022 that was sent to a reference laboratory for a urine culture had the following errors: A. The Urine Culture and Sensitivity was indicated as a Preliminary Urine Culture, despite the label on the report issued by the laboratory designating the report as the "Final Copy" in the upper right corner of the report. B. The antimicrobial sensitivity results on the reference laboratory report did match the antibiotics results transcribed by the laboratory for the final report. The final report issued by the laboratory did not include the results for the gentamicin, cephalothin, amoxicillin /clavulanic acid, and sulfamethoxazole sensitivities. The final report issued by the laboratory included results for amoxicillin and trimeth/sulfa results, which were not tested by the reference laboratory. 3. A review of one random patient final report that

	had been audited by the laboratory as part of the September, 2022 quality assessment revealed that the specimen for a patient with the accession number 138980 dated August 31, 2022 that was sent to a reference laboratory for Total Alpha Fetoprotein (Total AFP), Hepatitis B Surface Antibody (HBsAb), and Hepatitis B Surface Antigen (HBsAg) had the following errors: the patient result for the HBsAg of Non-Reactive appeared in the column labeled "Out of Range" on the laboratory final report instead of the column labeled "In Range". The result is correctly reflected as "In Range" on the reference laboratory final report. 4. A review of a random patient final report for a patient with the accession number 165486 dated October 23, 2023, that was sent to a reference laboratory for a urine culture indicated that the report was a Preliminary Urine Culture. The result transcribed into the LIS matched that of the reference laboratory report, which stated, "Final Report Mixed Urogenital Flora." The label on the report indicated that it was the "Final Copy" on the upper right corner of the report. 5. The findings were confirmed during an interview with the laboratory supervisor and office manager conducted on October 31, 2023 at approximately 11:30 AM that the reference laboratory results were manually entered into the laboratory information system. This is a repeat deficiency that was previously cited on the CLIA recertification survey conducted on June 30, 2017. The laboratory performs approximately 346,400 chemistry tests and 5000 hematology tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random audit of four patient final test reports between the dates of February, 2022 and October, 2023 that had been reviewed as part of the laboratory quality assessment process, and an interview with the laboratory supervisor and the office manager, the laboratory failed to ensure that the name and address of the laboratory where the test was performed. Findings include: 1. A review of a random patient final report that had been audited by the laboratory as part of the February, 2022 quality assessment revealed that a specimen for a patient with the accession number 125897 that was sent to a reference laboratory for a urine culture did not have the name and address of the reference laboratory that performed the testing on the report issued to the providers. The culture was performed at Quest Diagnostics, located at 4230 Burnham Ave., Las Vegas, NV 89119. 2. A review of a random patient final report that had been audited by the laboratory as part of the April, 2022 quality assessment revealed that a specimen for a patient with the accession number 131054 that was sent to a reference laboratory for a urine culture did not have the name and address of the reference laboratory that performed the testing on the report issued to the providers. The culture was performed at Biological Laboratory Inc., located at 620 W. Covina Blvd., San Dimas, CA 91773-2956. 3. A review of a random patient final report that had been audited by the laboratory as part of the September, 2022 quality assessment revealed that a specimen for a patient with the

	accession number 138980 that was sent to a reference laboratory for Total Alpha Fetoprotein (Total AFP), Hepatitis B Surface Antibody (HBsAb), and Hepatitis B Surface Antigen (HBsAg) did not have the name and address of the reference laboratory that performed the testing on the report issued to the providers. The tests were performed at Biological Laboratory Inc., located at 620 W. Covina Blvd., San Dimas, CA 91773-2956 4. A review of a random patient final report for a patient tested on October 23, 2023, with the accession number 165486 that was sent to a reference laboratory for a urine culture did not have the name and address of the reference laboratory that performed the testing on the report issued to the providers. The culture was performed at Biological Laboratory Inc., located at 620 W. Covina Blvd., San Dimas, CA 91773-2956 5. The findings were confirmed during an interview with the laboratory supervisor and the office manager conducted on October 30, 2023 at approximately 3:00 PM. The laboratory performs approximately 346,400 chemistry tests and 5000 hematology tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a random audit of four patient final test reports between the dates of February, 2022 and October, 2023 and an interview with the laboratory supervisor and the office manager, the laboratory failed to ensure that the reports issued included the pertinent reference or normal values, as determined by the laboratory performing the tests, were available to the authorized person who ordered the tests and to the individual responsible for using the test results. Findings include: 1. A review of a random patient final report that had been audited by the laboratory as part of the September, 2022 quality assessment revealed that a specimen for a patient with the accession number 138980 dated August 31, 2022 that was sent to a reference laboratory for Total Alpha Fetoprotein (Total AFP), Hepatitis B Surface Antibody (HBsAb), and Hepatitis B Surface Antigen (HBsAg) failed to include the following reference intervals or normal values on the final report issued by the laboratory: A. The result for the Total AFP included two discrepant reference ranges on the final report. The laboratory's LIS reference range was 0.0-15 ng/ml. The reference range entered in the notes for the report issued by the laboratory was 0.89-8.78 ng/ml. The reference range on the reference laboratory report was 0.89-8.78 ng/ml. B. The results for the HBsAb and HBsAg did not include reference values on the final report. The reference value of "Non-Reactive" was included on the reference laboratory final report. 2. The findings were confirmed during an interview conducted on October 30, 2023 at approximately 3:30 PM with the laboratory supervisor and the office manager. The laboratory performs approximately 346,400 chemistry tests and 5000 hematology tests annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Laboratory Director was not met. The laboratory director failed to ensure that the laboratory quality assessment program detected and corrected errors when failures in quality occurred.(Refer to D6094) and failed to ensure that a current approved procedure manual was available to all testing personnel. (Refer to D6106).
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 random audit of eight patients tested between the dates of January 21, 2022 and October 10, 2023, including two patients tested for HbA1c on the dates of November 18, 2022 and October 10, 2023, a review of the laboratory quality assessment records between the dates of February, 2022 and September, 2022 and between the dates of November, 2022 and September, 2023, a review of four random patient reference laboratory final reports, a review of the laboratory temperature logs, and an interview with the laboratory supervisor and the office manager, the director failed to ensure that the established quality assessment process identified and corrected errors in quality when they occurred. Findings include: 1. A review of the laboratory quality assessment checklists between the dates of February, 2022 and September, 2022, and between the dates of November, 2022 and September, 2023 revealed that the quality assessment program failed to identify failures in quality that required corrective action in the pre-analytical, analytical, and post-analytical phases of testing. 2. A random audit of two patients tested on the dates of November 18, 2022 and October 10, 2023 revealed that the in-use extendSURE HbA1c quality control solutions were not stored in accordance with the manufacturer's instructions. (Refer to D5411) 3. A random audit of two patients tested on the dates of November 18, 2022 and October 10, 2023 revealed that the quality control reference ranges established by the manufacturer for the extendSURE HbA1c quality control solutions in use after March 27, 2023 by the laboratory were not indicated for the methodology and instrumentation employed by the laboratory. (Refer to D5469) 4. A random audit of eight patients tested between the dates of January 21, 2022 and October 10, 2023 revealed that there were multiple refrigerator, freezer and room temperature excursions, and humidity excursions with no documentation of corrective action between the dates of January, 2022 and March 2023. (Refer to D5785) 5. A review of random patient final reports between the dates of February 15, 2022 and October 23, 2023 revealed that two of three reports for urine culture identification and sensitivity that were sent to reference laboratories had errors in the reporting of the organism name and discrepancies in the reporting of the antimicrobial sensitivities. (Refer to D5801) 6. A review of random patient final reports between the dates of February 15, 2022 and October 23, 2023 revealed that one of one reports for total AFP, HBsAg, and HBsAb reported the HBsAg in the "out of range" column when the result was non-reactive. (Refer to D5801) 7. A review of random patient final reports between the dates of February 15, 2022 and October 23, 2023 revealed that four of four reports for send out tests failed to indicate the name and address of the laboratory where the test

