Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2081860	11/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Americahealth Inc Idaho Falls	1995 E 17th St, Idaho Falls, ID	

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
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 testing record review and interview with the testing personnel (L) on 11/5/2020, the laboratory failed to at least twice annually, verify the accuracy of any test or procedure it performs that is not included in subpart I for unregulated analytes and tests in accordance with of 42 C.F.R. 493.1236(c)(1). The findings include: 1. The laboratory initiated Liquid Chromatography Mass Spec (LC/MS) for Urine Toxicology testing June 1, 2020. The laboratory did not have policies or procedures established to perform verification of accuracy for its urine toxicology testing methods. 2. The laboratory initiated Primier BioTech SARS CoV-2 rapid IgM/IgG antibody testing, a moderate complexity platform as determined by the FDA emergency use authorization (EUA) for the manufacturer Hangzhou Biotest Biotech Co. Ltd and distributed by Primier BioTech. a. The laboratory did not have policies or procedures to establish verification of accuracy for the SARS CoV-2 antibody testing. The laboratory had no documentation of verification of accuracy being performed for the SARS CoV-2 antibody testing prior to testing and reporting patient specimens. 3. The laboratory testing personnel (L) confirmed by interview on 11/05/2020 that the laboratory had not established policies and procedures for performing twice annual verification of accuracy for the testing methods listed above. 5. The laboratory reports performing 1,115 Urine Toxicology patient specimens annually, and 1000 SARS CoV-2 antibody patient specimens.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, their policies and procedures and interview with the testing personnel (L) on 11/05/2020, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. The findings include: 1. The laboratory records indicated gaps of documented QC being performed for the dates June 1, 2020 and June 3, 2020 for the LC/MS urine toxicology testing. The laboratory did not have documentation of corrective actions taken. 2. The laboratory's maintenance logs for the LC/MS urine toxicology testing revealed that the laboratory's humidity percent, refrigerator, and freezer temperatures were not within the laboratory's established ranges. The laboratory had no documentation of assessments or corrective actions taken for the discordant values listed in their polices and procedures. See D5781. 3. The patient specimen sendout refrigerator (located in the Urgent Care department) lacked documentation of temperatures for five (5) days in October 2020. The laboratory had no documentation of specimen assessments or corrective actions taken for the dates in which temperatures had not been documented. 4. The laboratory initiated SARS CoV-2 rapid antibody testing in July 2020, the laboratory did not have documentation of external controls being performed each day of patient testing, or with each new lot, or new testing personnel. 5. The laboratory's Quality Assessment (QA) plan states that, "The LC/MS should be reviewed for up-to-date entries and to verify that QC is performed for every day of testing", and that these logs would be reviewed and signed quarterly by the laboratory director and the QA officer. The laboratory did not have documentation of quarterly or daily assessments performed. 6. The testing personnel (L) confirmed by interview that the laboratory did not have documentation of Quality Assessment procedures being performed. 7. The laboratory reports performing 3,415 waived and non-waived patient specimens annually.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and interview with the testing personnel on 11/5/2020, the laboratory failed to at least once a day patient specimens are assayed or examined perform and document a negative and positive control material for SARS CoV-2 antibody testing. The findings include: 1. By interview with the testing personnel (L) on 11/5/2020, the laboratory initiated Premier BioTech SARS CoV-2 rapid antibody testing in its urgent care setting in July 2020. The laboratory did not have documentation of controls being performed since

	initiating testing. a. The Primier BioTech SARS CoV-2 rapid antibody test cassettes is manufactured by Hangzhou Biotest Biotech, CO. Ltd with an FDA EUA including authorization to distribute as Primier BioTech. b. The manufacturers instructions include the recommendations to perform external QC each day of patient testing, with each new lot, and each new testing personnel. 2. The testing personnel (L) confirmed by interview on 11/5/2020 that external controls were not being performed for the SARS CoV-2 rapid antibody testing on. 3. The laboratory performed 1000 SARS CoV-2 rapid antibody tests from July 2020 to the date of survey.
D5457	CONTROL PROCEDURES CFR(s): 493.1256(d)(4)(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-- For thin layer chromatography-- (4)(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and (4)(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of the laboratory's quality control logs for the LC/MS/MS urine toxicology testing and interview with the high complexity testing personnel (L) on 11/5/2020, the laboratory failed to include at least one control material on each plate and process it through each step of patient testing, including extraction processes. The findings include: 1. Review of the LG/MS control logs and review of the instrument processing logs for June 1, 2020 to October 31, 2020, the laboratory had ran only the calibrators during the processing portion of the testing on 6/1/2020 and 6/3/2020 and no control material. 2. The laboratory testing personnel (L) confirmed by interview on 11/5/2020 at 4:45 p.m., that control materials had not been ran for the patient testing runs on 6/1/2020 and 6/3/2020. 3. The laboratory reported patient Urine Toxicology results for 32 patients on 6/1/2020 and 15 patients on 6/3 /2020.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's corrective action policies and procedures and interview with the testing personnel (L) on 11/5/2020, the laboratory failed to follow

