



PT MACROCITRA ARDANASEJATI

INDONESIA



HISTORY

 Founded **1991** distribute medical equipment to Indonesia Market.

Experienced **30** years PT MACROCITRA ARDANASEJATI always provide **best service** and **quality** for laboratories and hospitals both private and government .

OUR PRODUCTS



[®] PRE-ANALYTICAL SYSTEM



PT Macrocitra Ardanasejati
Indonesia

25

1996

Founded in Guangzhou, China

2003

ISO certified & CE marking, started to export

2009

IPO in China GEM; Ticker symbol: 300030

2010

Gel & Clot Activator Tube **US FDA** cleared, #1 FDA approved blood collection tube in China

2014

First oversea subsidiary founded in San Diego, U.S.A.

2015

Business development of services, information



WHAT WE DO



High Compatibility

----- Forwarded message -----
From: A [redacted]@roche.com>
Date: 2017-08-18 17:32 GMT+08:00
Subject: Re: Question about IMPROVE tubes
To: "Gu [redacted]@roche.com">
Cc: Yur [redacted]an@roche.com>,
Le [redacted]@roche.com>, Tr [redacted]ig@roche.com>

Dear Lu,
yes, all IMPROVE tubes you've sent us are qualified for LCP1. These are the following:

Vendor	Article Number /Ref. No	Cap Color	Dimensions	Tube Name	System
Improve	623050202_1	Light yellow	13x100	IMPROVE_13	LCP1
IMPROVE	623050202	Light yellow	13x100	IMPROVE_13	LCP1
Improve	161005	Light yellow	13x100	IMPROVE_13	LCP1
Improve	624070202	Light yellow	16x100	IMPROVE_09	LCP1
Improve	622030202	Intensive ochre	13x75	IMPROVE_33	LCP1
Improve		Intensive ochre	13x75	IMPROVE_33	LCP1
IMPROVE	622350202	Golden	13x75	IMPROVE_33	LCP1
IMPROVE	101620676	Golden	13x75	IMPROVE_33	LCP1
Improve	662040202	Intensive green	13x75	IMPROVE_34	LCP1
IMPROVE	662040202	Intensive Green	13x75	IMPROVE_34	LCP1
Improve	663050202	Intensive Green	13x100	IMPROVE_21	LCP1



SIEMENS



Ortho Clinical Diagnostics
a *Johnson & Johnson* company



HOW WE DO



#1 FDA 510K

First and only FDA cleared blood collection tube
and full line of blood collection needles in China



cGMP, ISO, QSR820, Brasil GMP, KFDA, MDSAP,...

International main stream quality management system



Continues Improvement

Overall quality management & total employee involved

Main drafter of China National Standard of Vacuum Tubes Performance

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Guangzhou Improve Medical Instruments Co., Ltd.
c/o Ms. Diana Hong
General Manager
Shanghai Midlink Business Consulting Co., Ltd.
Suite 5D, No. 19, Lane 999, Zhongshan No. 2 Road (S)
Shanghai, China 200030

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 12 2010

Re: k093910
Trade Name: IMPROVACUTER® Gel & Clot Activator Tube
Regulation Number: 21 CFR §862.1675
Regulation Name: Blood specimen collection devices
Regulatory Class: Class II
Product Codes: JKA
Dated: July 05, 2010
Received: July 07, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-0609
Silver Spring, MD 20993-0002

August 27, 2013

Innovative Medical Technologies, Incorporated
Mr. Brad Brown
President
15059 Cedar Street
LEAWOOD KS 66224

Re: K123987
Trade/Device Name: Improve Blood Collection Set and Improsafe Blood Collection Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 24, 2013
Received: July 26, 2013

WS
中华人民共和国卫生行业标准
WS/T 224—2018
代替 WS/T 224—2002

真空采血管的性能验证
Performance verification of vacuum tubes for venous blood specimen

前言

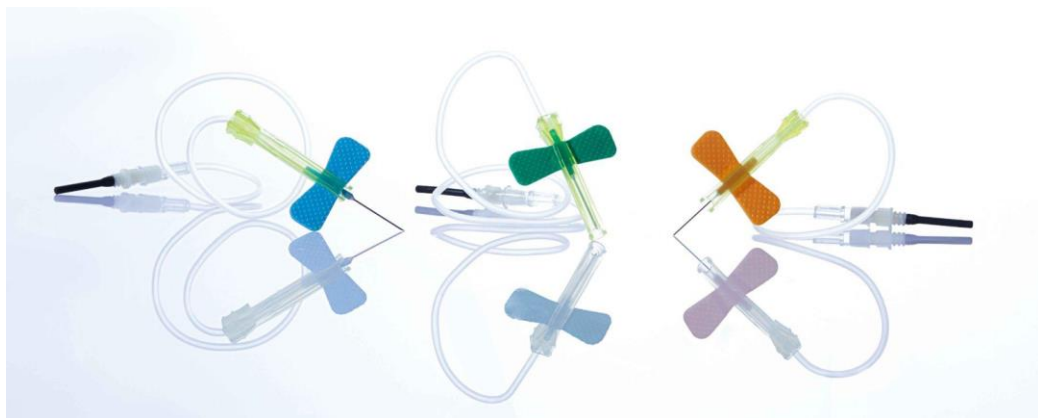
本标准按照GB/T 1.1-2009给出的规则起草。
本标准代替WS/T 224-2002《真空采血管及其添加剂》。
与WS/T 224-2002相比，除编辑性修改外主要变化如下：
——标准名称修改为《真空采血管的性能验证》；
——增加了真空采血管的临床评价指标（见4.4~4.6和4.8）；
——删除了原标准中部分由生产厂商测试的内容（2002年版4~7和9~13）；
——修改了管体强度标准，将相对离心力提高到3000g（见4.3，2002年版）。

本标准起草单位：广东省人民医院、中山大学孙逸仙纪念医院、广州医科大学附属第一医院、同济大学附属同济医院。

本标准主要起草人：邹伟民、李红玉、林勇平、万海英、邓冠华。



PRE-ANALYTICAL SYSTEM



BLOOD COLLECTION TUBE (BCT)



Serum BCT



Whole Blood BCT



Plasma BCT

ADVANTAGES OF IMPROVACUTER®

The background of the slide features a collection of medical equipment, including several vials with different colored caps (blue, green, yellow, red, pink, grey, purple), syringes, and coiled tubing, all rendered in a light blue, semi-transparent style.



