

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  99D2146167	<b>(X3) Date Survey Completed</b>  08/29/2022
<b>Name of Provider or Supplier</b>  Igenomix Slu	<b>Street Address, City, State</b>  Calle Narcis Monturiol Estarriol N'11, Not Available, FN	
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>D5775</b>	<p>Based on a record review and email communication with Quality Assurance (QA) staff, the laboratory failed to have a system in place to document the comparison of test results using different instruments since July 2020 for Next Generation Sequencing (NGS) testing for Carrier Genetic Test (CGT), Endometrial Receptivity Analysis (ERA), Products of Conception (POC), and for Fluorescent In Situ Hybridization (FISH) testing for Sperm Aneuploidy Test (SAT). The laboratory performs approximately 250,000 tests annually. Findings: 1. A review of laboratory records revealed that the laboratory failed to perform instrument comparisons for seven thermal cyclers for CGT testing, Biometra Trio 48 serial # 3626156, Biometra TProfessional TRIO serial # 2701229, Biometra Tone serial # 3931268, Biometra 96 Gradient serial # 3021548, Biometra TOne 96 serial # 3804179, Bio-Rad C1000 Touch serial # CT01435, Bio-Rad C1000 Touch 96 serial # CT024998; and for two sample preparators Qiagen QIASymphony SP serial # 35680 and # 35055. 2. A review of laboratory records revealed that the laboratory failed to perform instrument comparisons for two automated electrophoresis instruments for CGT and ERA testing, Agilent 4200 TapeStation System serial # DEDAA01390 and DEDAA00696; and for two Real Time-PCR instruments Thermofisher QuantStudio 5 serial # 272531158 and 272530364. 3. A review of laboratory records revealed that the laboratory failed to perform instrument comparisons for two thermal cyclers for ERA testing, Bio-Rad C1000 serial # CT028319, and # CT049881. 4. A review of laboratory records revealed that the laboratory failed to perform instrument comparisons for three automated template preparators for ERA, CGT, and POC testing, Thermofisher Ion Chef System serial # 242470664, # 242470711, and # 242471185. 5. A review of laboratory records revealed that the laboratory failed to perform instrument comparisons for two next-generation sequencers for ERA and POC testing, Thermofisher Ion S5 XL System serial # 245723900245 and # 2772816080057; and for three reporter software Thermofisher Ion Reporter Server System serial # 2XVVR22, DPZQKD3, and 4JLHW52. 6. A review of laboratory records revealed that the laboratory failed to perform instrument comparisons for two denaturation and hybridization system for SAT testing, Abbott Molecular ThermoBrite System serial #</p>

	<p>815S01563, and # 102402958. 7. A review of laboratory records revealed that the laboratory failed to perform instrument comparisons for two thermal cyclers for POC testing, Biometra Tprofessional serial # 2810130, and # 2501229. 8. Email from QA staff not listed on the CMS-209 on 08/17/2022 at 03:51 AM, confirmed the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different instruments.</p>
<b>D6168</b>	<p>Based on a review of personnel records and email communication with Quality Assurance (QA) staff, the laboratory did not have the education equivalency documentation required to qualify 2 of the 29 testing personnel for the specialty of clinical cytogenetics for high complexity testing. ( Refer to D6171).</p>
<b>D6171</b>	<p>Based on a review of personnel records and email communication with Quality Assurance (QA) staff, the laboratory failed to have education equivalency documentation to qualify 2 of the 29 testing personnel. Findings: 1. A review of personnel records revealed that 2 of the 29 testing personnel designated on the Laboratory Personnel Report (CMS-209), did not have foreign education equivalency documentation to qualify them as testing personnel. 2. Email from QA staff not listed on the CMS-209 on 08/05/2022 at 05:56 AM, confirmed the laboratory failed to have education equivalency documentation for the 2 testing personnel.</p>