Evaluation of VACUETTE®
Sodium Heparin Tubes

Background:

Greiner Bio-One, Austria has sold plastic evacuated tubes (VACUETTE®) for venous blood collection since 1986.

The VACUETTE® Sodium Heparin blood collection tube can be used for the collection, transport and processing of whole blood. Clotting is inhibited by the presence of sodium heparin coating the interior of the tube.

Heparin functions as an anticoagulant by activating antithrombins, which block the coagulation cascade and result in the production of plasma, instead of serum and clotted cells.

Study Objective:

A clinical evaluation was performed to assess the equivalence of VACUETTE® Sodium Heparin and Lithium Heparin tubes.

Study design:

The following tube types were used in this study:

Sample ID	Description
A	VACUETTE® 4 ml NH Sodium Heparin
B	VACUETTE® 4 ml LH Lithium Heparin

Venous blood was collected from 40 outpatients and healthy hospital staff volunteers using VACUETTE® Blood Collection Accessories. Two tubes were collected from each donor (A and B) in random order to prevent systemic bias.

Directly after venipuncture, the tubes were carefully inverted according to the instructions given by the tube manufacturer. After mixing, the tubes were transported to a laboratory within one hour of procurement, and centrifuged for ten minutes at 3000g, after which plasma was separated from the cellular components of the blood sample.

A chemistry profile was performed within two hours of blood collection using the HITACHI 917 Chemistry Analyzer (Roche).
A ferritin test, prolactin test and a thyroid profile were performed within six hours of blood collection using the Abbott AxSYM® System.
Aliquots for estradiol testing were stored at -20°C until analysis was performed using a Diagnostic Products Corporation RIA Kit on an LKB 120 Analyzer.
Analysis was performed with the instruments' accompanying reagents.

Conclusion:

The VACUETTE® Sodium Heparin tube demonstrated similar performance to the VACUETTE® Lithium Heparin tube.

Slight differences observed between these tube types may have been caused by either physiological and/or analytical attributes. Preanalytical factors such as the preparation of the patient for specimen collection, and more specifically, diurnal variation, diet, venipuncture technique and transport may affect analyte recovery.

Chemistry Profile: No statistically significant differences were found in chemistry profile results for those paired samples collected in Sodium Heparin and Lithium Heparin tubes using Student's T-test at p(0.05) level.

Thyroid Profile: No statistically significant differences were found in the thyroid panel results for those paired samples collected in Sodium Heparin and Lithium Heparin tubes using Student's T-test at p(0.05) level.

Hormones: No statistically significant differences were found in Prolactin and Estradiol results for those paired samples collected in Sodium Heparin and Lithium Heparin tubes using Student's T-test at p(0.5) level.

The results in detail can be found in the Annex.

References:

(1) Greiner Bio-One, Evacuated Blood Collection System For In Vitro Diagnostic Use. Product Insert. Kremsmünster, Austria (2001)

(2) NCCLS Guideline Document, Clinical Laboratory Technical Manuals – Third Edition; Approved Guideline. GP2-A3, Wayne, Pennsylvania (1996)

(3) NCCLS Guideline Document, Interference Testing in Clinical Chemistry. EP4, Villanova, Pennsylvania (1986)

(4) Henry J.B., Clinical Diagnosis & Management by Laboratory Methods. "Preparing Patients and Specimens for Laboratory Testing", 18th Edition, W.B. Saunders Company, Philadelphia, Pennsylvania, p.77 (1991)

(5) Sacher R.A. and McPherson R.A., Widmann's Clinical Interpretation of Laboratory Tests, 11th Edition. F.A. Davis Company, Philadelphia (2000)

(6) Wallach J.W., Interpretation of Diagnostic Tests, 7th Edition. Lippincott Williams & Wilkins, Philadelphia (2000)

(7) Young D.S., Effects of Preanalytical Variables on Clinical Laboratory Tests, 2nd Edition. AACC Press, Washington D.C. (1997)

Annex / Results in detail:

Chemistry Profile			
Analyte	**Lithium Heparin Mean**	**Sodium Heparin Mean**	**Statistically significant**
Albumin [g/l]	41.7	41.4	no
ALT [U/l]	25.1	23.4	no
AP [U/l]	92.9	94.1	no
AST [U/l]	20.4	20.5	no
Calcium [mmol/l]	2.33	2.33	no
Chloride [mmol/l]	102.5	103.0	no
Cholesterol [mmol/l]	4.66	4.66	no
Creatine [mmol/l]	77.6	77.8	no
Creatine Kinase [U/l]	142.8	144.0	no
Glucose [mmol/l]	5.42	5.32	no
γGT [U/l]	26.7	27.0	no
LDH [U/l]	165.4	167.5	no
Magnesium [mmol/l]	0.80	0.80	no
Ferritin [µg/l]	103.6	103.1	no
Phosphate [mmol/l]	0.94	0.93	no
Potassium [mmol/l]	3.90	3.90	no
Triglycerides [mmol/l]	1.45	1.45	no
Total Bilirubin [µmol/l]	9.25	9.18	no
Total Protein [g/l]	74.9	74.9	no
Urate [µmol/l]	302.4	302.3	no
Urea [mmol/l]	6.13	6.11	no

Thyroid Profile			
Analyte	**Lithium Heparin Mean**	**Sodium Heparin Mean**	**Statistically significant**
TSH [mU/l]	2.23	2.12	no
fT4 [pmol/l]	13.45	13.46	no
fT3 [pmol/l]	2.81	2.97	no

Hormones			
Analyte	**Lithium Heparin Mean**	**Sodium Heparin Mean**	**Statistically significant**
Prolactin [µg/l]	10.17	10.21	no
Estradiol [pmol/l]	133.0	135.9	no