Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0440143	03/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
American Health Mw, Llc	10126 Woodfield Lane, Saint Louis, MO	

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
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 review of the bacteriology procedure manual and interview with the general supervisor, the laboratory failed to follow the Inoculum Density policy for 2017 and to date 2018. Findings: 1. The Determination of Inoculum Density procedure 12-231.1 M states, the "procedure (prompt inoculum check) allows you to verify inoculums densities in colony forming units/ml (CFU/ml) for aerobic and facultatively anaerobic bacteria in the laboratory. This will ensure that proper technique is being followed by technical staff and panels are not over or under inoculated which could lead to erroneous results." The procedure effective date was March 14, 2016. 2. The laboratory did not have documentation to show it performed this procedure in 2017 or 2018, to date. 3. Interview with the general supervisor on March 20, 2018 at 1:30 PM confirmed, the laboratory failed to follow the policy during 2017 and to date March 20, 2018.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on review of instrument test result comparisons and interview with the general supervisor the laboratory failed to define a relationship between erythrocyte sedimentation rate (ESR) methodologies for 2016 and 2017. Findings: 1. Review of test result comparisons on the Excyte 20 ESR instrument and the back up Excyte mini ESR instrument showed no relationship between test results using the two instruments for 2016 or 2017. 2. Interview with the general supervisor on March 29, 2018 at 1:00 PM confirmed the laboratory failed to ensure ESR test result comparisons on both instruments were performed.
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 review of four of four patient test reports, laboratory policy and interview with the general supervisor, the laboratory failed to monitor and evaluate the quality of the postanalytic system for reporting positive blood culture results. (Refer to # D5813)
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of four of four selected blood culture test reports from 2017, laboratory policy, hours of operation, and interview with the general supervisor, the laboratory failed to immediately alert individual(s) responsible for clinical use of positive blood culture (panic value) results reported from the VersaTREK blood culture instrument. Findings: 1. Review of four patient test reports revealed the laboratory failed to immediately alert pertinent individual(s) for the following positive blood cultures: a) On October 9, 2017 at 11:30 PM VersaTREK instrument reported a positive blood culture result on patient "A". On October 10, 2017 at 10:11 AM the positive blood culture result was called to the responsible entity. b) On September 24, 2017 at 5:44 AM VersaTREK instrument reported a positive blood culture result on patient "B". On September 24, 2017 at 7:56 AM the blood culture result was called to the responsible entity. c) On September 30, 2017 at 12:20 AM the VersaTREK instrument reported a positive blood culture result on patient "C". On September 30, 2017 at 7:40 AM the blood culture result was called to the responsible entity. d) On June 29, 2017 at 6:36 AM the VersaTREK instrument reported a positive blood

	culture result on patient "D". The laboratory did not have documentation to show the result was called to the responsible entity. 2. Review of AHA Panic Values policy number 3-201M (attachment B) revealed the laboratory defined a positive blood culture result as a panic value. Attachment E of policy 3-201M states," a panic value defined by AHA policy may require immediate intervention. Therefore, these test values are called to ordering provider as soon as they are finalized twenty-four hours a day seven days a week. A panic value may be called to the ordering provider during the middle of the night." 3. Review of the the laboratory's hours of operation revealed the laboratory is closed from 8:00 PM to 7:00 AM Monday through Friday. On Saturdays the laboratory closes at 6:00 PM and reopens on Monday at 7:00 AM. The laboratory did not have a system to monitor positive blood culture results reported from the instrument when the laboratory is closed and unattended. 4. Interview with the general supervisor on March 20, 2018 at 1:30 PM confirmed the laboratory failed to immediately contact responsible entities for positive patient blood culture results.
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 quality management plan (quality assessment) and interview with the general supervisor the director failed to provide overall management and direction by failing to maintain the written quality assessment program. (Refer to # 6094)
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 management plan (quality assessment), patient blood culture and MRSA (Methicillin Resistant Staph Aureus) culture procedures, and interview with the general supervisor, the laboratory director failed to ensure the quality assessment programs were followed and to identify failures in quality as they occur. Findings: 1. The laboratory's quality management plan (policy number 6-101.6M #5) Panic (Critical) Value Notification and Documentation states, " Used to monitor certain result values which have been deemed to be panic values requiring immediate notification to the individual utilizing such results. See procedure 3-201M Critical and STAT Results Notification, Call, Read-Back and Documentation." 2.Review of policy 3-201M (AHA Panic Values) revealed the policy deemed positive blood culture results and positive MRSA cultures as panic values. 3. Policy number 3-201.11 M (Critical and STAT Results Notification, Call, Read-Back and Documentation) states, "critical laboratory results are test values that warrant immediate action by medical personnel to avoid possible harm to the patient." 4. Review of patient blood culture procedures revealed the laboratory did not have a

	system to detect positive blood culture results reported from the blood culture instrument when the laboratory is closed. The laboratory is closed for 11 of 24 hours each day Monday through Friday, closed for 13 of 24 hours on Saturday and closed on Sunday. The laboratory is closed for 37 consecutive hours from Saturday 6:00 PM to 7:00 AM Monday. The blood culture instrument continuously monitors patient culture bottles for growth twenty-four hours a day, seven days a week. Testing personnel do not work-up positive blood cultures when the laboratory is closed. 5. Review of the MRSA culture procedure revealed the laboratory did not have a system to monitor positive MRSA culture results when laboratory is closed from Saturday 6:00 PM to 7: 00 AM Monday. 6. Interview with the general supervisor on March 20, 2018 at 1:30 PM confirmed, the director failed to ensure the laboratory followed the written quality management plan for blood culture and MRSA culture panic values.