Rubber stopper

Surface treatment technology
for rubber stopper



Control of
pre-analytical
variation

1. Surface treatment technology for rubber stopper



- **Sealing performance**
- **Decapping & Recapping**
- **Precipitates release**

- Surface treatment technology for rubber stopper is applied for
- a) keeping the vacuum: 24 months
 - b) facilitating decapping and recapping
 - c) preventing the precipitates releasing from rubber stopper

1. Surface treatment technology for rubber stopper

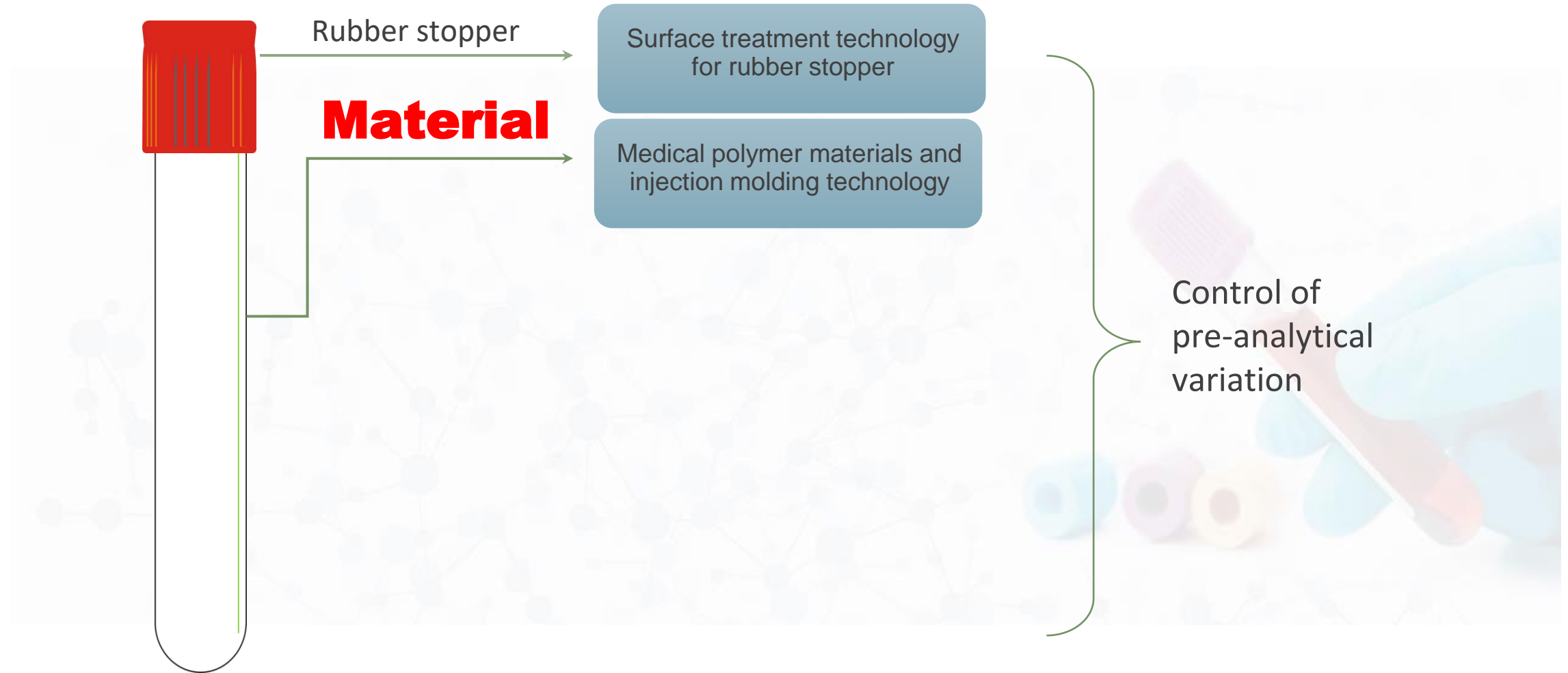
No.	Brand	Sample Qty (pcs)	Probability of cap and <u>stopper separation</u>
1	**	150	0.017 %
2	****	NA	NA, screwed cap
3	IMPROVE	300	0.000049 %

What is
Needle
Bounces?

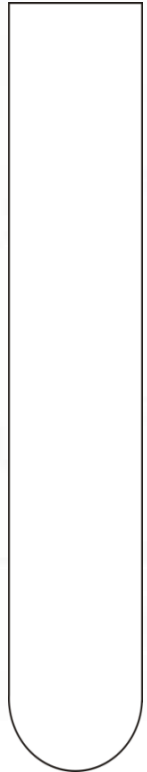


1. Surface treatment technology for rubber stopper

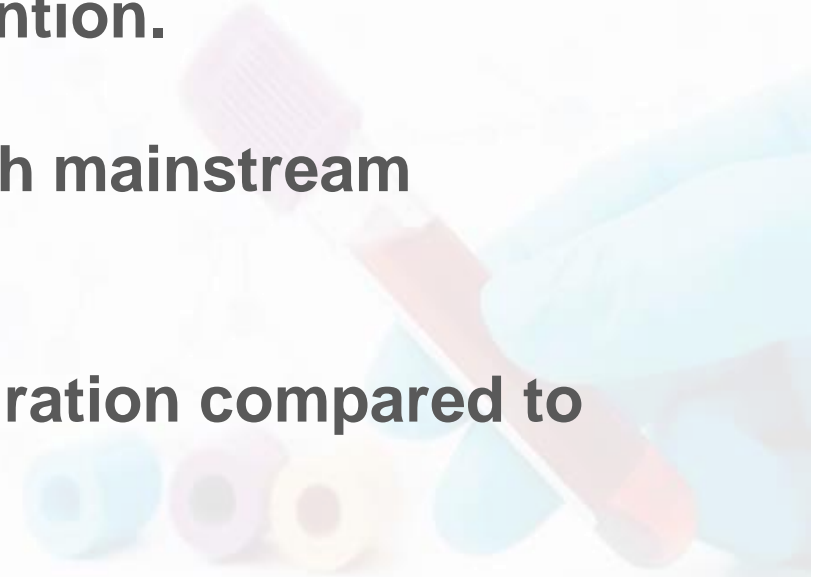
No.	Brand	Sample Qty (pcs)	Probability of <u>needle-bounce</u>
1	**	150	33.9 %
2	****	125	72.6%
3	IMPROVE	300	0



2. Medical polymer materials and injection molding technology



- Longer vacuum and liquid retention.
- Constant size compatibility with mainstream analyzers
- Relative higher temperature duration compared to other brand BCTs.
- Relative longer low temperature duration compared to other brand BCTs.



