BioVendor provides complete assay services for the detection of selected protein markers in samples of human or animal origin.

The BioVendor Analytical Testing Service offers comprehensive sample analyses for analytes measured by our assays. BioVendor is a direct assay kit manufacturer, giving our staff a unique understanding of assay performance. Our assays are fully validated for clinical studies. We can also modify and validate our existing assays to other types of matrices (urine, breast milk, tissue biopsy extract, CSF, BALF, saliva, etc.).

**Samples**

- Detailed records of the handling of samples are maintained according to SOPs, including the following: delivery date, acknowledgement of receipt, storage conditions, number of samples, date of measurement, and evaluation of appearance.
- Samples are stored at -80°C from the time of receipt to 6 months beyond the date of the Final Report.
- We require a minimum sample quantity of 0.25 ml. The transfer tube should be screw capped with an individual sample number or bar code and samples should be packed with dry ice.

**Data Generation**

BioVendor conducts all work confidentially, accurately, and in response to our clients' needs and expectations. Results are communicated on a timely basis and in an easily understood format. Custom reports developed to meet our clients' needs are available in Microsoft® Excel (including *.xls *.csv *.dbt and *.dif formats) and Microsoft® Word.

Over the course of the project, we use a single lot of the assay kit and generate and store both electronic data and printouts:

1. Raw data (absorbance at 450 nm), each plate (run) will contain standards, Quality Control High, Quality Control Low all in doublet and 39 (or 40) samples in doublet determinations unless otherwise specified. Typically, any samples that read high off the standard curve will be pre-diluted and retested if the assay has proven linearity of sample dilution.

2. Measuring date, name of operator and supervisor.

3. Calculated data: corresponding standards are used for standard curve construction (using four-parameter function) and calculation of analyte concentration in samples. Quality Assurance.
Equipment

- Deep freezers -80°C (New Brunswick Scientific)
- ELISA kits
- Microplate shakers with controlled temperature (Biosan)
- Microplate washers (TECAN Columbus)
- Microplate absorbance reader (Biotek)
- Microplate chemiluminescence reader (Biotek)
- Microplate Data Collection & Analysis Software Gen5 (Biotek)
Quality Assurance

BioVendor’s Department of Quality Assurance ensures complete oversight of all projects. Over the course of a project, we monitor intra-assay and inter-assay performance by using Quality Control High and Quality Control Low on each plate (run). Results are presented as intra-assay and inter-assay coefficients of variation (CV) calculated according to the formula: Expected / Obtained and expressed as a %. These outputs are available in both the Analytical (Validation) and Final Report.

• Routine internal audits and inspections
• Data audited for integrity and reliability
• Security measures to ensure electronic data retrieval
• Inspections to ensure compliance of protocols and laboratory SOPs
• Access to reports is limited to authorized personnel
• Use of serum based Quality Controls (High and Low)
• Availability of Internal Quality Controls (IQC1, IQC2, IQC3, IQC4) in case of any need for referee measurements

Reporting of Results

1. Analytical Report (=Validation Report) is available for each microplate and contains intra- and inter-assay CVs for Quality Controls
2. Testing Service Protocol contains the raw data (absorbance) and calculated data for Standards, Quality Controls and samples
3. Results Summary contains identifiers (sample numbers) and measured values
4. Final Report

Analysis Schedule

The following schedule is arranged before testing.

<table>
<thead>
<tr>
<th>Timeline - shipping:</th>
<th>dd/mm/yy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timeline - analysis:</td>
<td>dd/mm/yy – dd/mm/yy</td>
</tr>
<tr>
<td>Timeline - data transfer:</td>
<td>dd/mm/yy – dd/mm/yy</td>
</tr>
<tr>
<td>Timeline - analytical report:</td>
<td>dd/mm/yy – dd/mm/yy</td>
</tr>
<tr>
<td>Disposal of samples:</td>
<td>dd/mm/yy</td>
</tr>
</tbody>
</table>

Pricing

The total price consists of the price of the kit plus the price of the service, 200 EUR ($250).

Prices include all necessary assay reagents, sample preparation, labor, raw data generation, and final data compilation into an easy-to-interpret format. Prices may vary according to the assay performed. Additional charges may be applicable for customers that require specific validations for processes such as cross reactivity and verification of performance characteristics with samples.

Prices of the kits and more information about prices is available at www.biovendor.com.

Unlike standard reference laboratories, we specialize in the development and manufacture of recombinant proteins, antibodies and ELISA kits. As a result, our quality assurance programs are designed to evaluate all types of laboratory activity, including test performance, standard procedures, equipment, and personnel.

**BioVendor’s R&D efforts are aimed at rapidly growing fields of interest within the international research and diagnostic community.**

- Obesity/Metabolic syndrome/Diabetes
- Cardiovascular physiology
- Renal disease and injury
- Bone metabolism/Osteoporosis
- Immune response/Infection/Inflammation
- Neural tissue damage markers

To view our current comprehensive list, please visit www.biovendor.com. We have developed over 150 assays and are continually adding to our product line.

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