Greiner Bio-One VACUETTE® Sodium Heparin Tubes Evaluation

Principle

The Greiner 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.[1] A clinical evaluation was performed to assess the equivalence of the Greiner VACUETTE® Sodium Heparin and Lithium Heparin tubes.

Sample Population

Samples were collected from forty outpatients and healthy hospital staff volunteers.

Specimen Collection

Two tubes were drawn from each donor as follows: 1) one Greiner VACUETTE® Sodium Heparin tube, 4.0ml, 13x75mm (Product Listing #454051); and 2) one Greiner VACUETTE® Lithium Heparin tube, 4.0ml, 13x75mm (Product Listing #960857). Blood samples were obtained using the standard phlebotomy technique.

Handling Techniques

The tubes were thoroughly mixed immediately following blood collection, transported to the laboratory within one hour of procurement, and centrifuged for ten minutes at 3000 x g, after which plasma was separated from the cellular components of the blood sample. The paired sodium and lithium heparin samples were tested in parallel.

Instrumentation

A chemistry profile was performed within two hours of blood collection using the ROCHE/HITACHI 917 Chemistry Analyzer. 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 1260 Analyzer.

Statistics

For the statistical evaluation, results from paired samples were compared using the Student t test. The results are summarized in Tables 1, 2 and 3.[2,3,4]

Discussion

Chemistry Profile: No statistically significant differences ($p>0.05$) were found in chemistry profile results for those paired samples collected in the Greiner VACUETTE® Sodium Heparin Evaluation and Lithium Heparin tubes, except for the following analytes: CO_2 and Sodium. The statistically significant differences (Student t value > critical t; $p < 0.05$) were not clinically significant and were probably due to the clinically narrow range of values. The CO_2 values had ranges of 21-31 mmol/L and 22-30 mmol/L for Lithium Heparin and Sodium Heparin tubes, respectively. The Sodium values had ranges of 132-145 mmol/L and 138-146 mmol/L for Lithium Heparin and Sodium Heparin tubes, respectively. Other sources have documented the effect of using the sodium or potassium salt of fluoride, heparin, or EDTA with regards to the interference of specific analyte recovery.[1]

Thyroid Profile: No statistically significant differences ($p>0.05$) were found in the thyroid panel results for those paired samples collected in the Greiner VACUETTE® Sodium Heparin Evaluation and Lithium Heparin tubes.

Hormones: No statistically significant differences ($p>0.05$) were found in Prolactin or Estradiol results for those paired samples collected in the Greiner VACUETTE® Sodium Heparin Evaluation and Lithium Heparin tubes.

Conclusion

The Greiner VACUETTE® Sodium Heparin, 4.0ml, 13x75mm tube demonstrated similar performance to the Greiner VACUETTE® Lithium Heparin 4.0ml, 13x75mm 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 and venipuncture technique and transport[4] may affect analyte recovery. In addition, attention should be focused on analytical factors such as the methodologies and reagent systems employed and the instruments chosen to perform the analyses. Furthermore, it must also be noted that differing results may be derived from different instruments.[4,7] Caution should always be exercised, therefore, when determining the statistical or clinical significance of an analyte result derived from a test, method or instrument evaluation.[8] Careful examination of the comparative evaluation results should identify those variables – both preanalytical and analytical – and the significance these variables have on an institution's reportable test results.

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Table# 1: Chemistry Profile

Analyte	Lithium Heparin (Li Hep) Mean	Sodium Heparin (Na Hep) Mean	Mean Difference (Li Hep-Na Hep)	Student t statistic	p
Albumin (g/L)	41.7	41.4	0.3	0.529	0.598
Alanine Amino Transferase (U/L)	25.1	23.4	1.7	0.409	0.683
Alkaline Phosphatase (U/L)	92.9	94.1	-1.2	-0.127	0.899
Aspartate Amino Transferase (U/L)	20.4	20.5	-0.1	-0.048	0.961
Calcium (mmol/L)	2.33	2.33	0.00	0.362	0.718
Chloride (mmol/L)	102.5	103.0	-0.5	-0.755	0.453
Cholesterol (mmol/L)	4.66	4.66	0.00	-5.1E-15	1.000
CO_2 (mmol/L)	25.03	23.83	1.20	2.194*	0.031**
Creatine (mmol/L)	77.6	77.8	-0.2	-0.056	0.956
Creatine Kinase (U/L)	142.8	144.0	-1.2	-0.030	0.976
Glucose (mmol/L)	5.42	5.32	0.11	0.232	0.817
Gamma Glutamyl Transferase (U/L)	26.7	27.0	-0.3	-0.067	0.948
Lactate Dehydrogenase (U/L)	165.4	167.5	-2.1	-0.152	0.879
Magnesium (mmol/L)	0.80	0.80	0.00	0.430	0.669
Ferritin (µg/L)	103.6	103.1	0.5	0.016	0.987
Phosphate (mmol/L)	0.94	0.93	0.01	0.025	0.980
Potassium (mmol/L)	3.90	3.90	0.00	-0.121	0.904
Sodium (mmol/L)	139.4	141.1	-1.7	-3.25*	0.002**
Triglycerides (mmol/L)	1.45	1.45	0.00	0.002	0.998
Total Bilirubin (µmol/L)	9.25	9.18	0.07	0.079	0.937
Total Protein (g/L)	74.9	74.9	0.0	0.000	1.000
Urate (µmol/L)	302.4	302.3	0.1	0.003	0.997
Urea (mmol/L)	6.13	6.11	0.02	0.019	0.985

*Statistically significant: student t statistic > critical t (±1.99)
**Statistically significant: p<0.05

Table# 2: Thyroid Profile

Analyte	Lithium Heparin (Li Hep) Mean	Sodium Heparin (Na Hep) Mean	Mean Difference (Li Hep-Na Hep)	Student t statistic	p
TSH (mU/L)	2.23	2.12	0.11	0.240	0.811
Free Thyroxine (pmol/L) – T4	13.45	13.46	-0.01	-0.013	0.989
Free Triiodthyronine (pmol/L) – T3	2.81	2.97	-0.16	-1.119	0.267

Table# 3: Hormones

Analyte	Lithium Heparin (Li Hep) Mean	Sodium Heparin (Na Hep) Mean	Mean Difference (Li Hep-Na Hep)	Student t statistic	p
Prolactin (µg/L)	10.17	10.21	-0.05	-0.038	0.970
Estradiol (pmol/L)	133.0	135.9	-2.9	-0.088	0.930

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