BD Vacutainer® Glukoz ve Özellikli Tüpler

BD Vacutainer® Glukoz Tüpleri; içerdiği formül sayesinde *in-vitro* Glukolizi inhibe eder ve 24 saat boyunca Glukoz stabilitesini sağlayarak laboratuvar etkinliğinizi arttırır ve hasta sonuçları güvenliğine katkıda bulunur. NaF Na2EDTA seçeneği ile tek tüpten Glukozun yanı sıra Laktat, HbA1c, Homosistein ve Etanol gibi diğer hassas analizlere de olanak sağlar.

BD Vacutainer® ACD Tüpleri, aktif antikoagülan Tri-sodyum sitrat, sitrik asit ve dekstroz içeriği ile eritositlerin korunmasına katkıda bulunur. 2 farklı formülasyon seçeneği ile kan bankası ve immuno-hematoloji analizlerinizin tam doğruluğuna yardımcı.

BD Vacutainer® EDTA Aprotinin Tüpler, içerdiği antikoagülan ve proteolitik inhibitor sayesinde polipeptid hormon ve enzim analizlerinde güvenilir bir seçenek.

BD Vacutainer® Eser Element Tüpleri, Antimon, Arsenik, Kadmiyum, Kalsiyum, Krom, Bakır, Demir, Kurşun, Magnezyum, Manganez , Civa, Selenyum ve Çinko analizleri için serum ve K2EDTA plazma tüpü seçenekleri ile.

BD Vacutainer® Plus Vakumlu Sekonder Tüp (EST), örnek alikotlama ve atık tüp ihtiyacı gibi steril, plastik, vakumlu tüpe ihtiyaç duyduğunuz heryerde.

Technical Assistance

For more specific information on BD Vacutainer® products, please call BD Technical Services at **(800) 631-0174.**

Whenever changing any manufacturer's blood collection tube type, size or storage condition for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data and their own previously generated data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if the change is appropriate.

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BD Vacutainer®
Trace Element Plus Tube
Technical Brief

BD Helping all people live healthy lives

Introduction

BD has been selling glass evacuated blood collection tubes for over 50 years. In the early 1990s, BD introduced BD Vacutainer® Plus Tubes as an alternative to conventional glass tubes. BD Vacutainer® Plus Tubes are considered "engineering controls" under the Occupational Safety and Health Administration (OSHA) guidelines. As a progressive advancement toward safety, BD has recently added to the BD Vacutainer® product line a BD Vacutainer® Trace Element Serum Plus Tube and a BD Vacutainer® K_2EDTA Trace Element Plus Tube. To support customers in the conversion process from glass to plastic, BD evaluates product performance and provides this information to its customers.

Objective

In addition to tube material differences (glass versus plastic), BD uses a clot activating coating in plastic serum tubes, which is not used in glass serum tubes. The purpose of this study was to evaluate if there are matrix effects on measurement of select trace elements caused by the coating in the BD Vacutainer® Serum Trace Element Plus Tube.

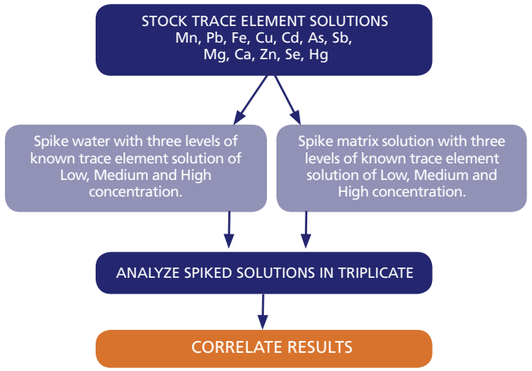
For this study, a matrix effect was defined as a shift in the response (+ or -) within the linear range of the particular element tested.

Methods and Materials

The instrument used for the analysis is an Atomic Absorption Analyzer with appropriate reference lamps for the elements being tested.

Stock standards of the following trace element solutions were used to spike the samples: Manganese (Mn), Lead (Pb), Iron (Fe), Copper (Cu), Chromium (Cr), Cadmium (Cd), Arsenic (As), Antimony (Sb), Magnesium (Mg), Calcium (Ca), Zinc (Zn), Selenium (Se), and Mercury (Hg).

