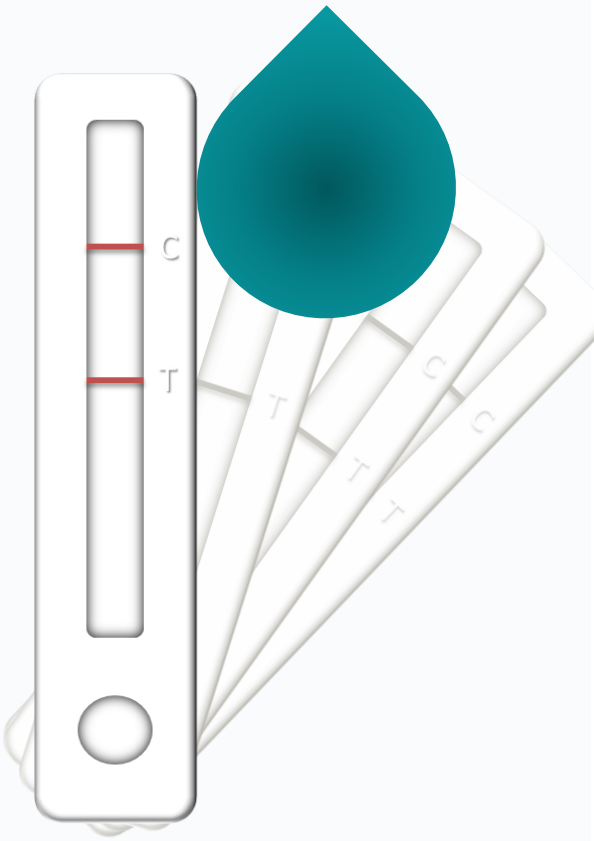
BIOTEM
Custom antibodies & services



IMMUNOASSAY DEVELOPMENT

IMMUNOASSAY *Development*

Immunoassays allow the detection and quantification of various antigens and/or antibodies in different types of samples (serum, plasma, urine, saliva, environmental media, ...). They are based on the specific recognition between one or more antibodies and an antigen. BIOTEM proposes contracts with **guaranteed results** for the development and validation of **ELISA** and **LFIA tests** (rapid tests, Lateral Flow Immunoassay).

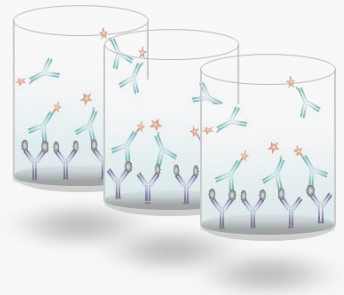
Thanks to the **ISO 13485:2016** certification, the tests developed by BIOTEM can be used as *in vitro* diagnostic medical devices (IVD) and in all types of applications:

Human health, Animal health, Industrial quality control, Agriculture, Biosecurity, Drugs, Environment, etc.

ELISA Tests

Principally used for R&D and for *in vitro* diagnostic, ELISA tests are enzymatic immunoassays for the detection and quantification of analytes in equipped laboratories:

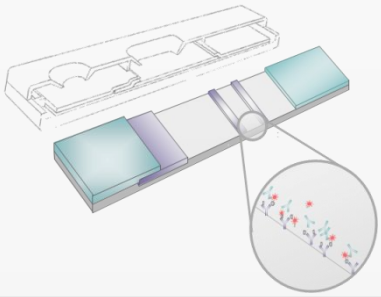
- **Simultaneous measurement** of a large number of samples
- **Duration**: 30 minutes to several hours
- **Quantitative results**
- **Optimal limit of detection**
- **Reliable and robust**



LFIA Tests

Lateral Flow tests (immunochromatography system assays) are based on the migration of nano or micro particles on strips for analytes detection in several areas.

- **Rapid test** (<15 minutes)
- **Reliable and easy-to-use** (no special equipment required nor trained staff)
- **Semi-quantitative** or **quantitative results**
- **Non-refrigerated storage**
- **Economical industrial production**



RESULTS COMMITMENTS & SUCCESS FEE

The assay development includes several steps that BIOTEM implements in its process in order to **meet customer specifications**. An experienced team advises on development strategies and provides the best conditions for BIOTEM to support customers in their project development.

The Client and BIOTEM define together a contract containing:

- **Success criteria definition**
- **Validation methods**
- **Success fees clause** (payment in case of success only)

>100% SUCCESS FEES

Guaranteed results contract is the best commitments that BIOTEM is proud to propose to its Clients which reflects BIOTEM's excellence.

In occasional cases, it will not be feasible to offer results commitments (mostly when success criteria cannot be clearly defined). BIOTEM will send intermediary phases reports including the results and further development work suggestions. After a discussion with BIOTEM, the Client decides on the continuation of the project (GO/no GO).

Project Strategy & Specifications

For each project, our team explores with the client the challenges of the project and defines together the specifications. At the end of this phase BIOTEM will propose/recommend one or several strategies for the project development.

Client's Specifications

- Analytes to be detected /quantified
- Type of test
- Performance and analytical characteristics
- Matrix (Blood, Saliva, Urine, Serum, etc.)
- Specific constrains

Biological Material

- Antigens
- Antibodies (pAb or mAb)
- Reference samples & assay methods
- Robustness of sample preparation methods
- Storage and stability of the biological components

Feasibility Study

The feasibility study is the first experimental step of the development process during which BIOTEM evaluates and selects the **best components available** (antibodies, antigens, membranes, conjugates, etc.). BIOTEM initiates the development of different **prototypes** according to the development strategy previously defined.

Development & Optimization

BIOTEM optimizes prototypes initially developed during the feasibility study. During this phase several validations of the prototypes are undertaken in order to ensure that the development is in line with the project specifications.

Regular contacts with our technical team guarantee the best conditions for BIOTEM to support customers in their project development.

Validation

BIOTEM and the Client jointly carry the formal evaluation (laboratory or field trials) of the performance and the several characteristics of the test. This validation phase is performed to meet Client's specifications.

- Limit of detection
- Linearity / Parallelism
- Specificity
- Precision
- Inter- and Intra-assay reproducibility
- Robustness
- Stability studies of the test and its components

Quality Assessments

Validation according to the regulation and CE Marking assistance.

ISO 9001:2015 and **ISO 13485:2016 (IVD)** certifications.

CERTIFICATION ISO 13485 : 2016

Application Fields

Human Health
Animal Health
Industrial Control Quality
Agriculture
Bio Warfare
Drugs
Environment

Target Experiences

Virus
Bacteria
Hormones
Drugs
Antibiotics
Small Molecules

Expertise

High quality monoclonal antibodies
Exclusive tracers (gold, latex, etc.)
Optimized antigen preparation
Plate, dipstick or cassette
Several matrix

Industrial Production

- Full equipped laboratory for IVD medical device production
- Large scale production
- Marketing & Packaging
- Post market follow-up

BIOTEM – Custom Antibodies & Services
info@biotem.fr - www.biotem-antibody.com
Tel: +33 (0)4 76 65 10 91

BIOTEM

Parc d'Activités Bièvre Dauphine

885, rue Alphonse Gourju

38140 Apprieu – France

Tel : +33 (0)476 65 10 91

info@biotem.fr