2. Medical polymer materials and injection molding technology

Comparison of different PET tubes at **60°C** and RH50%



2. Medical polymer materials and injection molding technology

Comparison of different PET tubes under 70°C by an end user in China

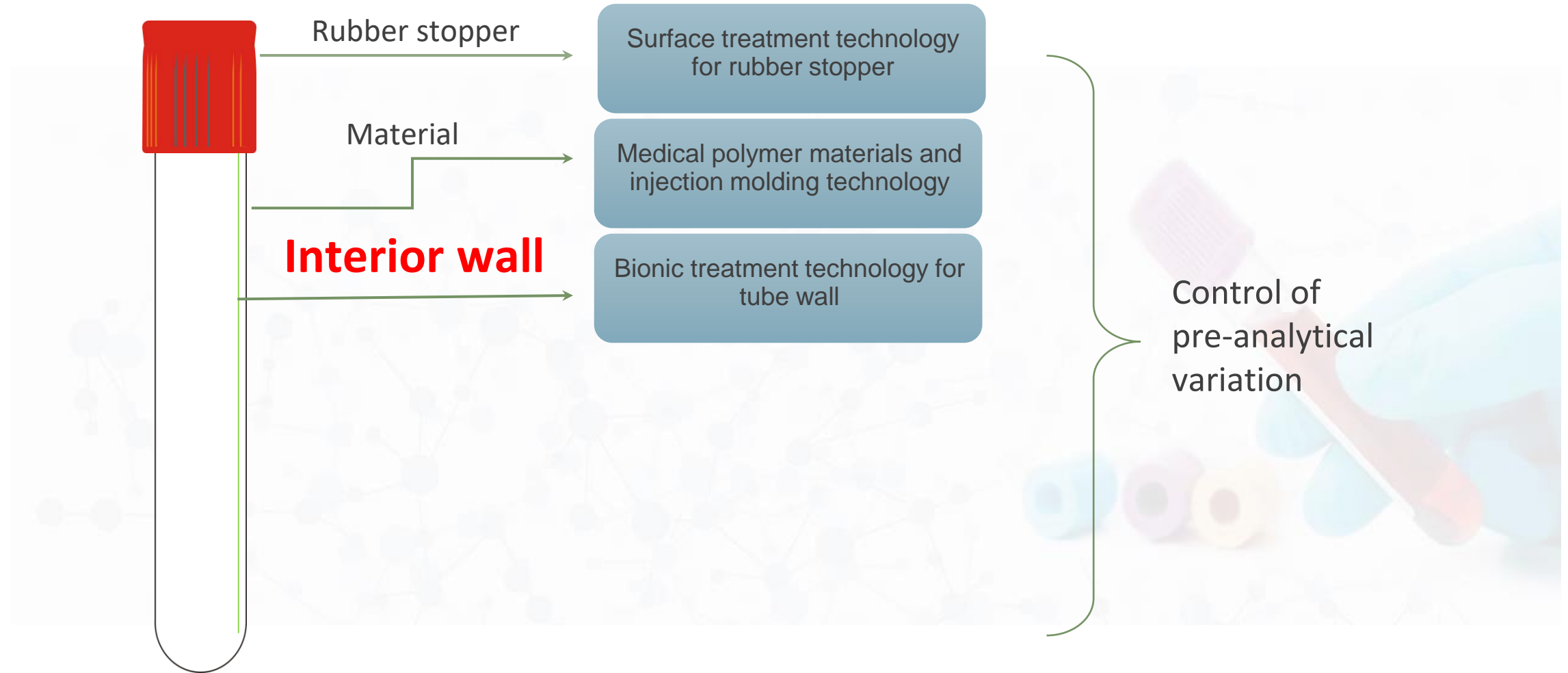


IMPROVE

2. Medical polymer materials and injection molding technology

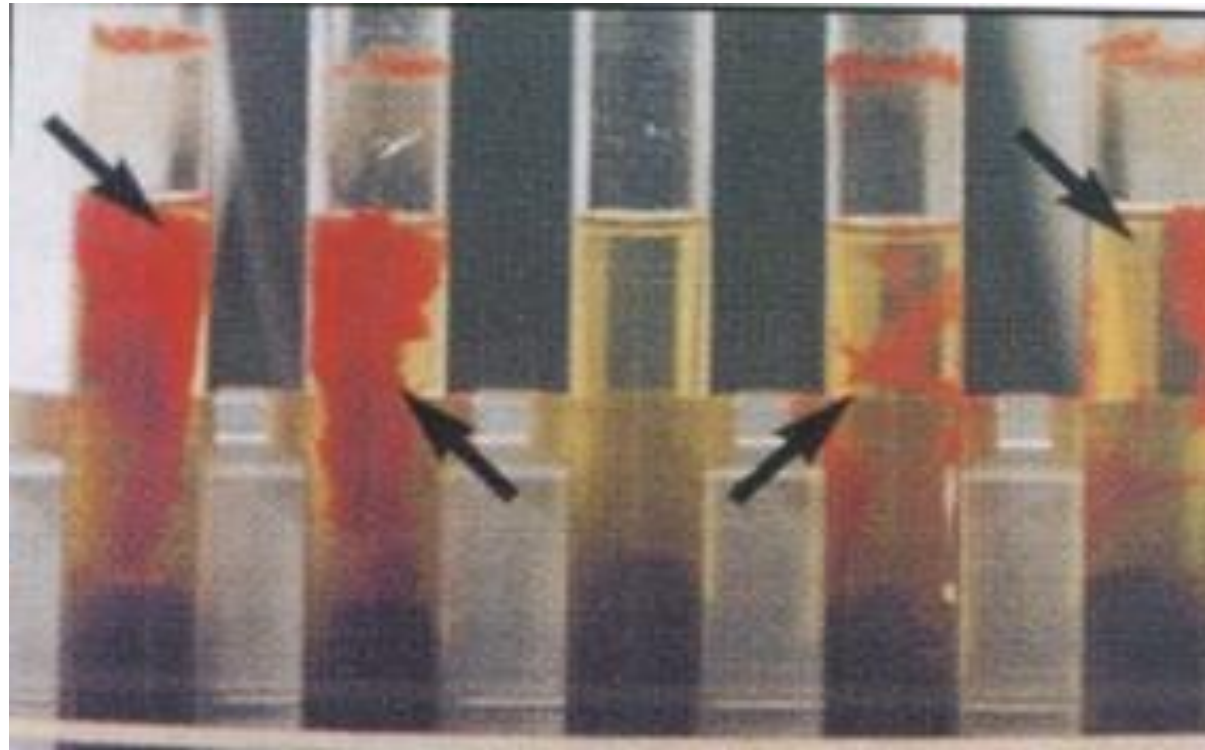
Comparison of different PET tubes at **-80°C**

Brand	Size	Additive	Qty(pcs)	Qty of ruptured tubes(pcs)			
				1h	2h	3h	24h
****	5/100	EDTAK2	20	6	6	6	6
**	5/100	EDTAK2	20	3	3	3	3
IMPROVE	5/100	EDTAK2	20	0	0	0	0

