rhelise™ kit

A device for simple cost effective sampling of blood for the use in diagnostic tests.

Description of the rhelise™ kit

The rhelise™ kit has been developed with the view for a layman to use the kit.
The rhelise™ kit consists of a lancet, a capillary (50 µl), a vial with an extraction solution. As an option barcode labels and a pre-addressed envelop can be added to the kit.

The extraction solution is the key component of the kit. For each biomarker/pharmaceutical the extraction solution will be optimized with the aim that the compound should be stable in the solution more than for 14 days at room temperature.

As a quality assurance of the sample the extraction solution contains an internal standard, that is related to the compound that will be analyzed. The internal standard will indicate that the sample is intact.

Taking a sample

With the lancett the finger is punctured. The blood that flows from the wound is captured by a capillary of 50µL. When the capillary is filled the sample is transferred to the vial with the extraction solution. The vial is vigoursly shaken, the blood immediately denatures which prevents any degradation of the sample. The sample could be sent by regular mail to the laboratory for analyzes.

Value of the rehlise™ kit

1) For the individual there is no requirement to go to a primary care unit to give a sample, which saves time and eventually loss of income.

2) There is no need for large blood volumes and there will be no cost for transportation and storage at cold temperatures.

3) The extraction solution will stabilaze the compound to be analyzed, which means that the reliability of the sample will be higher than if other methods are used.

4) If the compound that is analyzed requires that sampling is to be taken at short intervals the rhelise™ kit gives an unique possibility to facilitate this.

5) At the laboratory the sample could, after centrifugation, be analyzed directly, without any extraction procedures. This will also facilitate automatization of the process.

6) The rhelise™ kit in combination with the LC-MS/MS technique will give an unique possibility to take blood samples and have an analyzing method with extremly good sensitivity and specificity.

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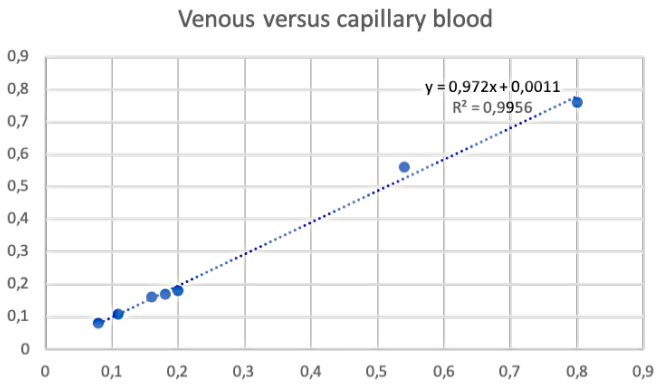
The rhelise™ kit could be used for all biomarkers/ pharmaceuticals detected by the LC-MS7MS technique

Comparision of samples taken from venous blood and capillary blood

The figure shows phosphatidylethanol concentrations in whole blood for 7 indiviual.



rhelise™ kit assays

Prof of concept has been made by two different compounds phosphatidylethanol and tamoxifen with metabolites.

Phosphatidylethanold (PEth)

PEth is a biomarker for long term alcohol consumption. It is an unnatural phospholipid that can only be formed in the presence of alcohol, which theoretically provides a 100% specificity for alcohol consumption. The half-life is 5 days, menaning that the molecule could be detected 3-4 weeks the alcohol has been cleared out of the blood.

An analyzing method was developed for LC-MS/MS and in conjunction with that method the rhelise™ kit was developed. The extraction solution in the rhelise™ kit contains the deuterated PEth as internal standard. The solution will keep the PEth molecule intact in room temperature for more than 14 days.

Tamoxifen, Z-endoxifen and 4OH-tamoxifen

About 80% of women that have been treated for breast cancer are prescribed tamoxifen to reduce the incidence of relapse. Tamoxifen is the world's most widely used breast cancer drug and the single most effectove way to reduce mortality in breast cancer. The treatment lasts between 5 to 10 years. All women worldwide are prescribed the same dose of tamoxifen, 20 mg/day, independent of their body mass index, age or metabolism.

An LC-MS/MS method was developed for the analyzing of tamoxifen, z-endoxifen and 4-OH tamoxifen. Toghether with the method a capillary kit was developed that contains an extraction solution including the internal standards for the three different compounds. The extraction solution stabilize the compounds for att least 14 days in room temperature.

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