Measurement of Blood Loss by Alkaline Hematin

KCAS
Bioanalytical & Biomarker Services

Clinical trials for drug therapies or surgical techniques treating menorrhagia, endometriosis, uterine fibroids or adenomyosis, often require menstrual blood loss (MBL) measured at screening and post-treatment endpoints as an efficacy marker. KCAS has validated the alkaline hematin biomarker, a rapid spectrophotometric assay, acknowledged as the definitive MBL efficacy biomarker by regulatory agencies and recognized experts in the women's health field.

Methodology

The method involves pummeling used feminine hygiene products in a solution and measuring the resulting hematin absorbance against calibration curves. To allow us to rapidly reports results, the historic method was re-tooled and validated in accordance with current FDA Guidance for Method Validations. The validation summary below documents product selectivity, kinetic conversion, calibration design, best fit analysis, precision and accuracy, dilution integrity and stability.

Investigative

We performed side-by-side comparisons to determine the accuracy of pictograms (e.g., PBAC) for products currently on the market and our research found that pictograms are not only inaccurate but lead to false conclusions regarding the inclusion or exclusion of subjects into a clinical study. Comparisons have been presented at Women's Health conferences and our posters can be viewed by visiting www.kcasbio.com.

Indications

The alkaline hematin technique definitively and quantifiably determines MBL, and is commonly used for women's health clinical trials as an MBL endpoint for:

- Menorrhagia
- Endometriosis
- Adenomyosis
- Uterine Fibroids

Logistical Support

KCAS facilitates all aspects of the alkaline hematin project, including:

- Generating a custom laboratory manual & patient instructions
- Presenting site training at investigator meetings
- Creating sample collection kits
- Providing kits, storage/shipping containers and shipping materials to clinical sites
- Coordinating re-orders and available for on-demand clinical site support

We utilize a custom Access/SQL database for data management and reporting that incorporates the unique aspects of multi-site AH clinical trials. The database's specific report format and frequency is tailored to the client's specific study design and needs.

Why KCAS?

- **Experience:** Since 2006, KCAS has measured more than 137,000 samples from more than 10,000 menstrual cycles. Our method is validated to FDA Guidance for Validations standards and has been audited by both device and pharma clients.
- **Logistics:** No other lab has the know-how to help you design and facilitate the collection of AH samples across multiple domestic or international clinical sites.
- **Proven Record:** KCAS' alkaline hematin data has been a part of multiple NDA submissions that have met FDA approval. KCAS has supported several programs for drugs and devices and our data reporting complies with FDA expectations.