Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0689660	10/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Tpmg Regional Genetics Laboratory	5755 Cottle Rd Bldg 26, San Jose, CA	

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
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 observation of two ABI-3500XL Genetic Analyzers, review of laboratory records, and interview with the Laboratory Director and Technical Supervisors, it was determined that the laboratory failed to have a procedure to twice annually compare results from different instruments/analyzers performing the same function. Findings included: a. The laboratory's Molecular Tests and Equipment record stated ABI-3500XL Genetic Analyzers were utilized in multiple molecular genetics tests. b. The laboratory was unable to provide for review documents comparing results between the two Genetic Analyzers for each molecular genetics test in 2018. c. The Laboratory Director (Technical Supervisor-1) and Technical Supervisors affirmed (10/17/19 at 5pm) the aforementioned lack of documents comparing results at least twice annually; and that the various molecular genetics tests were analyzed by either ABI-3500XL Genetic Analyzer. d. The reliability and quality of results reported for each molecular genetics test using different Genetic Analyzers could not be assured in the absence of documented test results comparisons. Based on the Laboratory Testing Declaration (10/10/19), the laboratory reported approximately 10,829 results for 22 molecular genetics tests in 2018. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation of duplicate instruments and analyzers, interview with laboratory personnel, and the lack of documents, it was determined that the laboratory failed to establish written policy and procedures to monitor and assess the analytic phase of testing when using different equipment for the same function. Findings included: a. The laboratory had two QIA Symphony for automated extraction of nucleic acid material from specimen and two ABI-3500XL Genetic Analyzers. b. The laboratory was unable to provide for review written policy, procedure, and documents for twice annually comparing results from the different equipment performing the same function. c. The Laboratory Director (Technical Supervisor-1) and Technical Supervisors affirmed the aforementioned lack of written policy and procedures. d. See D5775.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory test requisitions and reports for chromosome analysis; and interview with laboratory personnel, it was determined that the laboratory failed to have ongoing processes to monitor, assess, and correct postanalytic problems when identified. Findings included: a. Discrepancies in preanalytic and postanalytic records were observed in 3 out of 22 laboratory reports for chromosome analysis: 1) Laboratory reports dated 3/01/18 for Amniotic Fluid Chromosome Analysis procedures #465006 and 465007 named a Req(uesting) Prov(ider) who was not the Authorizing Provider requesting the test. 2) A Laboratory report dated 2/15/19 for Cancer Chromosome Analysis named a Req(uesting) Prov(ider) who was not the Authorizing Provider on the test requisition form. c. Testing personnel: Laboratory Director and Technical Supervisors, affirmed (10/17/18 at 6pm) that the aforementioned discrepancies in preanalytic and postanalytic records had not been identified or addressed in a written policy. d. The reliability of preananlytic and postanalytic records documenting the authorized provider requesting testing could not be assured. Based on the estmated annual test volume (10/11/19) approximately 18,351 cytogenetics reports were isssued each year.