Two sets of trace element standards were prepared. One set of standards was prepared in water, the second in the trace element tube coating solution. Both sets of standards were prepared in concentrations of low, medium, and high levels for the linear range of the analyzer for trace element detection.



mg/L = PPM, µg/L = PPB.
Graphite Furnace (GF)

Atomic Absorption (Perkin Elmer) analysis was used for evaluation of all elements by the methods defined in Table 1. Each solution concentration–low, mid and upper for each aqueous and coating solution–was assayed in triplicate and an average of the three results was calculated. Reagent grade water blank was assayed on the AA instrument before each solution.

Data Analysis

The data for all elements in both the aqueous and coating solution were evaluated for equivalence using a one-way ANOVA and a paired t test.

If the results were statistically equivalent, then no matrix effect was observed; if the results were statistically different and analytically acceptable, then a conclusion of no matrix effect would also be documented. Analytical equivalence is defined as results equal to or lower than the current claims for BD's current glass trace element product. These claims are in the following table.

BD Vacutainer® Trace Element Tubes Contamination Upper Limits

Analyte	Glass (µg/L)	Plus (µg/L)	Analyte	Glass (µg/L)	Plus (µg/L)
Antimony	0.8	–	Lead	2.5	0.3
Arsenic	1.0	0.2	Magnesium*	60	40
Cadmium	0.6	0.1	Manganese	1.5	1.5
Calcium*	400	150	Mercury**	–	3.0
Chromium	0.9	0.5	Zinc*	40	40
Copper	8.0	5	Selenium	–	0.6
Iron	60	25			

Water extraction analyzed by*Flame, **Cold Vapor, all others flameless AAS

BD Vacutainer® Tubes for Lead Testing Contamination Upper Limits

Analyte	Glass (µg/L)	Plus* (µg/L)
Lead	10	2.5

0.1N nitric acid extraction analyzed by flameless AAS

RESULTS and DISCUSSION

Results of the Trace Element Study are summarized below.

TABLE 2–Results of Standard Solutions *Statistically Significant

ELEMENT	CONCENTRATION	SOLUTION	AVG Absorbance Value n=30
Mn	0.05 mg/L	Aqueous	10
		Coating	11
	0.500 mg/L	Aqueous	96
		Coating	96
	1.000 mg/L	Aqueous	190
		Coating	190
Pb *	5.0 µg/L	Aqueous	25
		Coating	26
	15.0 µg/L	Aqueous	80
		Coating	88*
	30.0 µg/L	Aqueous	161
		Coating	161
Fe	0.050 mg/L	Aqueous	4
		Coating	4
	0.500 mg/L	Aqueous	40
		Coating	40
	1.000 mg/L	Aqueous	77
		Coating	77
Cu	0.050 mg/L	Aqueous	7
		Coating	7
	0.500 mg/L	Aqueous	65
		Coating	65
	1.000 mg/L	Aqueous	129
		Coating	129
Cr	5.0 µg/L	Aqueous	16
		Coating	16
	15.0 µg/L	Aqueous	44
		Coating	44
	30.0 µg/L	Aqueous	96
		Coating	98
Cd	0.40 µg/L	Aqueous	16
		Coating	15
	1.0 µg/L	Aqueous	43
		Coating	43
	2.0 µg/L	Aqueous	84
		Coating	85

TABLE 2–Results of Standard Solutions *Statistically Significant

ELEMENT	CONCENTRATION	SOLUTION	AVG Absorbance Value n=30
As	1 0.0 µg/L	Aqueous	28
		Coating	24
	30.0 µg/L	Aqueous	79
		Coating	83
	75.0 µg/L	Aqueous	187
		Coating	187
Sb *	5.0 µg/L	Aqueous	27
		Coating	27
	15.0 µg/L	Aqueous	83
		Coating	95*
	30.0 µg/L	Aqueous	170
		Coating	186
Mg	0.050 mg/L	Aqueous	41
		Coating	42
	0.250 mg/L	Aqueous	180
		Coating	181
	0.50 mg/L	Aqueous	336
		Coating	335
Ca	0.250 mg/L	Aqueous	17
		Coating	18
	2.500 mg/L	Aqueous	143
		Coating	145
	5.000 mg/L	Aqueous	261
		Coating	259
Zn	10.0 mg/L	Aqueous	20
		Coating	20
	30.0 mg/L	Aqueous	167
		Coating	167
	75.0 mg/L	Aqueous	307
		Coating	308
Se	10.0 µg/L	Aqueous	18
		Coating	17
	30.0 µg/L	Aqueous	39
		Coating	39
	75.0 µg/L	Aqueous	98
		Coating	98
Hg	1.000 µg/L	Aqueous	45
		Coating	45
	4.000 µg/L	Aqueous	162
		Coating	165
	8.000 µg/L	Aqueous	311
		Coating	314

