

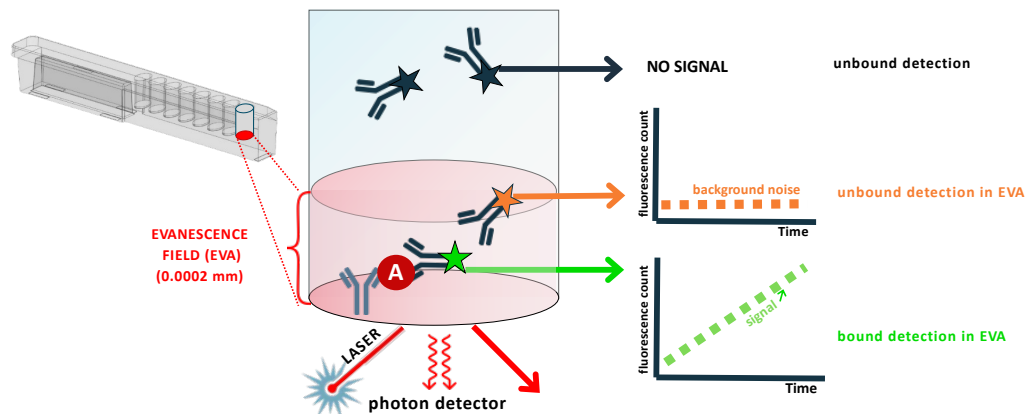
# ElioDX™ Total Human Immunoglobulin G (IgG) Kit

Product number RP-TNS10039

**Product description** The ElioDX™ Total Human Immunoglobulin G (IgG) Kit is an evanescent immunoassay intended for the in vitro quantitative determination of total human IgG in human biological fluids, including serum, plasma, and saliva. The assay is wash-free and delivers rapid results within 10 minutes.

**Intended use** The ElioDX™ Total Human Immunoglobulin G (IgG) Kit is intended for use on ElioDX™ Readers in combination with software provided by ELIONOVA AG. For research use only. Not for use in diagnostic procedures.

**Key features** EVA technology by ELIONOVA works by generating an evanescent field of exciting light at the bottom of the well. The exciting laser light beam (635nm) is totally reflected at the liquid - solid interface. A 200 nm bottom layer of the adjacent liquid is selectively illuminated: only fluorophores localized in this evanescent field absorb the laser beam photons and subsequently emit light of longer wavelength. The liquid above the 200nm range is not illuminated. An analyte captured at the bottom of the well is detected by an antibody labelled with a fluorophore, which now can absorb light and then emit light of a longer wavelength. The emitted light leaving the device through the bottom is recorded in real time. Fluorophores not being bound to the bottom within the evanescent field (as the specific analyte of interest is not present) do not create a signal.



**Figure 1.** The ElioDX™ system uses evanescent field (EVA) technology for specific fluorescence detection. Detection antibodies labeled with fluorophores bound to the analyte generate signals (green star) within the evanescent field. Unbound antibodies cause low background fluorescence (orange star), while fluorophores outside the field produce no signal (black star). This reduces background and enables sensitive, real-time quantification.

**Contents and Storage**

Components	Quantity	Storage
ElioDX™ Total Human IgG Cuvette	10	2 - 8 °C
ElioDX™ 5X Assay Diluent A	4 x 5 ml	2 - 8 °C

**Note:**

Each well of the cuvette contains all necessary assay reagents.

Only open individual cuvettes immediately before use.

Unused cuvettes must remain sealed and should be returned to cold storage (2°C to 8°C) promptly after opening the kit.

**Stability**

Unopened cuvettes are stable at 2°C to 8°C up to the stated expiry date.

**Materials required but not provided**

The following materials are not included in the kit, but will be required to perform this assay:

- ElioDX™ Reader
- Sterile distilled H<sub>2</sub>O
- 2 µL to 1000 µL adjustable single channel or multichannel micropipettes with disposable tips, Lobind tubes, Tissue.

**Precautions**

- Do not touch the sides of the cuvette located near the wells with your fingers, as this may negatively impact optical measurement.
- This product **must be used** in accordance with the principles of Good Laboratory Practice (GLP). **Wearing suitable personal protective equipment (PPE), including laboratory coats, masks, and gloves, is mandatory.**
- Do not pipet by mouth. Do not eat, drink or smoke in areas where the kit and samples are handled.
- Avoid contact of skin or mucous membranes with samples and with samples dissolved in the kit.
- Do not use kit reagents beyond expiry date on label.
- The kit is intended for research use only and not for use in diagnostic or therapeutic procedures.

**Preparation of samples**

Serum, plasma and saliva were tested with this assay.

Samples should be aliquoted and stored frozen at –20 °C to preserve analyte stability. Repeated freeze–thaw cycles should be avoided. Prior to the assay, frozen samples should be allowed to thaw slowly at room temperature and mixed gently. Further recommendations for specific sample preparation are as follows:

- Plasma: Collect plasma using heparin, Sodium Citrate, or EDTA. Centrifuge samples at 2`000 x g for 10 minutes.
- Serum: Collect samples into a serum separator tube. After clot formation, centrifuge samples at 2`000 x g for 10 minutes and collect serum.

**Assay Procedure**

Bring all reagents, samples and cuvettes to room temperature before use. Centrifuge the sample again after thawing before the assay. It is recommended that all samples be assayed in duplicate.

1. Register cuvette to ElioDX™ Cloud according to **ElioDX™ Cloud User Manual**
2. Dilute each sample in 1X ElioDX™ Assay Diluent A to a final dilution of 1:32,000. This can be achieved by performing two sequential dilutions: first, dilute 5 µL of sample in 795 µL of 1X ElioDX™ Assay Diluent A (1:160), then dilute 5 µL of this mixture in 995 µL of 1X ElioDX™ Assay Diluent A (1:200).
3. Aspirate 20 µL of diluted sample and transfer into the defined well.

**Note:** Use reverse pipetting for improved accuracy and consistency.

1. After adding the sample, place the cuvette on the provided **StarLab® Vortex Mixer and shake at 800 rpm for 30 seconds** to homogenize the solution.

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- Carefully clean the **outside and bottom** of the cuvette surface using a clean tissue (e.g., **Kimberly-Clark™ reference 7552** or equivalent).
  - Insert the cuvette into the **ElioDX™ Reader** and start the measurement according to the reader's operating instructions.

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**Data Export and Analysis**

Download the data from ElioDX™ Cloud following the instructions provided in the **ElioDX™ Cloud User Guide**.

Use the provided **ElioDX\_HIGG\_calculation\_Lot\_(please check your lot number on the aluminum pouch).xlsx** to calculate the concentration of unknown samples. Import the exported data into the template and follow the embedded instructions to generate quantitative results.

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