	its corrective actions procedures to document all corrective actions when equipment or methodologies perform outside of established operating parameters or performance specifications. The findings include: 1. The laboratory policy's list the required temperatures for the refrigerators and freezers in order to maintain patient specimens and reagents for optimum performance, and room humidity % for testing patient specimens. 2. The laboratory did not have documentation of corrective actions taken for variances of temperatures for the refrigerator, the freezer and the room humidity records in accordance to the laboratory's policy and procedures. Refrigerator Freezer Humidity (2-8 C) (-15 to-30 C) 25%-80% b. During review of the temperature logs From 3/312020 to 7/31/2020, 14 days out of 73 days reviewed, the freezer ranges were warmer than the -15 Celsius required. 3/31/2020 (-13.4) 4/02/2020 (-13.8) 4/07 /2020 (-13.5) 4/08/2020 (-13.3) 4/14/2020 (-14.0) 5/08/2020 (-13.4) 5/15/2020 (-13.5) 5/18/2020 (-13.3) 5/21/2020 (-14.0) 6/16/2020 (-13.4) 6/18/2020 (-13.8) 6/23/2020 (-13.5) 6/24/2020 (-13.3) 6/29/2020 (-14.0) c. Review of the refrigerator temperature logs for the dates 3/31/2020 to 7/31/2020 revealed three days in which the maximum temperatures fell outside of the laboratory ranges: 5/01/2020 (18.7), 6/03/2020 (18.7) and 7/06/2020 (18.7). d. Review of the laboratory's humidity logs revealed that between the dates 3/31/2020 to 7/31/2020 the humidity % was within the laboratory's established range only nine (9) days of the 73 days reviewed. 3. The laboratory testing personnel (L) confirmed by interview on 11/5/2020 at 1:45 p.m. that they believed the values listed in the policy/procedures were incorrect, and that the laboratory did not have a procedure for documenting corrective actions as specified in the laboratory's policies and procedures. 4. The laboratory reports performing 1,115 urine toxicology patient specimens from June 1, 2020 to November 4th, 2020.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the laboratory's test menu, record review of testing personnel education and training documents and interview with the laboratory director and testing personnel on 11/5/2020, the laboratory failed to have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. The Findings include: 1. The laboratory failed to have documentation that all personnel performing moderate and waived testing as having earned a high school diploma or equivalent. See D6065. 2. The laboratory failed to have documentation of training and competency for testing personnel performing moderate and waived testing. See D6066.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an

	accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on personnel record review, review of the laboratory testing menu and interview with the laboratory director and the testing personnel (L) on 11/5/2020, the laboratory failed to have documentation that personnel performing moderate and waived testing as having earned a high school diploma or equivalent. The findings include: 1. The laboratory reactivated the previous CLIA certificate at this location under new ownership and a new laboratory director. 2. During review of the laboratory testing being performed at this location, it was revealed that the urgent care waived testing personnel were under the current CLIA Certificate of Compliance. 3. The laboratory director stated during interview on 11/5/2020, that he was not aware that he was responsible for the testing being performed in the urgent care setting down the hall. 4. The urgent care initiated SARS CoV-2 testing on a moderate complexity platform as classified by the FDA, under an emergency use authorization (EUA), and additionally performs seven (7) other CLIA waived tests. 5. The laboratory did not have documentation of education for testing personnel in the urgent care testing area, nor did the laboratory have documentation of training or competency' for the testing personnel in the urgent care setting. 6. The testing personnel (L) and the laboratory director confirmed by interview on 11/5/2020 at 5:30 p.m. that they did not have documentation of education or training for the three (3) testing personnel in the Urgent Care setting. 7. The laboratory reports performing 1300 waived tests and 1000 non-waived tests by the Urgent Care testing personnel annually.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on personnel record review, review of the laboratory testing menu and interview with the laboratory director and the testing personnel (L) on 11/5/2020, the laboratory failed to have documentation of training appropriate for the testing performed prior to analyzing patient specimens. The findings include: 1. The laboratory did not have documentation of training for three (3) testing personnel performing moderate and waived testing. See D6065.
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 systemic nature of the deficiencies identified, the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The findings include: 1. The laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D6093. 2. The laboratory director failed to ensure that the quality assessment programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D6094. 3. The laboratory director failed to 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. See D6102.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 review of the laboratory's quality control logs and interview with the laboratory testing personnel (L) on 11/5/2020, the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: 1. The laboratory director failed to ensure that at least once a day patient specimens are assayed or examined perform and document a negative and positive control material for SARS CoV-2 antibody testing. See D5449. 2. The laboratory director failed to ensure that, for liquid chromatography mass spec testing, at least one control material is included on each plate for Urine Toxicology. See D5457.
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 review of the laboratory's quality assessment policy and procedures and interview with the testing personnel (L) on 11/52020, the laboratory director failed to ensure that the quality assessment programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include. 1. The laboratory failed to at least once a day patient specimens are assayed or examined perform and document a negative and positive control material for Urine Toxicology and SARS CoV-2 antibody testing. See D5449. 2. The laboratory failed to follow thier corrective actions policy by documenting corrective actions when tempertures fell outside of the laboratory's established temperature