	was performed. (Refer to D5805) 8. A review of random patient final reports between the dates of February 15, 2022 and October 23, 2023 revealed that one of one report for total AFP, HBsAg, and HBsAb reported discrepant reference ranges for the Total AFP. (Refer to D5807) 9. A telephone conversion with the office manager on November 15, 2023 at approximately 9:30 AM revealed that the personnel transcribing the results for the reference laboratory tests was not qualified to report results for moderate or high complexity testing in the categories of chemistry and microbiology. The personnel transcribing the send out results did not have a minimum of an associate degree in a chemical, physical or biological science or medical technology. 11. The findings were confirmed during interviews with the laboratory supervisor and the office manager conducted on October 30-31, 2023 This is a repeat deficiency that was previously cited at CLIA recertification surveys dated June 30, 2017, October 18, 2019, and November 19, 2021. The laboratory performs approximately 346,400 chemistry tests and 5000 hematology tests annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a review of the chemistry procedure manual and the operator's manual for the Beckman Coulter DxC AU 700 chemistry analyzer, and an interview with the laboratory supervisor and the office manager, the director failed to ensure that a current approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings include: 1. A review of the Beckman Coulter DxC AU 700 operator's manual revealed that the manual available to the personnel was incomplete. Chapters one through four were not in the operators manual, with the exception of pages 1-25 and 1-26 from chapter one. 2. A review of the chemistry procedure manual revealed that there was no procedure for the hemoglobin A1c test performed on the Beckman Coulter DxC AU 700. 3. A review of the chemistry procedure manual revealed that the procedures for the general chemistry tests were not current for the chemistry instrument in use. The procedures were written and approved for the Beckman Coulter AU 480. The procedures were originally written and approved in 2015. The general chemistry instrument currently in use in the laboratory is the Beckman Coulter DxC AU 700. 4. The laboratory failed to update the LCMS procedures entitled, "Standard Solution Preparation for Pain Panel Analytes," "Extraction of Drugs of Abuse Analytes from Human Urine," and "Quantitation of Pain Panel Analytes by High Performance Liquid Chromatography Tandem Mass Spectrometry (LC/MS)", to reflect the removal of methylphenidate from the laboratory test menu. 5. The findings were confirmed during an interview with the laboratory supervisor and the office manager on October 31, 2023 at approximately 12:00 PM. The laboratory performs approximately 346,400 chemistry tests annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8)

	Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory training and competency assessment records, and an interview with the laboratory supervisor, there was no documentation of semi-annual training and competency assessment for two of three testing personnel in the performance of hematology, general chemistry, endocrinology and moderate complexity toxicology testing during the first year of employment. Findings include: 1. A review of the laboratory records for training and competency assessment revealed that there was no semi-annual training and competency assessment for two of three testing personnel in the performance of hematology testing on the Sysmex XN-550, general chemistry testing on the Beckman Coulter DxC AU 700, moderate complexity toxicology on the Beckman Coulter AU 480, and endocrinology on the Beckman Coulter Access 2 immunoassay analyzer. 2. One of the personnel lacking semi-annual training and competency assessment had a hire date of December 8, 2021 and a termination date of March, 2023. The second personnel lacking semi-annual training and competency assessment had a hire date of April 18, 2022 and a termination date of March, 2023. 3. The findings were confirmed during an interview with the laboratory supervisor and the office manager conducted on October 30, 2023 at approximately 11:30. The laboratory performs approximately 346,400 chemistry tests and 5000 hematology tests annually.