Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2091671	10/31/2019
Name of Provider or Supplier	**Street Address, City, State**	
Amerihealth Laboratory	4225 Office Parkway Suite 110, Dallas, TX	

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	An entrance conference was held 10/30/2019 with the executive admin, technical supervisor-1, general supervisor, and testing persons 2 and 3. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 10/30/2019 - 10/31/2019, this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR for the specialties /subspecialties in which it was surveyed. 493.1240 Preanalytic Systems 493.1441 Laboratory Director, High Complexity An exit conference was held on 10/31/2019 with the executive admin, technical supervisor-1, and general supervisor. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided. ---------- 493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance. This STANDARD is not met as evidenced by: Based on review of the laboratory's 116 documentation, bill of sale documents, and in interview with staff, the laboratory failed to notify the State Agency (SA) within 30 days of change in ownership and notify the SA no later than 6 moths after deletions in test methodologies. Findings included: 1. During the entrance conference held on 10/30/2019 at 9:00 am, the executive admin stated the laboratory had undergone a change in ownership effective 05/2019. The executive admin was unable to provide documentation of notification to the SA within 30 days of the change. 2. The "COMPANY AGREEMENT" (bill of sale documents) documentation included a date of 06/25/2019. The SA never received

	a notification of the change of ownership within 30 days. 3. During the entrance conference held on 10/30/2019 at 9:00 am, the laboratory staff stated urine toxicology test by method of liquid chromatography-mass spectrometry (LCMS) was discontinued 11/2018 and Respiratory Pathogen Panel test by method of Luminex MagPix was discontinued 11/2018. (this was consistent with 116 documentation) The laboratory did not notify the SA no later than 6 months after deletions of LCMS and MagPix testing.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of patient test requisitions, patient test reports, and in interview with staff, the laboratory failed to retain 2 of 2 patient instrument printouts for urine drug screen and validity test results from 08/2019. Findings included: 1. Review of patient test requisitions and patient test reports for 07/2019 and 08/2019 revealed the laboratory did not retain AU400 instrument printouts with test results for the following: Patient ID CSTOX1-30 urine was collected on 07/03/2019 at 12:40 pm and analyzed for opiates and validity on 08/22/2019 at 11:17 am. Patient ID CSTOX1-31 urine was collected on 07/03/2019 at 2:45 pm and analyzed for opiates and validity on 08/22/2019 at 11:18 am. (validity included pH, creatinine, and specific gravity) 2. During an interview on 10/31/2019 at 11:40 am, the laboratory staff reviewed and confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy, client services manual, patient test requisitions, patient test reports, and in interview with staff, the laboratory failed to meet the requirements of the preanalytic systems. The laboratory failed to follow their own written policy for testing urine drug screens and validity within 14 days from collection on the AU400 analyzer for 2 of 2 patient specimens in 08/2019. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

	Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, client services manual, patient test requisitions, patient test reports, and in interview with staff, the laboratory failed to follow their own written policy for testing urine drug screens and validity within 14 days from collection on the AU400 analyzer for 2 of 2 patient specimens in 08/2019. Findings included: 1. Review of the laboratory's policy "Urine Drug Screen and Validity" stated, "Stability & Storage: Room Temperature: 14 days" and "Unacceptable Specimen: ...Specimens that are older than 14 days." Client services manual stated, "2. Specimen Handling/Storage/Stability: ...b. A Specimen stored at room temperature (15-30 degrees C) is stable for 14 days." 2. Review of patient test requisitions and patient test reports for 07/2019 and 08/2019 revealed the laboratory analyzed urine specimens for opiates and validity (pH, creatinine, specific gravity) on the AU400 analyzer greater than 14 days, as follows: Patient ID CSTOX1-30 urine was collected on 07/03/2019 at 12:40 pm and analyzed on 08/22/2019 at 11:17 am. Elapsed time of 49 days, 22 hours, and 37 minutes between collection and analysis. Patient ID CSTOX1-31 urine was collected on 07/03/2019 at 2:45 pm and analyzed on 08/22/2019 at 11:18 am. Elapsed time of 49 days, 22 hours, and 38 minutes between collection and analysis. The laboratory was unable to provide AU400 instrument printouts for the above patient test results. Note: The laboratory discontinued testing urine drug screens 08/22/2019. 3. During an interview on 10/31 /2019 at 11:40 am, the laboratory staff reviewed and confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, client services manual, patient test requisitions, patient test reports, and in interview with staff, the laboratory failed to have a quality assessment system in place for ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems, as evidenced by: 1. The laboratory failed to follow their own written policy for testing urine drug screens and validity within 14 days from collection on the AU400 analyzer for 2 of 2 patient specimens in 08/2019. Refer to D5311.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the

	performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of verification studies, extended stability study, and in interview with staff, the laboratory failed to establish analytical specificity, to include interfering substances when specimen storage was modified (modification of FDA-cleared test system) for Luminex NxTag RPP. Findings included: 1. Review of Luminex NxTag RPP verification study conducted 04/17/2017 through 04/21/2017 included verification of the following performance characteristics: a) Accuracy b) Precision c) Positive/Negative Agreement d) Reportable Range e) Reference Range 2. Manufacturer requirements for storage of RPP specimens stated, "...up to 12 months in -70 to -80 degrees C." Review of an "Extended Stability Study of RPP Specimens" document (implemented 01/15/2018) included assessing performance of specimens stored at -20 degrees C for 1 month. The laboratory modified the FDA-cleared test system preanalytical requirements and and did not establish analytical specificity, to include interfering substances. 3. During a telephone interview on 10/31/2019 at 11: 30 am, technical supervisor-2 (TS-2) stated the "Extended Stability Study of RPP Specimens" was done to give clients an option to be able to freeze at -20 degrees Celsius, but stated that frozen specimens were never received. TS-2 confirmed the laboratory did not establish analytical specificity, to include interfering substances, when the preanalytical requirements were modified. Note: the client services manual for RPP specimens did not indicate storage of -20 degrees Celsius as an option.
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 review of the laboratory's policy, client services manual, patient test requisitions, patient test reports, and in interview with staff, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure test systems developed provided quality laboratory services for preanalytic phase of testing. Refer to D6082. 2. The laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6094.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, client services manual, patient test requisitions, patient test reports, and in interview with staff, the laboratory director failed to ensure test systems developed provided quality laboratory services for preanalytic phase of testing. The laboratory failed to follow their own written policy for testing urine drug screens and validity within 14 days from collection on the AU400 analyzer for 2 of 2 patient specimens in 08/2019. Refer to D5311.
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 policy, client services manual, patient test requisitions, patient test reports, and in interview with staff, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The laboratory failed to have a quality assessment system in place for ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Refer to D5391.