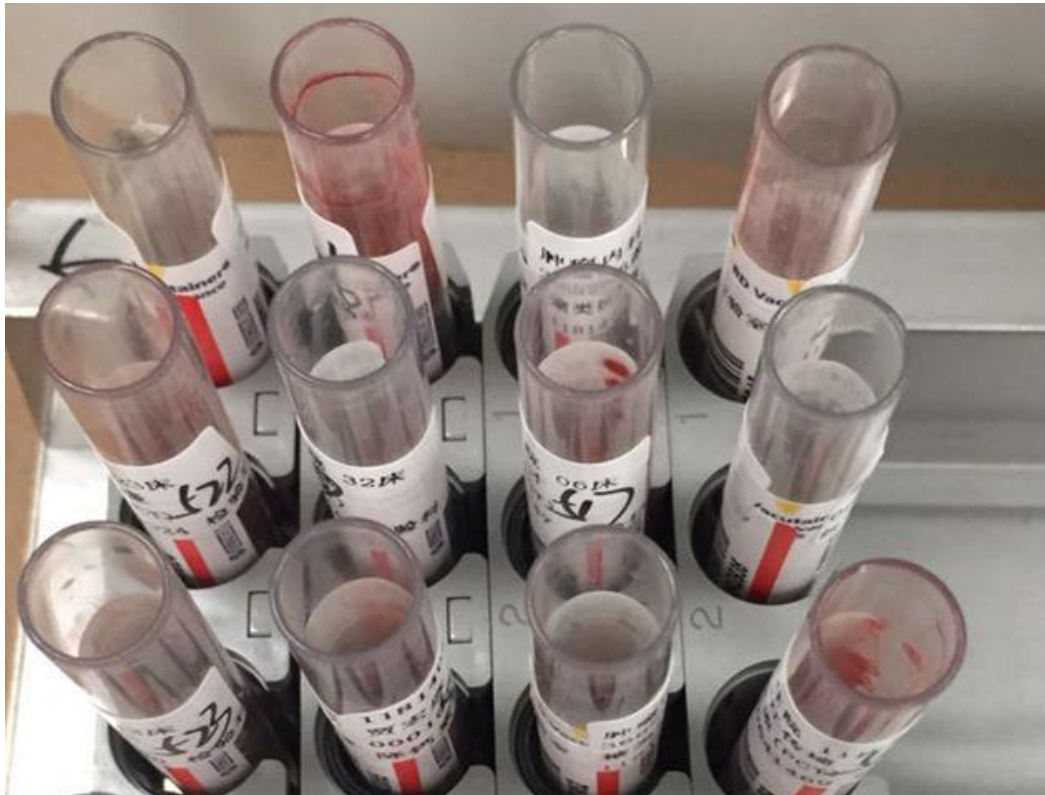


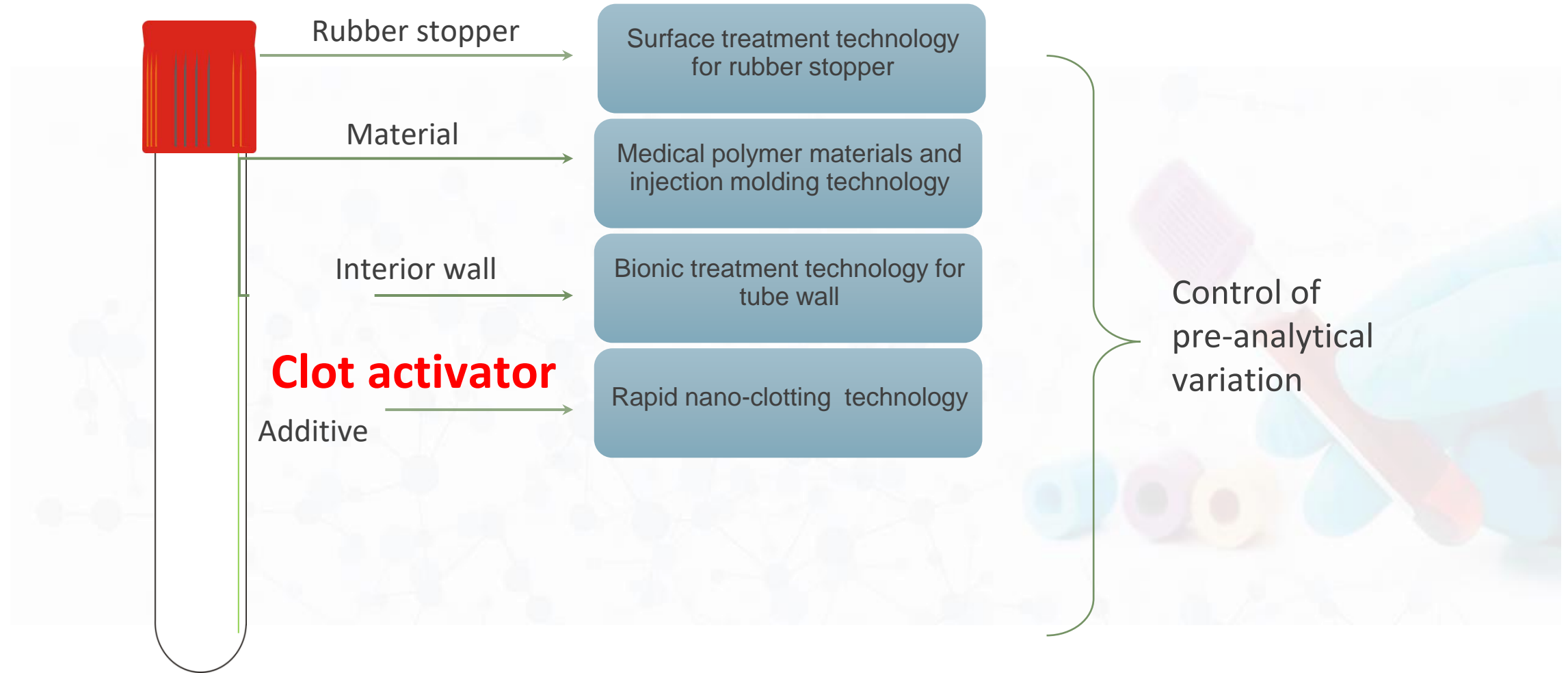
3. Bionic treatment technology for tube wall

The integrity and compactness of bionic treatment



3. Bionic treatment technology for tube wall

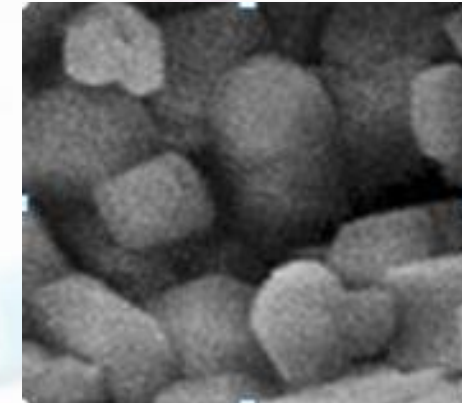
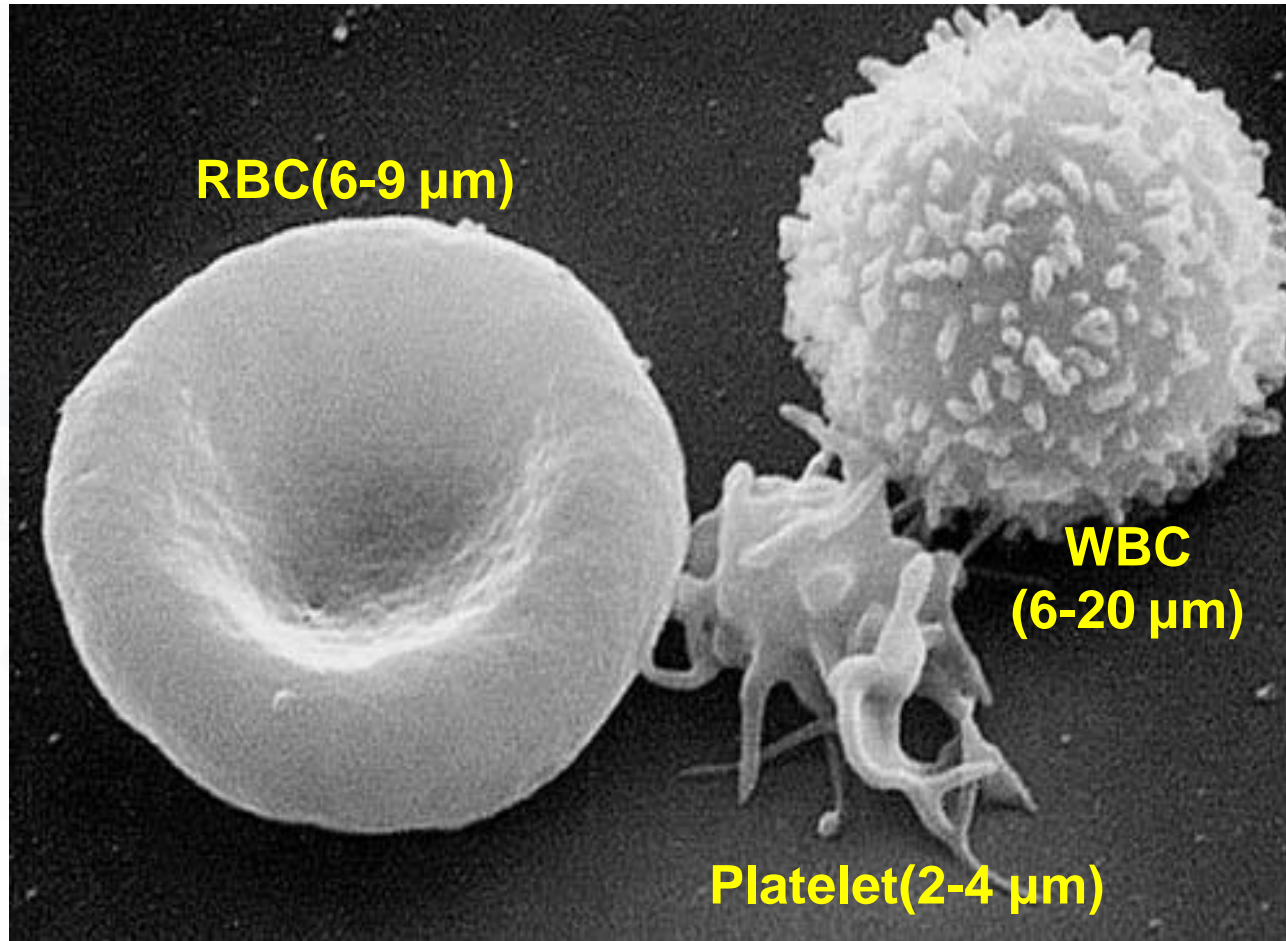




