

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2057775	(X3) Date Survey Completed 03/12/2018
Name of Provider or Supplier Cynvenio Biosystems Inc	Street Address, City, State 2260 Townsgate Rd Ste 2, Westlake Village, 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. See D5441 and D5453</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on Surveyor review of patient test records, policies and procedures, lack of quality control (QC) data, and interview with the laboratory Director and Technical Supervisor, the laboratory failed to monitor the accuracy and precision of each phase of the analytic testing process by not using control procedures that will detect immediate errors and errors occurring over time. The findings include: a. The laboratory enriched the circulating tumor cells (CTC) from whole blood of the patient LB11336 through a proprietary method, and tested for mutation in DNA of 50 genes in the enriched CTC; however, no control material was included during patient testing. b. The laboratory recovered circulating cell free DNA (cfDNA) from plasma of the patient LB11336 and LB11319, and tested for DNA mutation and allele frequency in the recovered cfDNA without including any control materials during the testing process. c. The laboratory Director and Technical Supervisor, on 3/12/2018 at 3:10 pm, confirmed that no control material is used for the above tests. d. The laboratory's testing declaration form, signed by the laboratory Director on March 12, 2018, stated that the laboratory performs 607 tests annually.

D5453

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(iv)(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 test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on Surveyor review of patient testing records, quality control data, and interview with the laboratory Director, Technical Supervisor and testing personnel, the laboratory failed to include two control materials, including one that is capable of detecting errors in the extraction process. The findings include: a. The laboratory extracted circulating cell free DNA (cfDNA) from plasma of the patient LB11336 and LB11319, and tested for DNA mutation and allele frequency in the extracted cfDNA without including any control materials during the extraction process. b. On 3/12/2018 at 4:05 pm Laboratory Technical Supervisor affirmed that no QC material is used during the testing procedure. c. The laboratory's testing declaration form, signed by the laboratory Director on March 12, 2018, stated that the laboratory performs 607 tests annually.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Surveyor review of patient test records, and policy, procedure and QC

records for CTC and cfDNA testing, and interview with the Laboratory technical supervisor and testing personnel, it was determined that the laboratory director failed to ensure the quality controls are established to assure the quality of laboratory services provided (See D5441 and D5453).