

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 10D2121836	<b>(X3) Date Survey Completed</b> 02/01/2021
<b>Name of Provider or Supplier</b> Clarity Genetics Llc	<b>Street Address, City, State</b> 5231 Nw 33rd Ave, Fort Lauderdale, FL	
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>D0000</b>	A recertification survey conducted on 02/01/2021 found that the Clarity Genetics LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory was not in compliance with state requirement that testing personnel is required to have a Florida License. Finding include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 01/30/2021 revealed that there was 1 testing person (TP). -Review of Personnel files revealed that the TP had no Florida License as Medical Technologist. During an interview on 02/01/2021 at 10:00 am with TP, he confirmed that he has no Florida License as Medical Technologist.</p>
<b>D5805</b>	<p><b>TEST REPORT</b> 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>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory test report failed to list the correct laboratory director, for 4 out of 4 patients report reviewed from January of 2021. Findings Include: Review of the final report for patient 1 (CLARGX-03321), 2 (CLARGX-03328), 3 (CLARGX-03326) AND 4 (CLARGX-03329), showed that the reports failed to have the correct laboratory director. During an interview on 02/01 /2021 at 11:30 am, with laboratory manager, he confirmed that the reports of reference failed to include the correct laboratory director.