4. Rapid nano-clotting technology

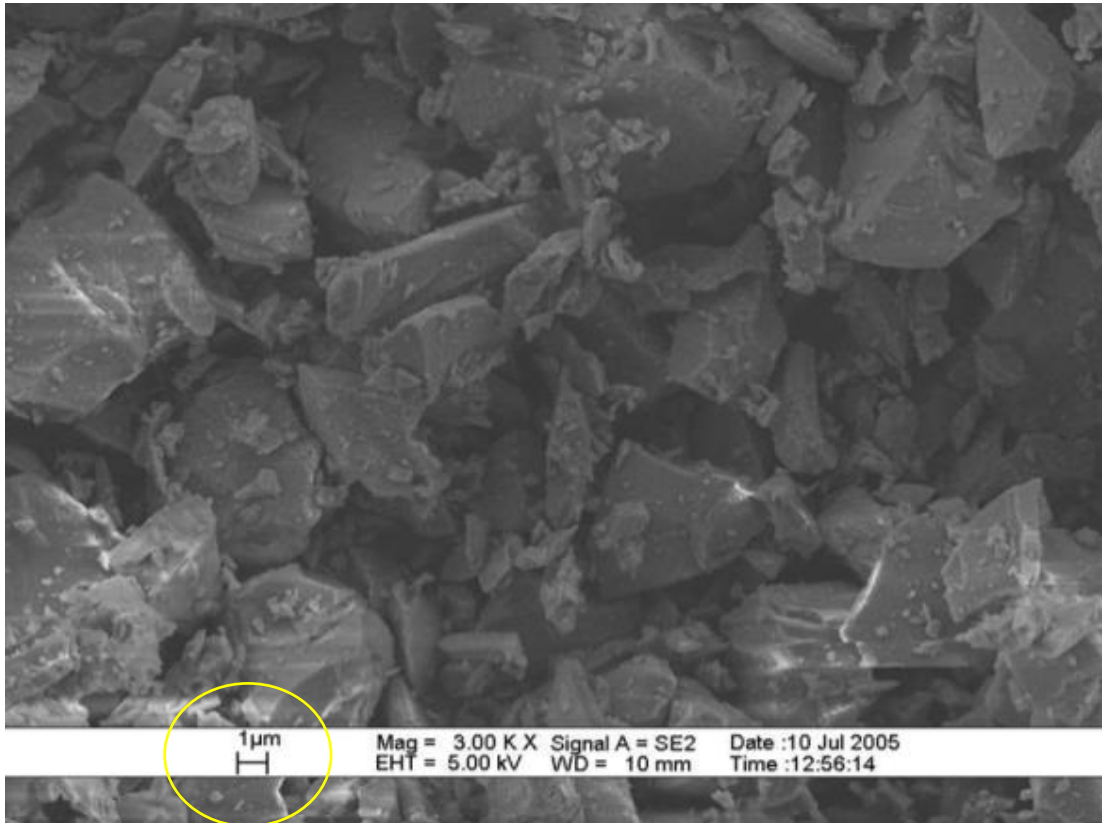
- Nano meter size SiO_2 with constant size, uniformly dispersed in the tube inner wall and mixed with blood completely to accelerate the blood coagulation cascade.
- High quality serum is obtained within **15 mins** under room temperature.

