

 **TERUMO[®]**
TERUMO MEDICAL CORPORATION

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CERTIFICATE OF ANALYSIS

Date: January 5, 2005

Product Description: CapiJect[®] Capillary Blood Collection Tubes

1. All Terumo Medical Corporation products are manufactured in accordance with established product specifications, and in accordance with the US Food, Drug and Cosmetic Act, Chapter 21, Part 820, pertaining to Quality System Regulations (Good Manufacturing Practices for Medical Devices).
2. CapiJect[®] Capillary Blood Collection Tubes are tested for lead content on a periodic basis. Product codes representative of the product line are tested according to the 1997 CDC guidelines, Appendix C.1². Residual lead levels meet the CDC requirement of no more than 5 ppb residual lead on both an average and individual basis.

The most recent test results are summarized in the table below.

<u>Product Code</u>	<u>Lot No.</u>	<u>Avg. Pb Content (ppb)</u>
T-M	YA0431	0.41
T-MG	XM1231	0.41
T-MLH	XN0831	0.58
T-MPS	XM2631	0.17
T-MQK	Multiple	0.80
T-MLHG	XN0431	0.77

Average lead level of all CapiJect[®] Tubes: 0.62

Kathleen Little, PhD
Quality Systems Manager