



## FREQUENTLY ASKED QUESTIONS

### Q. Why do I get different readings on the same milk sample?

- A. Be sure to thoroughly mix the milk sample before drawing it into the tube.

Traditionally, if you were reading a creatatocrit with calipers or a hematocrit reader, you wouldn't be able to discern anything less than a .5% difference (and that takes really good eyesight). In the Rush Hospital study with the mothers doing creatatocrits, 85% of the differences between the mother and the nurse were <1.0% creatatocrit. You should expect it to be <1% difference, and probably within about a .5% difference. The Creamatocrit Plus is digital and is programmed with the regression equation, so it takes precision to an entirely different level. It would be unlikely that you would get two results that are identical for that reason. Minor differences in the way you read the creatatocrit or place the cursor will produce minor changes in creatatocrit percentage. You wouldn't be able to see these minor changes with the older methods, but because this is electronic and mathematical they will appear. You may want to spin two tubes of the milk sample and average the two results for a total.

### Q. How can I stop the sealant from blowing out of the tubes?

- A. Some sealants do not work well. Use HemataSeal™ sealant.

Be sure you use the following procedure for sealing the tubes:

1. Fill the tube ½ to ¾ full.
2. Let the milk flow down the tube until it is near the dry end. Then place your finger over the wet end of the tube to stop the flow. (Stop the milk before it gets to the area where the sealant will go - that area should remain dry.)
3. Immediately insert the dry end vertically into the sealant, pushing it to the bottom of the tray. Twist the tube when removing it from the sealant to prevent the sealing plug from being extracted. Repeat.
4. Gently tap the sealed end of the tube on a flat surface to help insure proper sealant contact in the tube.

Note: Do not push the holes out of the clay with your finger, as it can result in a thinned layer of sealant or air bubbles.

### Q. Sometimes there is a "tail" or line of cream running down the inside of the tube. Will it affect the result?

- A. It will not affect the result. Simply ignore it when marking the interfaces on the tube.

### Q. Do I have to use Creamatocrit Plus tubes or can I use any brand of plain tubes?

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

### Q. How do I perform quality control on the instrument?

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.

### Q. Is Creamatocrit Plus CLIA waived?

- A. The results obtained by using the Creamatocrit Plus as intended are not subject to CLIA because they do not provide information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. The measurement of creatatocrit and estimated calories in human milk is an analysis of a food. It is acknowledged that accurate nutritional information on human milk, fortified human milk, and infant formula is important as part of nourishing neonates and infants, but that does not cause the creatatocrit determination to be "diagnostic".

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**Q: Is the Creatmatocrit Plus CE marked?**

A: Yes

**Q: Is the Creatmatocrit Plus FDA cleared?**

A: The Creatmatocrit 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 Creatmatocrit 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 Creatmatocrit 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 tube sealant be used?**

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