4. Rapid nano-clotting technology



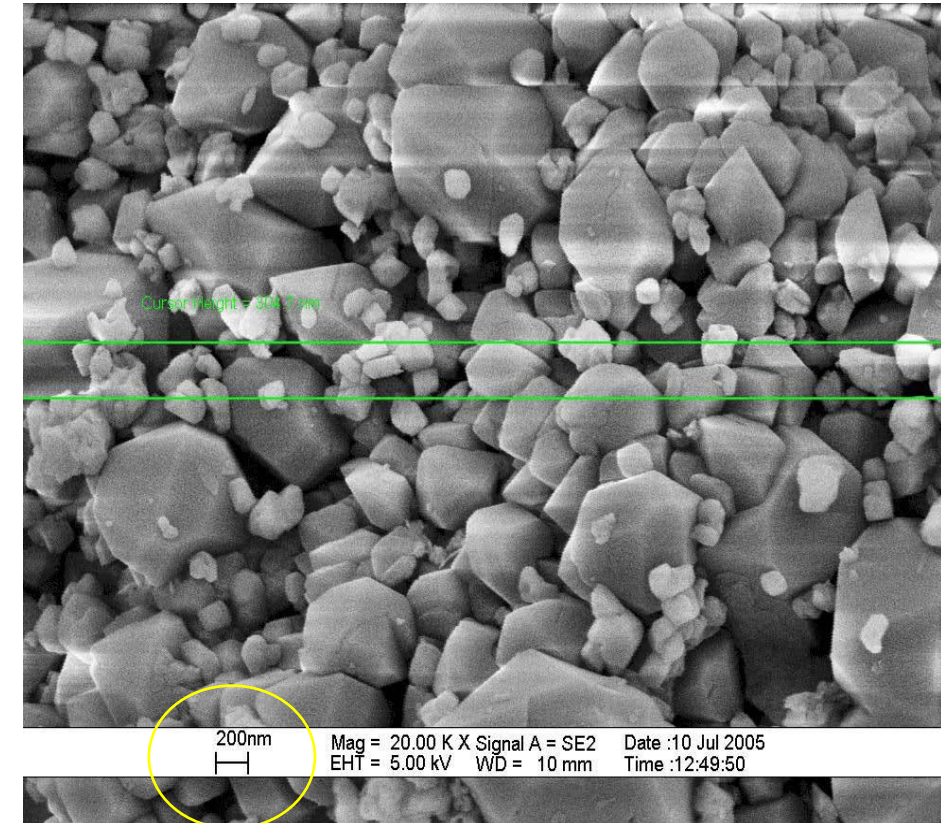
Improve clot
activator
200-900nm

4. Rapid nano-clotting technology



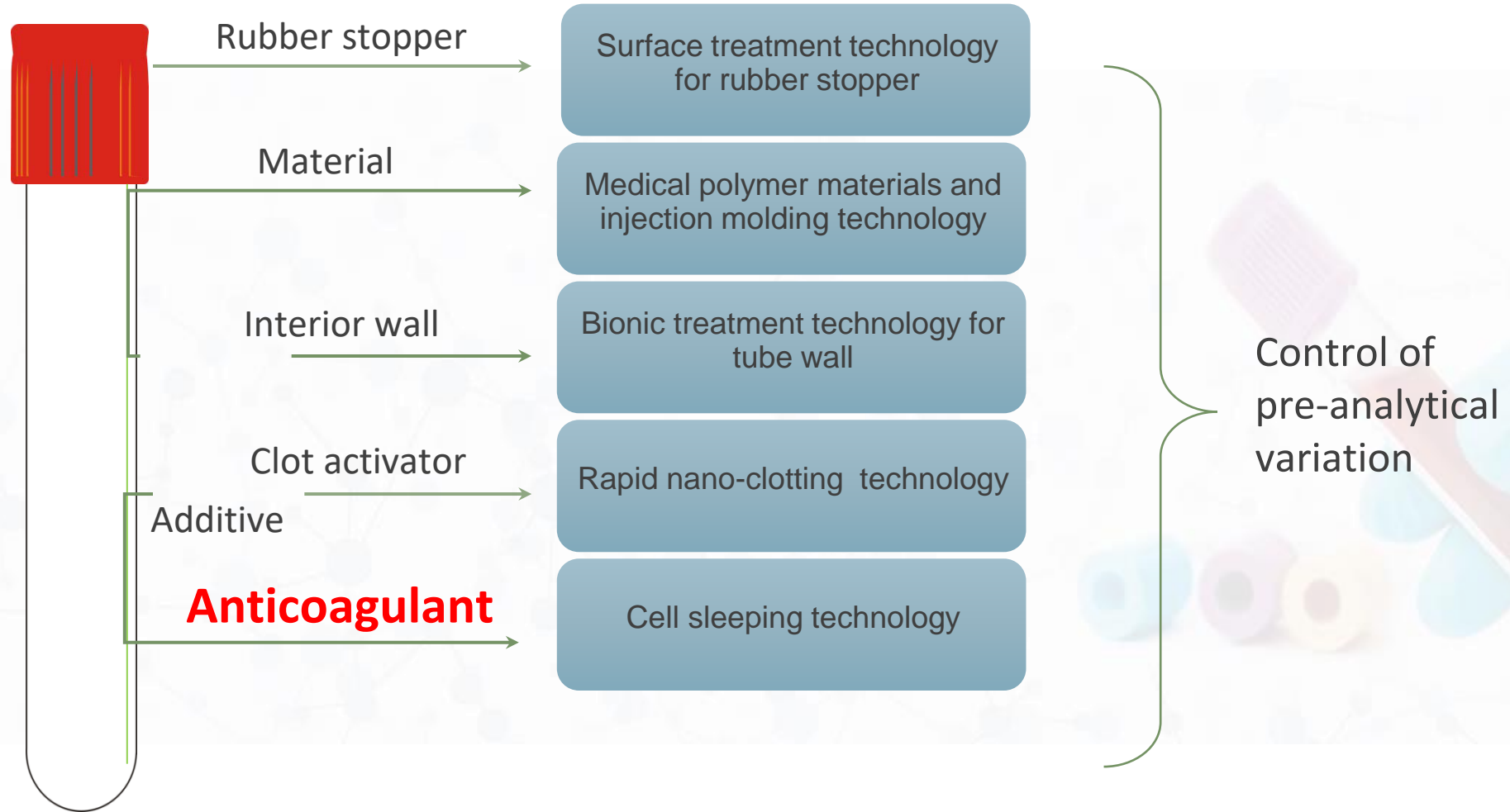
Other brand clot activator

1-3 μm, large particles with sharp edges



Improve clot activator

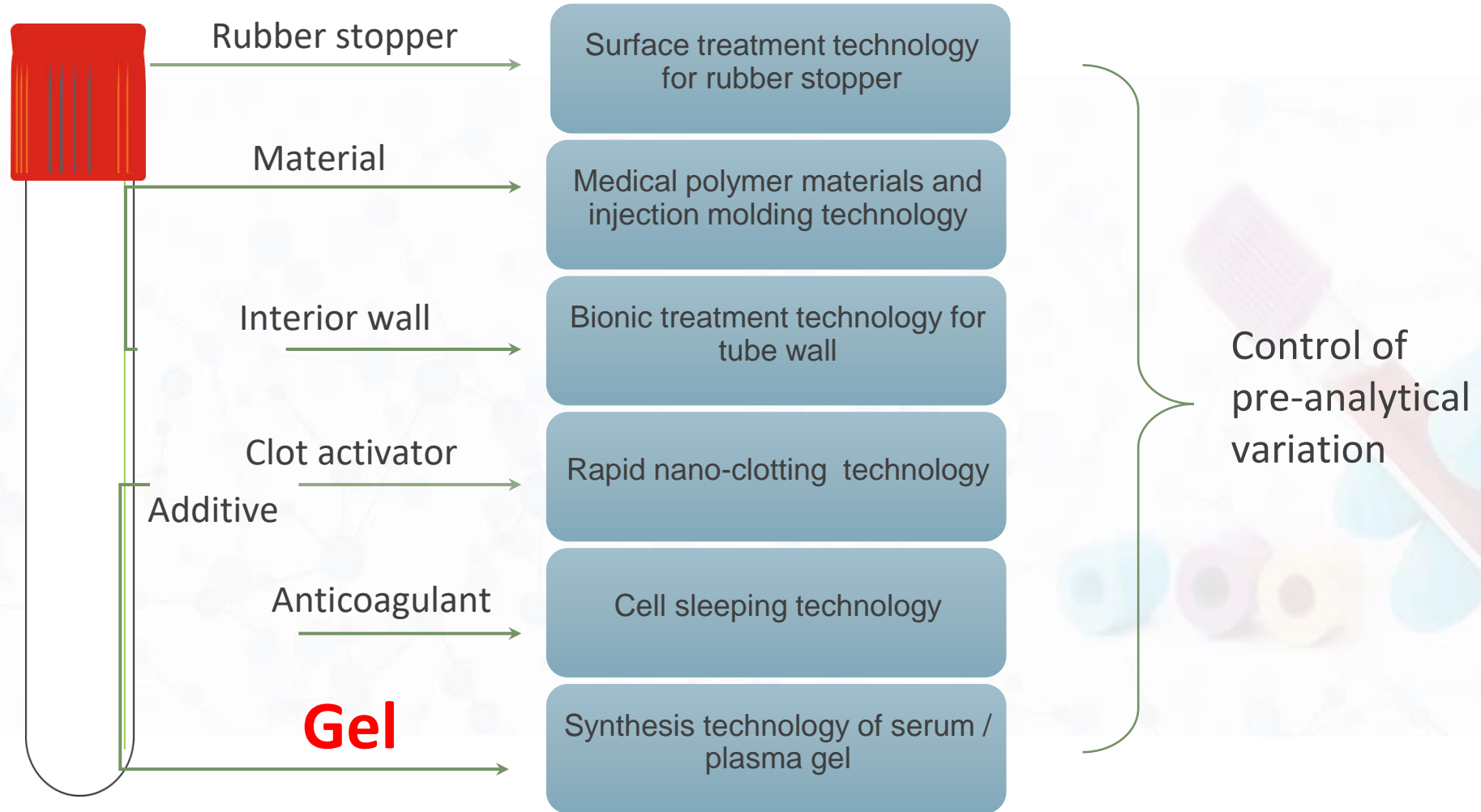
200-900nm, microspheres without sharp edges



