# Development of the test VIDAS® TBI for patients suffering from light traumatic brain injury

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 treatment 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 – The Data Protection Officer may be joined at: Privacyofficer@biomerieux.com.

The purpose of this data processing is development of an *in vitro* diagnostic test with a blood biomarker (bioMérieux VIDAS® TBI).

This test will help to define the need to carry out, or not, a TDM (tomodensitometry), in order to improve care for these patients.

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 blood leftover samples of the ALTERT TBI study (Traumatic Brain Injury), managed by Banyan company, have been extracted from the database of this study, performed between 2012 and 2014.

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 available during one year and half for carrying out of performance studies of the product, and for registrations, and then they will be stored 10 years, 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 and samples are addressed for research purposes, as well as the right of access, of rectification, of

limitation, of 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)”.