CONCLUSION

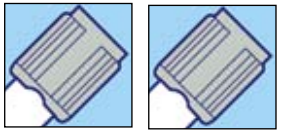
The results indicated no statistical differences between the results for the trace metals in the aqueous solution and those in the coating solution, with the exception of Antimony (Sb) and Lead (Pb), when measured in standard solutions by Atomic Absorption.

The elevated concentration of Antimony (Sb) contained in the tubes is a consequence of the manufacturing of the tube. Antimony (Sb) was analyzed in the study, but was never under consideration for a claim with this product because of its use in manufacturing the product.

For Lead (Pb), the responses for the lower and upper concentration ranges are identical and it is the mid range concentration that appears to have a positive bias with the coating solution. However, the variation seen is within the experimental error in making up the standard solution (weighing, pipeting) and while statiscally the responses are different, analytically the difference is not significant. By this it is meant that a regression of the three concentrations versus response will give the same standard curve for both the aqueous and coating solution matrices, hence the same experimental results for both test analyses.

BD Vacutainer® Plus Sodium Fluoride and Sodium EDTA Tube with BD Hemogard™ Safety Closure

Technical Information Sheet



368520, 368521

Single use, evacuated, sterile blood collection tubes containing disodium EDTA intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain a plasma sample, in which the glycolysis process has been inhibited. These products are intended for use by healthcare professionals.

Manufacturing Information

Manufacturing Location:	BD Diagnostics - Preanalytical Systems, Belliver Industrial, Estate, Plymouth, Devon, PL6 7BP, UK
Standards & Certificate numbers:	ISO 9001:2000 & FM28628 & ISO 13485:2003 & FM79169 ISO 14001:2004 & EMS37154
Notified body:	BSI (0086)

Sterilisation

Sterilisation Location:	UK
Method:	Gamma Irradiation, Co-60
SAL:	10^{-6}
Standards applied:	EN552:1994 (ISO 11137)

Compliance

Directive:	European In Vitro Diagnostic Medical Device Directive 98/79/EC Risk Class – Non Annex II

Relevant Standards and Guidelines

Standards:	ISO 6710:1995, EN14820:2003
Guidelines:	Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Tubes and Additives for Venous Blood Specimen Collection. Approved Guideline - Fourth Edition. Document H1-A4. Wayne, PA, USA, 2004

Product Specifications

Product Number	368520	368521
Tube Material	Polyethylene Teraphthalate (PET)	
Tube Size (mm)	13 x 75	
Draw Volume (ml)	2	4
Fill Line Indicator?	No	
Additives	1.5mg/ml sodium fluoride 3mg/ml disodium EDTA	
Closure Material Cap	Polymer (low density polyethylene resin)	
Closure Colour	Grey	
Label Type	Paper	
Shelf-Life (months)	16	
Does product contain:		
- Latex (NRL)?	No	
- Dry Natural Rubber (DNR)?	No	
- Phthalates (eg. DEHP)?	No	
- Material of Animal Origin?	No	
Global Medical Device Nomenclature (GMDN)	35414	
Material Safety Data Sheet (MSDS)	VS8020017	
Product Storage	Do not expose to direct sunlight Store product between 4° and 25°C	
100 Unit Pack Weight (Kg)	0.67	0.67
100 Unit Pack Volume (m^3)	0.002380	0.002380
1000 Unit Pack Weight (Kg)	6.67	6.68
1000 Unit Pack Volume (m^3)	0.023038	0.023038

Packaging Specifications

Product Number	368520	368521
100 Unit Packaging Material	Expanded Polystyrene (EPS) / Polyolefin film	
100 Unit Packaging Weight (Kg)	0.020	0.020
100 Unit Packaging Volume (m^3)	0.000680	0.000680
1000 Unit Packaging Material	Cardboard	
1000 Unit Packaging Weight (kg)	0.298	0.298
1000 Unit Packaging Volume (m^3)	0.024645	0.024645

Labelling Information

All labelling complies with the requirements of the European In Vitro Diagnostic Medical Device Directive 98/79/EC and includes the CE mark.

