Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0707800	07/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
American Health S Llc Dba American Health	15712 Sw 41 St Suite 16, Davie, FL	

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 unannounced complaint survey, #2019010050, was conducted on 7/22/2019 at American Health Associates. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories.
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 record review and interview with laboratory personnel, the laboratory did not follow their policy and procedure for "Problem/Redraw Procedure". Findings include: -Review of "Problem/Redraw Procedure" revealed that for specimens with an accession number (after a specimen registration into the laboratory software a unique number is generated) that have pending tests, it is required a redraw. This policy and procedure require a code 667 (problem report) generated and a note added to the case of reference. The note should have the information of the notification to the ordering facility with name of the notified nurse, date and time, after this notification the laboratory should proceed to cancel the test. A redraw log is kept as part of this procedure. -Review of Missed Routine and redraw log and Failed log for May, June and July 2019, revealed 1 case with accession number 25791265 (on 6/5/2019), as recorded in the log, there was not enough amount of urine sample to perform the urine culture test. The lab did not generate a 667 code and the problem was not reported to ordering facility but the laboratory canceled the test. The case on the end user side still showed as pending on 7/23/2019. -Review of Urinalysis, June cases revealed a

	case with accession number 25751454 (on 6/17/2019), and final report on 6/24/2019, which stated no urine culture was performed due to an accident, but it was not reflected in the redraw log, no 667-code was generated, despite test being cancelled on 6/18/2019, and there was no notification to the ordering facility until 6/24/2019. Due to the fact that both cases lacked code 667, no problem report generated and they were not detected as pending tests. During an interview on 7/23/2019 at 2:00 pm, with Technical Supervisor, she confirmed the laboratory failed to follow their policy for Problem/Redraw Procedure for the cases of reference and the lack of documentation of the sample incident for case 25751454.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to notify of a delay in patient result to the ordering facility for 2 cases during June 2019. Findings include: Review of Turnaround reports for urine culture test revealed a turnaround time of 48 hours for test results (as per case 25735291, 2573426, 25734924, 25741515, 257429973). Review of case 25791265, revealed, test cancelation due to not enough sample and no notification sent to the facility. Review of case 25751454, revealed, test cancelation on 6/18/2019 due to a sample issue not properly documented and a delayed in the contact to the ordering facility until 6/24 /2019. During an interview on 7/23/2019 at 2:00 pm, with Technical Supervisor, she confirmed the laboratory failed to notify the ordering facility about the issues with pending urine culture after they passed their turnaround time .