	ranges. See D5781. 3. The laborortory failed to ensure that verification of accuracy had been performed for those tests not listed as regulated in 42 C.F.R. 493 subpart I. See D5217.
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 record review of the laboratory's testing menu and intierview with the testing personnel (L) on 11/5/2020, the laboratory director failed to 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. The findings include. 1. The laboratory direcetor failed to ensure that the testing personnel performing waived and moderate complexity testing had documentation of education. See D6065. 2. The laboratory director failed to ensure that prior to testing patent samples those performing waived and moderately comples testing recieved appropriate training and demonstrated they could perform the tests reliably and accurately. See D6066. 3. The laboratory director failed to ensure that a general supervisor was onsite to provide direct supervison when high complexity testing was being performed. See D6147.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review of quality control (QC) logs and interview with the testing personnel (L) the technical supervisor failed to establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. The findings include. 1. The laboratory initiated SARS CoV-2 testing and did not have a quality control program which established the parameter for acceptable levels of analytic performance and documentation were implemented to ensure that the QC levels are maintained throughout the testing process. See D5449. 2. The laboratory performs high complexity LC/MS urine toxicology and the technical supervisor failed to ensure that one level of control was ran with each patient test tray. See D5457.

D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing menu and interview with the laboratory director on 11/5/2020, the technical supervisor failed to ensure procedures for evaluation of the competency of the staff included, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. The findings include. 1. The laboratory initiated SARS CoV-2 testing in its urgent care setting that is staffed with medical assistants and phlebotomists. 2. The laboratory has no documentation of training or competency's for the four (4) testing personnel who perform testing in the urgent care setting. 3. The laboratory has one (1) testing personnel who performs high complexity urine toxicology testing, this testing personnel does not have initial competency documented that included the parameters listed above. 4. The laboratory testing personnel (L) and the laboratory director confirmed by interview on 11/5/2020 at 5:15 p.m. that the laboratory did not have training or competency assessments for testing personnel in the Urgent care department or a competency assessment for testing personnel (L) that included the six parameters required. 5. The laboratory reports performing 3, 415 waived and non-waived patient tests from June 1, 2020 to November 5, 2020.
D6146	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(2) The general supervisor is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under 493.1489. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) laboratory personnel form (209) and interview with the laboratory director and the laboratory high complexity testing personnel (L) on 11/5/2020, the general supervisor failed to provide day to day supervision of high complexity testing performed. The findings include: 1. By interview with the high complexity testing personnel (L), the individual stated they were trained virtually to set up and perform the LC/MS Urine Toxicology testing with the individual listed on the CMS-209 as the technical supervisor (TS) / general supervisor (GS). 2. By interview the high complexity testing personnel (L) and the laboratory director confirmed that the TS/GS has not been available for day to day supervision of high complexity testing, since the laboratory initiated high complexity patient testing in June of 2020. 3. The laboratory director confirmed by interview on ll/5/2020 at 5:00 p.m., that the individual identified as the TS/GS had not been able to be onsite or to provide daily supervision of the high complexity testing performed and to determine competency assessments. 4. The laboratory reports performing 1,115 high complexity urine toxicology patient specimens annually.