Unit Label

Contains lot number, product reference number, sterile symbol, product name and short description, additive type, draw volume, manufacturer name, single use symbol, expiry date and CE mark.

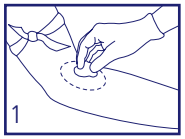
Shelf Label

Contains lot number, product reference number, sterile symbol, product name and short description, additive type, draw volume, manufacturer name, single use symbol, expiry date, CE mark, graphical instructions for use, quantity, and primary barcode (UCC/EAN 128).

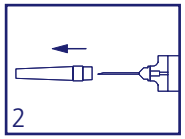
Case Label

Contains lot number, product reference number, sterile symbol, product name and short description, additive type, draw volume, manufacturer name, single use symbol, expiry date, CE mark, graphical instructions for use, quantity, primary barcode (UCC/EAN 128) and secondary barcode (UCC/EAN 128).

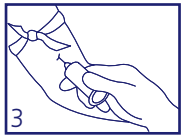
Instructions for Use



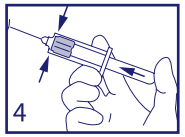
1. Apply tourniquet, disinfect venipuncture site. Note: arm should be in a downward position.



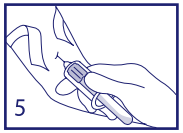
2. Assemble needle to holder and remove the needle shield.



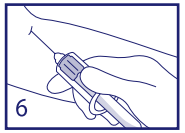
3. Perform venipuncture.



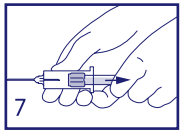
4. Insert tube fully into holder.



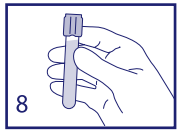
5. Release tourniquet.



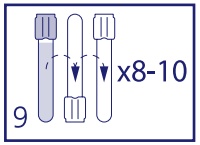
6. Hold tube in place until blood has stopped flowing.



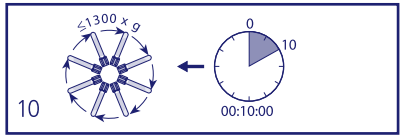
7. Remove tube from holder.



8. Hold tube in upright position.



9. Gently invert the tube 180° and back 8-10 times.



10. Centrifuge the tube for 10 minutes at ≤1300 x g (RCF).

Sample Storage & Stability

When plasma is in contact with the cells after centrifugation[1]:
≤ 24h: store sample at 25°C
≤ 48h: store samples at 2 - 8°C
Stability depends on analyte (See Section 5: Samples and Stability of Analytes [2] & Specific Analyte [3])

References

1. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Procedures for the Handling and Processing of Blood Specimens; Approved Guidline - Third Edition. Document H18-A3. Wayne, PA, USA, 2004
2. WHO, Use of Anticoagulants in Diagnostic Laboratory Investigations, Rev.2. Geneva, Switzerland: World Health Organisation; January 2002
3. Tietz N.W Ed, Clinical Guide to Laboratory Tests -Fourth Edition. W.B. Saunders, USA: 2006

Further Reading

- BD White Paper VS5904: BD Vacutainer ® Plus Sodium Fluoride EDTA: Evaluation of clotting, haemolysis and glucose at initial time of collection and after 24h storage at RT when compared to glass sodium fluoride/potassium oxalate tubes:2001
- Kazuo Uchida, Ryoichi Matuse, Enami Toyoda, Syoji Okuda and Shinobu Tomita. A new method of inhibiting glycolysis in blood samples. Clinica Chimica Acta, Volume 172, Issue 1, 29 February 1988, Pages 101-10
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- Evans M.J, Livesey J.H, Ellis M.J, and Yandle T.G. Effect of anticoagulants and storage temperatures on stability of plasma and serum hormones. Clinical Biochemistry 34 (2001): 107-112
- Guder W.G, Narayanan S, Wisser H. and Zavta B. Samples: From the Patient to the Laboratory. Third Edition. Darmstadt, Germany: Wiley-VCH; 2003

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