



Frequently Asked Questions Telimmune™ Plasma Separation Cards

Product Overview

The Telimmune™ Plasma Separation Card is a high-precision volumetric plasma collection device for use by medical professionals and consumers at-home.

Unlike common blood vials and blood spot cards, it efficiently separates plasma and supplies a very accurate volumetric sample ready for analytical analysis.

The Telimmune technology collects a 3.2 μ L aliquot of plasma from $\geq 25 \mu$ L of whole blood in three minutes and stabilizes for shipping in just 15 minutes.

Principal applications include but are not limited to population-based research, global clinical trials, neonatal screening for congenital disorders, toxicokinetic/pharmacokinetic studies, therapeutic drug monitoring, and healthcare accessibility initiatives in the developing world.

The cards are utilized by both medical professionals and remote users, and they boast the distinction of being the first commercial product to produce an exact quantity of plasma from a few drops of blood without a power source or centrifuge.

Product Usage and Audience

Q: What is the typical profile of an individual or organization that purchases Telimmune?

A: The device was developed for scientists, pharmaceutical companies, and government agencies who need to safely collect plasma samples in areas remote to the analytical laboratory. Other industries that have shown a need for plasma separation technology include pharmaceuticals, blood banks, research universities, hospitals, diagnostic labs, global clinical trials, therapeutic drug monitoring, and more.

Q: What assays are customers utilizing these cards to detect?

A: Telimmune cards have been utilized for the detection in a variety of assays including ferritin, helicobacter pylori (gastritis), vitamin D, HIV, genetic disorders, COVID-19, homocysteine, sickle cell, warafarin, IgG antibodies, and more.

Discover the data behind the detection of assays via numerous scientific reports, whitepapers, posters, and data sheets contained on our product literature webpage.

Q: What is the difference between Telimmune Uno and Telimmune Duo?

A: The Telimmune Duo Card collects two identical plasma samples, whereas the Telimmune Uno Card collects one sample. Each disc collects 3.2 μ L.

Competitive Advantages

Q: How does Telimmune differ from DBS cards?

A: Telimmune separates plasma from the sample, which is not possible with a DBS card. The DBS card only collects whole blood, which requires extensive sample preparation prior to analysis. More importantly, Telimmune offers the benefit of precise volumetric collection. The precise plasma volume enables determination of analyte concentration, eliminates hematocrit effect while the control spot ensures that an adequate sample has been collected.

In layman's terms – people have different amounts of red blood cells per volume, and this creates uncertainty when testing on diagnostics – Telimmune's precise plasma volume eliminates this potential testing bias and may also make tests easier to run.

Telimmune standardizes plasma sample collection and stabilizes the plasma specimen faster than any other technique including venipuncture. This is important because metabolite concentrations change in minutes when blood is drawn.

The final advantage is that the Telimmune Separation Card is pre-punched, predefined, and can easily be removed. It is easy to just peel the disk off and drop it off wherever is needed.

Q: In what ways is this solution cost controlled as opposed to whole blood tube or microtube collection?

A: By combining sample collection and plasma fractionation into a single, simple step, Telimmune greatly reduces ancillary costs associated with traditional methods for liquid plasma fractionation, refrigerated sample preservation and transport. In the laboratory, Telimmune offers opportunity for additional economic benefit by reducing costs associated with lab workflows for sample preparation prior to analysis.

Q: Why is Telimmune a preferred collection method in remote or offsite locations?

A: These cards were created for sampling in remote locations due to their portability and functionality in environments without a power source, as well extreme temperatures. In other words, Telimmune does not need refrigeration, heating, nor other restrictive storage like common venipuncture samples and the lower quality materials used to make DBS cards.

Purchasing

Q: Are there any limitations on who can purchase this?

A: The product is intended for professional, and laboratory use only and can be purchased online via our website.

Q: How does Telimmune pricing compare to similar products on the market?

A: The Telimmune Plasma Separation Card provides significant sample preparation and process related cost savings. The higher quality materials and science used to make Telimmune will also

ensure your samples arrive safely. We have a volumetric pricing model and are priced typically priced better than venipuncture and competitive with other plasma separation methods.

Please contact Telimmune directly to work with our team on your pricing needs.

Q: What countries are Telimmune cards for sale in?

A: There is no limitation on the countries that we sell into.

Q: What are the terms and conditions that come with a sale?

A: All sales are prepaid and shipping charges are the responsibility of the customer.

Technical Information and Competitive Advantages

Q: What sample size is needed for the Telimmune Uno and Telimmune Duo Cards?

A: A fingerstick sample is applicable for both cards. The Telimmune Uno requires $\geq 25 \mu\text{L}$ and the Telimmune Duo requires $\geq 60 \mu\text{L}$.

Q: How long does it take for the blood to dry after a fingerstick sample has been added to the card?

A: Please allow 15-minutes for the blood to dry before preparing the sample for mailing to a lab. The sampling process itself takes approximately 3 minutes.

Q: Is this product CLIA-waived or FDA approved?

A: Telimmune cards are FDA listed as a Class I medical device which means that a CLIA waiver is not required.

Q: Can this product be used for clinical trials?

A: The Telimmune Plasma Separation Card is approved for use in clinical trials. The product is designed to for use in an "LDT" (Lab Developed Tests), and is used as a GPR.

Q: How long is the card stable for?

A: The product is manufactured with a non-sampled shelf life of 24-months.

Q: How does the process of sending these into a lab work?

A: The cards can be sent the via a standard envelope in the mail and additional postage might not be required to the low weight of the sample.

Q: Are there any actions that a user can take to ensure accurate sample collection?

A: When applying the blood sample, it is important, that neither the finger itself or application pipette touches the sample port. Additionally, it is imperative that the minimum whole-blood volume (25 μL Telimmune Uno, 60 μL Telimmune Duo) to ensure volumetric plasma collection.

Q: How is a quality control sample prepared?

A: Add a known amount of standards, either applied or internal are recommended to standardize with any diagnostic methodology to freshly collected whole blood and store cold for no more than two weeks. The isotope labeled standard should differ in mass from the isotope standard added to the extraction solvent for quantification.

Q: What is the size of the collection disc?

A: The plasma collection discs are 6.4 mm (0.25inch) in diameter. This allows for a perfect fit when using a flat-bottom 96-well plate for automated analytical process.

Q: Do the Telimmune cards work with other analytical techniques?

A: Yes, approved techniques include ELISA, PCR, QPCR, Enzymatic, Chromatographic, Mass Spectrometry, and Colorimetric.

###