

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0928967	<b>(X3) Date Survey Completed</b> 05/20/2025
<b>Name of Provider or Supplier</b> Core Analytics Laboratory, Inc	<b>Street Address, City, State</b> 14735 Califa St, Van Nuys, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5205</b>	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy &amp; procedure, and interview with the laboratory technical supervisor on May 20, 2025, at 12:24 p.m., the laboratory failed to document complaints and problems reported to the laboratory. The findings include: 1. The laboratory stated that it received phone calls about complaints however, it did not have any documentation of any complaints and investigations. Therefore, the quality of the laboratory services cannot be assured and may have harmed patients. 2. The laboratory technical supervisor on May 20, 2025, at 12:24 p. m., affirmed that the Laboratory did not document complaints. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/13/2025, stated that the laboratory performed approximately 5,743,531 tests, annually.</p>
<b>D5311</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p>

This STANDARD is not met as evidenced by:  
 Based on Surveyor review of laboratory's specimen processing, storage and preservation, and interview with the laboratory technical supervisor on May 20, 2025, at 1:58 p.m., the laboratory failed to follow its procedure to process and store the specimens for 1 sample out of 5 samples, reviewed. The findings include: 1. The laboratory received a blood sample (250520084) that was collected on 5/20/2025 at 4:50 a.m. The laboratory's procedure instructed to centrifuge within 2 hours of collection to separate the serum. However, the laboratory did not centrifuge the blood sample even after 7 hours of collection. Therefore, the sample quality might have been compromised and the accuracy of the patients' test results rendered by the laboratory cannot be assured since it used compromised samples and may have harmed patient. 2. The laboratory technical supervisor on May 20, 2025, at 1:58 p.m., confirmed that the laboratory did not follow its procedure to centrifuge the blood samples. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/8/2025, stated that the laboratory performed approximately 5,743,531 tests, annually.

**D5813**

**TEST REPORT**  
 CFR(s): 493.1291(g)

(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 Surveyor review of laboratory's patient testing records, final reports, and interview with the laboratory technical supervisor on May 20, 2025, at 3:19 p.m., the laboratory failed to report the panic value to the responsible physician for 1 sample out of 10 samples, reviewed. The findings include: 1. The laboratory obtained a panic value for the platelet test for sample # 2401241707. However, the laboratory did not treat the result as panic value and did not report. It cancelled the test instead after talking to the nurse. The consequence of not reporting the panic value immediately may have harmed patient. 2. The laboratory technical supervisor on May 20, 2025, at 3:19 p.m., affirmed that the laboratory did not treat the result as panic value and did not report. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/8/2025, stated that the laboratory performed approximately 5,743,531 tests, annually.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, test records, final reports, and interview with the laboratory technical supervisor on May 20, 2025, at 3:19 p.m., the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The laboratory director's failure to ensure quality laboratory services has a consequence of potential erroneous test result reporting and patient harm. The findings include: See D5205, D5311 and D5813.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, and interview with the laboratory technical supervisor on May 20, 2025, at 1:58 p.m., the laboratory director failed to ensure that the laboratory used testing systems that provide quality laboratory services for all aspects of test performance. The laboratory director's failure to ensure quality laboratory services has a consequence of potential erroneous test result reporting and patient harm. The findings include: See D5311, D5311 and D5813.