5. Cell sleeping technology



- Cell sleeping technology inhibits cell metabolism and keep **stable plasma glucose level within 48h.**
- It provides complete protection for blood cells with less hemolysis.



6. Synthesis technology of Gel

- Gel quality judgement : 1) Degree of inertia and
2) Separation effect
- Self-control & Improvement for Gel Quality



(Density: 1.026-1.031)

Serum

(Density: 1.04-1.06)

Gel

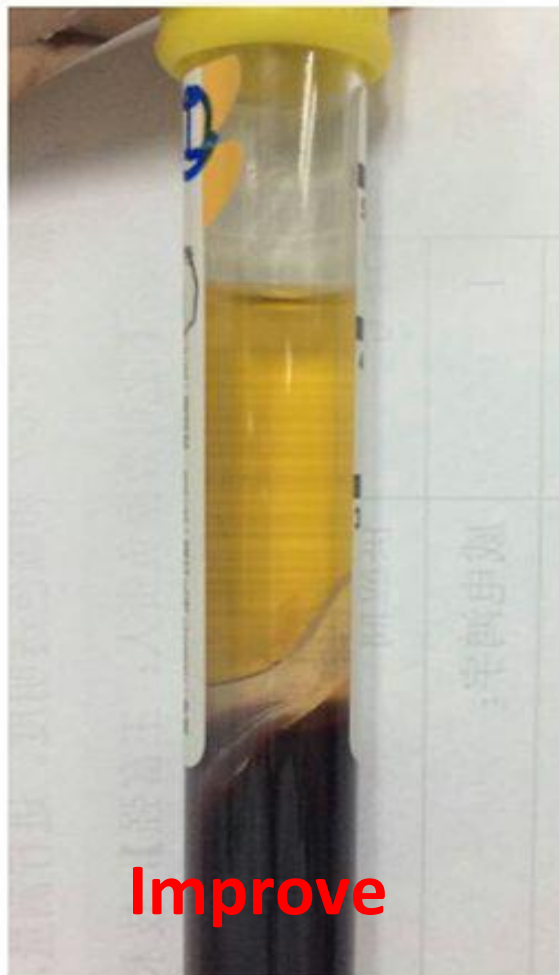
(Density: 1.092-1.095)

Blood Cells

6. Synthesis technology of serum / plasma gel

Comparison of different Gel tubes

with centrifugation in 1min after blood collection



HEMOLYSIS

IMPROVACUTER® POSTER Phlebotomy



IMPROVACUTER® Tube	Additive	Test Items	Inversions
No Additive Tube or Blood Culture Bottle	/	Biochemistry Test Immunology Test	0
Citrate Tube	Sodium Citrate 0.129mol/L(3.8%) 0.109mol/L(3.2%)	Coagulation Determinations on Plasma Specimens	3~5
ESR Tube	Sodium Citrate 0.129mol/L(3.8%) 0.109mol/L(3.2%)	Erythrocyte Sedimentation Rate (ESR)	3~5
Clot Activator Tube	Clot Activator	Serum Determinations in Clinical Chemistry	5~8
Gel & Clot Activator Tube	Gel & Clot Activator	Biochemistry Test	5~8
Heparin Tube	Lithium Heparin Sodium Heparin	Plasma Determinations in Clinical Chemistry and Hemorheology	5~8
Gel & Heparin Tube	Gel & Lithium Heparin Gel & Sodium Heparin	Plasma Determinations in Clinical Chemistry	5~8
EDTA Tube	EDTA. K2 EDTA. K3	Whole Blood Hematology Determinations	Liquid: 3~5 Spray Dried: 5~8
Glucose Tube	Sodium Fluoride/EDTA Sodium Fluoride/Oxalate	Glucose Determinations	5~8
Gel & EDTA.K2 Tube	Gel & EDTA. K2	Plasma Preparation for Molecular Diagnostic and Virus Load Testing	5~8

IMPROVACUTER® tubes are recommended immediate mixing after collection.
Insufficient mixing might result in inaccurate test results and the need to re-draw

*REF: NCCLS H3-A5 Vo 23. No.32, 8. 10. 2.

Storage

Storage tubes at 4-25°C (39-77°F) , unless there is other notice on the package or label.
Do not use tubes after their expiration date.

Barrier Information

Please set refrigerated centrifuges at temperatures between 15-25°C (59-77°F), and the yield of serum or plasma is ideal.

Centrifugation Reference

Centrifugation RCF and Time Recommendations		
Product	RCF (g)	Time (min)
No Additive Tubes	1500-2200	10
Clot Activator Tubes	1500-2200	10
Gel & Clot Activator Tubes	1800-2200	10
Plasma Tubes	1300-1800	10
Plasma Tubes with Gel	1500-1800	10
Sodium Citrate 9:1 Tubes (PT or Coagulation Tubes)	1500-2000	10

Clotting Instructions

Minimum Clotting Time Recommendations	
Product	Time(min)
No Additive Tubes	60
Clot Activator Tubes	30
Gel & Clot Activator Tubes	30

Instructions for Removal of Safety Cap



Instructions for Reinsertion of Safety Cap



IMPROVACUTER® Tube	Additive	Test Items	Inversions
No Additive Tube or Blood Culture Bottle	/	Biochemistry Test Immunology Test	0
Citrate Tube	Sodium Citrate 0.129mol/L(3.8%) 0.109mol/L(3.2%)	Coagulation Determinations on Plasma Specimens	3~5
ESR Tube	Sodium Citrate 0.129mol/L(3.8%) 0.109mol/L(3.2%)	Erythrocyte Sedimentation Rate (ESR)	3~5
Clot Activator Tube	Clot Activator	Serum Determinations in Clinical Chemistry	5~8
Gel & Clot Activator Tube	Gel & Clot Activator	Biochemistry Test	5~8
Heparin Tube	Lithium Heparin Sodium Heparin	Plasma Determinations in Clinical Chemistry and Hemorheology	5~8
Gel & Heparin Tube	Gel & Lithium Heparin Gel & Sodium Heparin	Plasma Determinations in Clinical Chemistry	5~8
EDTA Tube	EDTA. K2 EDTA. K3	Whole Blood Hematology Determinations	Liquid: 3~5 Spray Dried: 5~8
Glucose Tube	Sodium Fluoride/EDTA Sodium Fluoride/Oxalate	Glucose Determinations	5~8
Gel & EDTA.K2 Tube	Gel & EDTA. K2	Plasma Preparation for Molecular Diagnostic and Virus Load Testing	5~8

