Quality & Safety

Quality Control / Assurance of ELISA Reagents and Equipment

A CALIBRE SCIENTIFIC COMPANY

BIOREBA

Certified Quality Management System

BIOREBA maintains the internationally recognized certificate of Quality Management System (ISO 9001) for research and development, production and worldwide distribution of tests, test systems and equipment, as well as test service for customers since 2008. The Swiss certifying SQS is partner of the international IQNet. This certificate shall give us the incentive to continue serving our customers with best quality.

Personnel

The best management system means nothing without fully motivated and trained personnel. All laboratory employees are well trained and certified technicians («Biologie Laborant»), well familiarized with our «in house procedures». They are lead by scientists with PhD. Internal and external education activities acertain a continued high level of specific skills.

Preparation of ELISA reagents

For all of our ELISA reagents the double antibody sandwich method (DAS-ELISA) is used. An anti-pathogen IgG, polyclonal or monoclonal, is applied for the coating step, followed by the test sample, homogenized in buffer. An alkaline phosphatase conjugated anti-pathogen antibody, polyclonal or monoclonal, is then added, followed by the substrate p-nitrophenyl phosphate (see technical Information ELISA test procedure).

All reagents (IgG and conjugates) are standardized to be used at dilutions of 1:1000, optimized in certified Nunc-Immuno Plates MaxiSorb F96 with a working volume of 200 µl per well. Depending on the tissue tested (leaf, sprout, tuber, bark {phloem} or seed), different extraction buffers are applied.

Antibody purifications and enzyme conjugations are done according to specific standard operating procedures (SOP). Different procedures are used for the purification of polyclonal and various subclasses of monoclonal antibodies as well as for enzyme conjugations (proprietary information). IgG and conjugates are verified in tests at different steps of production and in a final QC.

Laboratory equipment

Our laboratory equipment is periodically controlled and maintained according to the specific recommendation of the suppliers. This is documentated according to the ISO 9001 quality standards. Below a selection of equipment related to the quality control of ELISA reagents:

Photometer (ELISA reader): Microtiter plates are read with a microplate reader, using double filters (405 and 492 nm). The instrument is controlled every 12 months by the supplier.

Plate washer: Plate washer operated and maintained according to the manufacturer's recommendations.

HOMEX 7: This sample preparation equipment (homogenizing/extracting) is maintained according to our guidelines for equipment. The HOMEX equipment is used with our extraction bags for the preparation of the test samples.

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Chemicals, buffers and consumables

Chemicals are purchased from suppliers who guarantee the purity and suitability for the desired application. Critical chemicals are tested before purchase of large quantities.

Buffers for QC of reagents are the same as prepared and tested according to our SOP for our large-scale use (and sale). Buffer preparations are registered in a control book. At end-dilution, they are not used longer than one week after preparation. The special buffer used for tuber sap extraction (Extraction Buffer «Bulbs and Tubers» in our catalogue) is prepared fresh every day (addition of egg albumin). See technical information «Buffer Formulations».

Microtiter plates: Certified NUNC MaxiSorp F96 microtiter plates are routinely used for standardisation and quality control of our reagents. We recommend not to use other type of microtiter plates, they may not give satisfactory results. If other plates are used, test performance **must** be controlled for each DAS-ELISA (each pathogen) by use of known infected samples. Test performance can be verified by comparing with our datasheets.

ELISA Test procedure

Plates (described above) are labeled with the pathogen name and the test number equivalent to the test indications in the test protocol. The protocol indicates the pattern of reagents, reagent dilution, antigen, buffers, incubation conditions. The protocols are retained for 10 years for further reference.

The tests are carried out as indicated in the «General ELISA Test Procedure» (see special leaflet). For QC tests, the coating incubation is 30° C for 4 hours, followed by washing and incubation of the antigen extracts overnight at 4°C. The next day, plates are washed and the conjugate incubated for 5 h at 30°C. After washing and adding the substrate solution, the absorbance is determined after 15, 30, 60 and 120 min. substrate incubation at 405/490 nm.

