

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 99D2146167	(X3) Date Survey Completed 07/22/2024
Name of Provider or Supplier Igenomix Slu	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An onsite recertification survey was conducted 07/22/2024. Standard level deficiencies were cited and the laboratory did not meet the following condition: 42 CFR 493.1487 Testing Personnel High Complexity Testing
D5305	Based on written procedures, patient final test reports, patient test requisitions, and interview with the general supervisor, the laboratory failed to ensure 2 of 3 test requisitions included the specimen date of collection for the sperm aneuploidy test (stability of 3 days). Findings included: 1. Review of the written procedure for sperm aneuploidy test (SAT) for specimen labeling, storage, and collection referred to "SAT Instructions." Review of the SAT instructions (provided to clients) stated, "After sample collection: ...We recommend shipping samples as soon as possible, preferably within 3 days of the sample collection in order to guarantee the quality of the sample." 2. Review of patient #75123976 final test report and the test requisition did not include a specimen collection date. The specimen was received 01/02/2024 and test results reported 01/08/2024. Review of patient #PAT-000387552 final test report and the test requisition did not include a specimen collection date. The specimen was received 09/14/2023 and test results reported 09/20/2023. The laboratory did not ensure a specimen collection date was documented for monitoring specimen stability (received within 3 days collection). 3. During an interview on 07/22/2024 at 4:27 pm, the general supervisor for SAT confirmed there were no specimen collection dates in the above test requisitions from 2023 and 2024.
D5801	Based on review of final test reports, test requisition forms, written procedures, and in interview with LabSamples staff, the laboratory failed to ensure the accurate specimen collection date was on the final test report for 1 of 3 reports reviewed. Findings included: 1. Review of patient #CGS-24J003 final test report included a specimen collection date of 06/14/2024 and a specimen received date of 06/14/2024 (specimen type: saliva; test: In vitae 569 gene panel). Review of patient #CGS-24J003 test requisition form for the above test included a specimen collection date of 06/09/2024. 2. Review of the laboratory's written "Sample Transportation, Reception and Handling

	<p>Procedure" on page 18 stated "C. How to create cases in Navision that are outsourced by the affiliates (igenomix group). See internal document harboured [sic] on the LabSamples departmental folder." The document was not available for review. 3. During an interview on 07/22/2024 at 4:10 pm, the individual from the LabSamples department stated since the patient specimen was an outsourced case, their affiliate group in Miami completed the patient registration and most likely used the date of receipt as the date of collection (06/14/2024). The laboratory failed to ensure the specimen collection date was accurately transcribed on the final test report for patient #CGS-24J003.</p>
D6168	<p>Based on review of the CMS-209 form, personnel records, and in interview with the general supervisor (GS), the laboratory failed to ensure individuals qualified to perform high complexity testing. The laboratory failed to ensure 1 of 43 testing persons (TP) qualified to perform high complexity testing (carrier genetic testing). Refer to D6171.</p>
D6171	<p>Based on review of the CMS-209 form, personnel records, and in interview with the general supervisor (GS), the laboratory failed to ensure 1 of 43 testing persons (TP) qualified to perform high complexity testing (carrier genetic testing). Findings included: 1. Review of the CMS-209 form included TP-29 listed as an individual who performs high complexity testing. 2. Review of personnel records for TP-29 included a bachelor's and master's degree that was not in a chemical, physical, biological or clinical laboratory science. In addition, TP-29 bachelor's degree did not include enough science courses per CFR 493.1489(b)(2)(ii). 3. During an interview on 07/22/2024 at 9:28 am, the GS of carrier genetic testing department confirmed that TP-29 began testing 08/16/2023.</p>