Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2068149	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Jfmc The Q Llc	235 South 14th Avenue, Laurel, MS	

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 review of proficiency testing (PT) records since the last survey on 9-20-17 and interview with the technical consultant on 10-29-19 at 2:15 p.m., the laboratory failed to verify the accuracy of urine drug screen testing performed on the moderate complexity Jant Accutest Split Cup 12 urine drug screen test, at least twice annually, since testing began on 7-30-18. Findings include: Review of proficiency testing records since 9-20-17 revealed no documentation of performance of PT for urine drug screen testing in order to verify accuracy. In an interview on 10-29-19 at 2:15 p.m., the technical consultant confirmed no verification of accuracy was performed, at least twice annually, for urine drug screen testing on the Jant Accutest Split Cup 12 urine drug screen test since testing began on 7-30-18.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of patient test records for urine drug screen testing with the moderate complexity Jant Accutest Split Cup 12 urine drug screen from 7-30-18 through 10-11-19, lack of documentation of verification of performance specifications, and interview with the technical consultant on 10-29-19 at 2:15 p.m., the laboratory failed to verify performance specifications for the Jant Accutest Split Cup 12 urine drug screen before reporting a total of forty patient test results. Findings include: Review of patient test records for urine drug screen testing with the moderate complexity Jant Accutest Split Cup 12 urine drug screen revealed patient testing was performed from 7-30-18 through 10-11-19, with a total of forty patient test results reported. There was no documentation of verification of performance specifications, such as accuracy and precision, available for review on the day of the survey. In an interview on 10-29-19 at 2:15 p.m., the technical consultant confirmed performance specifications were not verified for the Jant Accutest Split Cup 12 urine drug screen before it was put in use for patient testing on 7-30-18.
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 patient test records for urine drug screen testing with the moderate complexity Jant Accutest Split Cup 12 urine drug screen from 7-30-18 through 10-11-19, lack of documentation of performance of controls, lack of establishment of an Individualized Quality Control Plan (IQCP), and interview with the technical consultant on 10-29-19 at 2:15 p.m., the laboratory failed to include a positive and negative control each day of patient testing during this time frame, when a total of forty patient urine drug screen specimens were tested and results reported. Findings include: Review of patient test records for the Jant Accutest Split Cup 12 urine drug screen from 7-30-18 through 10-11-19 and lack of documentation of urine drug screen controls revealed a total of forty patient urine drug screen specimens were tested and results reported during this time frame with no documentation of performance of two levels of control. There was no documentation of establishment of an IQCP, required after 1-1-16 if two levels of control are not included each day of patient testing. In an interview on 10-29-19 at 2:15 p.m., the technical consultant confirmed an IQCP was not developed for urine drug screen testing with the Jant Accutest Split Cup 12 urine drug screen and controls were not performed.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, personnel records, patient test records for urine drug screen testing from 7-30-18 through 10-11-19, and interview with the technical consultant on 10-29-19 at 2:15 p.m., the laboratory director failed to ensure that testing personnel had appropriate training prior to testing patient specimens with the moderate complexity Jant Accutest Split Cup 12 urine drug screen, put in use for patient testing on 7-30-18. Findings include: Review of personnel records for testing personnel listed on the CMS 209 personnel form revealed no documentation of training for the moderate complexity Jant Accutest Split Cup 12 urine drug screen, put in use for patient testing on 7-30-18. In an interview on 10-29-19 at 2:15 p.m., the technical consultant confirmed there was no documentation of urine drug screen training for the testing personnel responsible for moderate complexity testing.