Antigen: (reference material) «Type pathogen isolates» and healthy plant samples are used as test antigen. These isolates were chosen as representative isolates during the development and characterization of the reagents. The reference material (e.g. virus isolates and healthy plants) is maintained at Agroscope, the Swiss centre of excellence for research in the agriculture and food sector, with which we have a cooperation agreement. In our tests, frozen and/or lyophilized samples are used as controls (ratio weight/ buffer generally 1:20). Tuber sap from sprouted potato samples is used fresh. Most plant tissue (such as leaf, sprout, bark and seed) is homogenized in our extraction bags using the HOMEX 7 equipment.

Lot-to-lot consistency

How do we define a «lot»? A lot generally represents a certain volume of reagents made from the same raw material (antiserum, hybridoma culture) that had gone through the same purification steps and has passed the quality control. Each new production lot of reagents is compared with the previous lots on the same microtiter plate(s).

A given lot is on stock for a limited time. BIOREBA's implemented quality control assures consistency from lot to lot. Each test is controlled by the quality control manager according to company rules and product specifications. Thus, even they are not identical *per se*, new lots are equivalent in performance to previous lots.

If a new reagent has passed the QC, a lot number and expiration date is assigned, a datasheet is filled, and the lot is transferred to the sales department. The sales department is allowed to sell the reagents up to a period as defined by internal rules.

From each lot, a reference sample is kept in the laboratory. A reference datasheet, test protocols from the final QC and the previous «preliminary tests» as well as the protocols from the purification and enzyme conjugation are archived a defined period of time to be referenced later on.

Summary of Quality Assurance

At BIOREBA AG, we have established control procedures that ensure highest quality standards for goods released to our customers. Products are manufactured in our laboratory by well-trained staff using state-of-the-art technology. Strict quality control applies to biological products (i.e. antibodies, enzyme-labeled antibodies) and non-biological products (i.e. chemicals, buffers, equipment).

Raw materials bought from external sources are controlled for quality according to proprietary procedures. Nonbiological products such as chemicals are purchased from suppliers who guarantee the purity and suitability for the desired application.

Animals used for antibody production are purchased only from controlled laboratories (i.e. with sanitary controls) with a special governmental permission for animal use. Work from immunization to collection of antiserum is done in our laboratory by trained technicians according to procedures approved by the state agency who regularly controls our procedure and work on the spot. Further processing (purification, enzyme-labeling, standardization etc.) is accomplished according to standard operating procedures (SOP) by specially trained technicians. The many different tasks are supervised and controlled according to procedures approved unter the ISO 9001 Quality Management System (see cerficate next page).

By following our quality assurance procedure, only products that have passed the quality control are released.

Equipment is constructed by manufacturers who are able to provide correct workmanship as well as EC-approval of the devices.

Temperature stability

BIOREBA ELISA products are shipped at ambient temperature. For long term storage please refer to the instructions given on the products and/or individual kit components. Exposure to high temperatures for a limited period of time during shipment will not affect the performance of BIOREBA ELISA products.

Shelf life

We guarantee a minimum shelf life of 12 months for our Individual ELISA Reagents, ELISA Reagent sets, and ELISA Complete kits as of delivery Ex Works Reinach, Switzerland.

Please note that ELISA Complete kit components may have different expiration dates. In an ELISA Complete kit all components are valid at least 12 months as of delivery.

On the data sheet (quality control) the expiration date refers to the antibodies (IgG / Conjugate) and to the positive and negative controls, which are the main components of our ELISA Complete kit.

Liability

BIOREBA AG guarantees that the ELISA reagents have been thoroughly tested and meet the specifications indicated on the product information and datasheet delivered with the products. BIOREBA AG can not be made liable for any damage occurred due to incorrect handling or storage of these products.

All our products are for laboratory use only. They are not to be used for human or animal applications. Should a product fail for reasons other than inappropriate handling or misuse, BIOREBA AG will replace the product free of charge or refund the purchase price.

BIOREBA AG shall not be liable for any direct or indirect, special or consequential damages of any kind resulting from the use of our products.

Certificate

The SQS herewith attests that the organisation named below has a management system that meets the requirements of the normative base mentioned.

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Scope

Agro-Diagnostics: Research and development, production and worldwide distribution of tests, test systems and equipment, as well as testing service for customers

Normative base

ISO 9001:2015 Quality Management System

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Adaptations from last version: modified information related to temperature stability.