

## Reuse of already collected data for health research

### **Title: Development of the *in vitro* diagnostics test VIDAS® NEPHROCLEAR™ CCL14 to assess the risk to develop severe and persistent acute renal failure**

In its research activities, bioMérieux may need to reuse data associated to biological samples of participants who accepted preservation and storage of their samples for research purposes in the field of health.

This research on collected data or on samples taken during care are called “research not involving the human being”. It does not involve any intervention or active participation of the person.

The use of information and associated studies, are part of a strict ethical, deontological and regulatory framework (Law “Informatique et Libertés” 1978 modified, and GDPR -General Data Protection Regulation entered into force in May 2018).

The Data Controller is bioMérieux SA, based Chemin de l’Orme in Marcy l’Etoile – France. The DPO – Data Protection Officer – may be joined at : [Privacyofficer@biomerieux.com](mailto:Privacyofficer@biomerieux.com).

The purpose of this data processing is development of an *in vitro* diagnostics test and specifically of an automated test to be used on VIDAS®3 instrument, determining quantitatively protein CCL14 in human urine, easier to use than the test of the company Astute Medical (acquired by bioMérieux in 2018) based on quantification of this same protein.

Legal basis of this data processing is the legitimate interest of Data Controller (GDPR – Article 6, section 1, point f) to pursue and develop its activity in the context of marketing of *in vitro* diagnostics tests.

For personal data, the legal basis of data processing is the necessity of processing for scientific research purposes (based on Article 9, point j).

The categories of personal data involved are health personal data linked to samples and enabling their characterization.

Those data, associated to urine leftover samples of the Nephroclear Ruby study, managed by Astute Medical company, have been extracted from the database of this study, performed between July 2013 and July 2014.

In 2022, a secondary objective of the study has been added and defined, which purpose is to do a preliminary evaluation of clinical performances, and to investigate on discordant results identified between the two techniques VIDAS and legacy ASTUTE.

It involves a high increase of the number of leftover samples to be reused in this study, and modification on data processing, with the addition of new categories of data from the ASTUTE database extraction, not needed in the first step of the study, particularly those on age, geographical origin, and on patient care (treatment and biological analysis during Intensive Care Unit stay).

The recipients of these data are research and development teams of bioMérieux, as well as regulatory bodies of countries where the product will be registered before marketing.

Personal data will be kept during three years in active database (access period) from February 2022, for realization of the product performances studies and registrations, then they will be recorded 10 years (retention time for archiving) after the production of the last batch of the product commercialized.

Analysis are always performed confidentially with coded data (pseudonyms) without any mention of family name and first name, and results are given on an aggregated form which does not enable any identification of subjects data of the study.

In GDPR (RGPD EU/2016/679), subjects have a permanent right to know to whom these data samples are addressed for research purposes, as well as the right of access, of rectification, of limitation, or opposition and of deletion of their personal data made available in the context of this research. They can exercise their rights by completing [the rights exercise form](#).

Moreover, these data may eventually be transferred to one or several European Union countries, but in respect of confidentiality and safety rules applied in Europe.

Subjects have too the right of opposition to the transfer of these data outside the European Union. Data processing in our context does not include any automated decision-making.

If answers are considered as non-satisfying, subjects may contact the French body “Commission Nationale de l’Informatique et des Libertés (CNIL)”.