



FREQUENTLY ASKED QUESTIONS

Q: Is the Creamatocrit Plus CE marked?

A: Yes

Q: Is the Creamatocrit Plus FDA cleared?

A: The Creamatocrit Plus requires no pre-marketing clearance, or specifically an FDA 510(k) clearance. Human lactated milk is classified as a medical food. Medical foods were defined in the Orphan Drug Act of 1988, and, as such, are not regulated as either a food or a drug by the FDA. The only requirement is that Good Manufacturing Practices (GMP) for conventional food is followed, mostly regarding labeling. Thus, since the sample type is not subject to any special regulation, there is no special classification for an analytical instrument that makes a physical measurement on lactated milk.

Q: What about Data Management? Can the results be interfaced with a computer or printer?

A: No

Q: Who are the competitors?

A: None. Although the creatmatocrit has been used widely in published research, it has only recently been incorporated into the clinical management of infants who are fed mothers' milk. The traditional method for measuring creatmatocrit is performed using a cumbersome, noisy laboratory centrifuge, calipers and conversion charts or graphs to determine calorie content. The laborious process limits its clinical use. The Creamatocrit Plus is lighter, quicker and quieter than the traditional method. The digital mechanism for measuring the cream and total volume columns is internal, eliminating the use of a hematocrit reader or calipers. The software has been programmed to automatically convert the creatmatocrit measure into lipid concentration and caloric density so that conversion charts or graphs are unnecessary.

If a full analysis of mothers' milk is required, high priced milk analyzers are available. But if the customer is looking for an easy, accurate, and affordable device for managing calories, engineering lactation to best serve the infant, and/or sustaining breastfeeding, the Creamatocrit Plus is a perfect fit.

Q: How often should tests be run?

A: This depends on the situation. If the device is used to support breastfeeding by showing the mother just how good her milk is, then perhaps one test is sufficient. In a Neonatal ICU, the mother's milk may be tested a number of times throughout a 24-hour period.

Q: Can any brand of plain tubes be used?

A: No, Creamatocrit Plus tubes must be used. Their specific type and inside diameter ensures the calculation of accurate results.

Q: Can any brand of tube sealant be used?

A: Some sealants do not work well with milk. HemataSeal™ performs well.

Q: What about quality control?

A: A control strip is included with the centrifuge. It can be used to confirm the tube reader is working correctly. Directions for performing a spin time and a tachometer test are in the manual.

If you have any questions, please contact Separation Technology Customer Service at 407-788-8791, 800-777-6668 (US and Canada) or at custserv@separationtechnology.com.