

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2032754	(X3) Date Survey Completed 10/02/2019
Name of Provider or Supplier Genovive	Street Address, City, State 250 Plauche Street, Harahan, LA	
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	A Certification Survey was performed on October 2, 2019 at Genovive, LLC, CLIA ID # 19D2032754. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained between 2 degrees Celsius to 8 degrees Celsius. Findings: 1. Review of the laboratory's temperature log revealed the acceptable temperature for the refrigerator as "2 to 8 degrees C." 2. Review of the laboratory's temperature logs for January 2018 through October 2019 revealed the refrigerator temperature was documented outside of the acceptable limits without documented corrective action for the following four (4) days: August 9, 2019: recorded temperature 1 degree Celsius August 26, 2019: recorded temperature 1 degree Celsius September 16, 2019: recorded temperature 9 degrees Celsius October 1, 2019: recorded temperature 1</p>

	<p>degree Celsius 3. In interview October 2, 2019 the Technical Supervisor confirmed the laboratory did not have documentation that corrective actions were performed for the identified dates.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to include on the report for non-FDA approved tests a disclaimer stating "The performance characteristics of this test were determined by Genovive, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration" Findings: 1. Review of random selection of patient final reports revealed the laboratory did not include the above disclaimer. 2. In interview on October 2, 2019, the Technical Supervisor confirmed the laboratory did not include the above disclaimer statement. 3. Review of the laboratory's test menu revealed the laboratory performs 4,575 genetic tests annually.</p>
<p>D6096</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)</p> <p>The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.</p>
<p>D6098</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8)</p> <p>The laboratory director must ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.</p>