DRG ELISA

CMV IgG

Buccal Swab (RUO)

A BioCheck COMPANY

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FIRST ELISA WORLDWIDE FOR THE DETERMINATION OF **CMV IGG FROM BUCCAL SWAB** SAMPLES

INTENDED USE

The DRG CMV IgG Buccal Swab ELISA is used for the quantitative and qualitative detection of IgG antibodies against Cytomegalovirus (CMV) in human buccal swab samples. (For Research Use Only. Not for use in diagnostic procedure.)

BACKGROUND INFORMATION

The cytomegalovirus (CMV) belongs to the human herpes viruses (human herpes virus 5). CMV is widespread worldwide and is considered the most common viral pathogen of congenital infection. Seroprevalence is dependent on age and socioeconomic factors of the population under study.[1]
CMV is used in prenatal diagnostics as part of TORCH serology, but CMV status also plays a major role in transplant medicine. In transplantation, the aim is for the donor to have the same CMV status as the patient. If the patient is CMV-negative, the donor should also be so that the patient is not reinfected with CMV. If, on the other hand, he is positive, the donor should also be positive, because the donor‘s immune system is then already CMV-experienced and trained accordingly.[2]
Whereas in the past CMV IgG could only be detected in blood, DRG has already been offering a CMV IgG ELISA for buccal swabs since 2018.
Buccal swabs are a non-invasive alternative to plasma-based CMV monitoring for non-diagnostic purposes such as donor screening for transplantation or population studies.

PRINCIPLE OF THE TEST

The DRG CMV IgG Buccal Swab ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA). Microtiter wells as a solid phase are coated with inactivated grade 2 Cytomegalovirus (CMV) antigen (strain AD-169). Samples and ready-for-use controls are pipetted into these wells. During subsequent incubation, CMV-specific antibodies of positive samples and controls are bound to the immobilized antigens. After a washing step to remove unbound sample and control material horseradish peroxidase conjugated anti-human IgG antibodies are dispensed into the wells. During a second incubation, this anti IgG conjugate binds specifically to

Representative Image (Photo: NH File Photo)

IgG antibodies resulting in the formation of enzyme-linked immune complexes. After a second washing step to remove unbound conjugate, the immune complexes formed (in case of positive results) are detected by incubation with TMB substrate and development of a blue color. The blue color turns into yellow by stopping the enzymatic indicator reaction with sulfuric acid. The intensity of this color is directly proportional to the amount of CMV-specific IgG antibody in the patient sample. Optical density at 450 nm is read using an ELISA microtiter plate reader.

ASSAY CHARACTERISTICS

- Assay Range: 0 – 80 DU/mL
- Incubation Times: 60 / 30 / 10 min
- Sample: Buccal Swab (Swabs not included in kit)
- Controls: Negative and Positive Control included in Kit
- Standards: 3 Standards 1-3 (Neg. Control is used as 0-Standard)
- Processing: Manual or automated possible (protocols available for Dynex DS2 and DSX
- No cross reactivity was found for Herpes-simplex Virus 1 and 2, Varicella zoster Virus and Epstein-Barr Virus (VCA).

BENEFITS

- **Buccal swab sampling is an attractive non-invasive alternative to blood drawings**
- **Simple sampling**
- **No appointment necessary for donors**
- **No risks associated with blood drawings**
- **Very good correlation to the blood test**
- **Reliable results**
- **To be processed on standard ELISA instruments (SLV-6110)**

ALREADY ESTABLISHED IN THE MARKET

Using this assay **DKMS Life Science Lab gGmbH** has shown that a CMV serostatus can be derived from dried swabs with good sensitivity (99.1%) and specificity (98.6%) in >80% of the samples when normalizing the CMV results against total protein (based on a BCA assay). [3,4] This accuracy is sufficient in the context of registering potential donors since all infectious disease markers are retested using serum before transplantation.

ORDERING INFORMATION

Available in single kit version (SLV-6110) and as 300 plate kit (SLV-6084).

References:

[1] RKI-Ratgeber Zytomegalievirus-Infektionen (https://www.rki.de/DE/Content/Infekt/EpidBull/Merkblaetter/Ratgeber_Zytomegalievirus.html)

[2] Be The Match. Medical guidelines—who can join? https://bethematch.org/support-the-cause/donate-bone-marrow/join-the-marrow-registry/medical-guidelines/. Accessed16 February 2020.

[3] J Infect Dis. 2021 Oct 13;224(7):1152-1159; Non-invasive determination of CMV serostatus from dried buccal swab samples: assay development, validation and application to 1.2 million samples; Geoffrey A. Behrens, Michael Brehm, Rita Groß, Jana Heider, Jürgen Sauter, Daniel M. Baier, Tatjana Wehde, Santina Castriciano, Alexander H. Schmidt, Vinzenz Lange

[4] Transpl Immunol. 2022 Oct 14;75:101729.doi: 10.1016/j.trim.2022. Reanalysis of unclear CMV status results from buccal swab samples of potential stem cell donors is an efficient donor registry strategy; Stefanie N Bernas, Geoffrey A Behrens, Henning Baldauf Daniel M Baier, Heike Fischer, Jens Pruschke, Falk Heidenreich, Katja Ruhner, Jan A Hofmann, Jan Markert, Johannes Schetelig, Vinzenz Lange, Alexander H Schmidt

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