Jurnal Pendukung

ORIGINAL ARTICLE

임상검사와 원동균리

http://dx.doi.org/10.15263/jnep.2016.38.2.2

Journal of
LABORATORY
MEDICINE / QUALITY
ASSURANCE

Comparison of Improvacuter EDTA Tube with BD Vacutainer EDTA Tube for Routine Hematological Analysis: Clinical Significance of Differences, Stability Study, and Effects of K₂ and K₃ EDTA

Sunyoung Ahn, Sun-Mi Cho, Hwachoon Shin, and Kyung-A Lee
Department of Laboratory Medicine, Gangnam Severance Hospital, Yonsei University College of Medicine, Seoul, Korea

Background: The type of blood collection tubes is an important pre-analytical factor that may affect test results. We compared the test results of the Improvacuter EDTA tube (Improve Medical, China) with those of the currently used BD Vacutainer EDTA tube (Becton Dickinson, USA) and investigated the effects of K₂ and K₃ EDTA additives. **Methods:** Peripheral blood samples from 100 outpatients were collected into the aforementioned tubes. The samples were evaluated for 17 hematological analyte hemoglobin A1c, and erythrocyte sedimentation rate (ESR). The results were analyzed using the paired t-test for comparison. Bland-Altman plots and Passing-Bablok regressions were used for analytes with statistically significant differences in the comparison. If the difference were not within total allowable error, they were defined as clinically significant. For stability testing, the initial results were compared against those from samples preserved for 72 hours.



Universidade Federal do Rio de Janeiro
Faculdade de Farmácia
Departamento de Análises Clínicas e Toxicológicas

Em, 07 de dezembro de 2009

Relatório de teste de tubos de coleta de sangue a vácuo.

Material e Métodos

Foram realizados testes em tubos de coleta de sangue a vácuo no período de 01 a 30 de novembro de 2009, procedentes de três fabricantes distintos, a saber:

- 1- Tubos marca BD Vacutainer contendo K2 EDTA lote nº 8310615 com validade até 03/2010.
- 2- Tubos marca Petrolid contendo K3 EDTA lote nº D19003 com validade até 05/2010.
- 3- Tubos marca Vacuplast contendo K3 EDTA lote nº 081105 com validade até 10/2010.

Foram colhidas amostras de 30 pacientes e voluntários sadios que compareceram em jejum de pelo menos 3 horas, ao Laboratório de Análises Clínicas da Faculdade de Farmácia da Universidade Federal do Rio de Janeiro (LACFAR – UFRJ).

Cada amostra de sangue foi coletada em cada um dos três tubos em estudo e os hemogramas automatizados foram realizados logo após a coleta e após manutenção das amostras 1 hora em temperatura de refrigerador (4° C), controlada por meio de termômetro digital.

Desta forma, cada paciente teve seu exame realizado 6 vezes. Três contagens a temperatura ambiente (TA) e três contagens a 4° C.

O equipamento utilizado para a realização dos hemogramas foi o Abbott Cell Dyn 1700. Foram confeccionadas lâminas de todos os pacientes usando sangue sem anticoagulante e utilizando as amostras de cada um das marcas em estudo em temperatura ambiente e após refrigeração. Todas as lâminas foram observadas em aumento de 1000X objetivando

Laboratório de Análises Clínicas da Faculdade de Farmácia – UFRJ
Av. Carlos Chagas Filho 373
Edifício de Ciências A 2º andar sala 47
Tel: (21) 2562-6423

Clinical evaluation of Clotting Activator Tube

2017-01

1. Methods

➤ Comparison Test

➤ Under the same conditions, 3 specimens were randomly selected for clinical testing, and the total coagulation time and serum quality (Serum production volume, Secondary serum precipitation, Clots on wall, hemolysis) of the specimens were observed.

2. Specimen Information

Item	Tube	Specification	QTY	Lot No.	Expiry Date	Product No.
Clot Activator Tube	BD	3/75	3	5232617	201612	a1, b1, c1
Clot Activator Tube	Greiner	3/75	3	A150635V	201612	a2, b2, c2
Clot Activator Tube	Improve	3/75	3	201702B	201702	a3, b3, c3
Clot Activator Tube	Some Brand	3/75	3	201702A	201702	a4, b4, c4
Clot Activator Tube	Gongdong	3/75	3	1602213	201802	a5, b5, c5

Note: All of the above products are accelerators based on inductive effects (mainly silica)

3. Process

- 3 volunteers as representative a, b, c, each collecting 5 tubes, randomly selected according to the above-mentioned brands, each person collects a tube of each brand;
- After the sample tube was collected, shake it upside down 5 times, stand still to observe the blood coagulation, record the clotting time and abnormalities if happened.
- After standing at room temperature (22-25 ° C) for 30-60 min, centrifuge (3000 r / min, 10 min), observe the blood state after centrifugation, whether there are clumps on the wall, precipitation, hemolysis and other abnormalities, and record the experimental results.

GUANGDONG ENTERPRISE KEY LABORATORY OF BLOOD COMPATIBILITY OF MEDICAL MATERIAL

4. Data Records and Analysis

Specimen Number	Clotting time (min)	Serum Volume	Clots on Wall	Secondary Serum Precipitation	Hemolysis	Compatibility Evaluation
a1	14	40-60%	No	No	No	General
b1	11	40-60%	No	No	No	
c1	12	40-60%	No	No	No	
a2	9	40-60%	No	No	No	Good
b2	10	40-60%	No	No	No	
c2	10	40-60%	No	No	No	
a3	6	40-60%	No	No	No	Very Good
b3	6	40-60%	Good	Good	No	
c3	6	40-60%	No	No	No	
a4	14	40-60%	No	No	No	General
b4	9	40-60%	No	No	No	
c4	10	40-60%	No	No	No	
a5	10	40-60%	No	No	No	
b5	9	40-60%	No	No	No	
c5	10	40-60%	No	No	No	



DEPARTMENT OF HEALTH & HUMAN SERVICE

5. Conclusion

In terms of the total coagulation time, f Greiner > Gongdong > Improve, which shows shortest, 3-5min faster than other brands. It is reported that is to say, the Improve Clot Activator tube under the same conditions than other brands.

In conclusion, Improve tube (Clot Activator) Under the same conditions, it can prevent serum quality of all products is very good. shortened to about 8 minutes, it is logically may have fibrin hanging on the wall due to serum production and quality.

Guangzhou Improve Medical Instruments Co., Ltd.
% Dianna Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K153388

Trade/Device Name: IMPROSAFE® Blood Collection Set With Pre-attached Holder, IMPROVACUTER® Blood Collection Set Pre-attached Holder, IMPROSAFE® Blood Collection Set, IMPROVACUTER® Blood Collection Set, IMPROSAFE® Multi Sample Needle, IMPROSAFE® Multi Sample Needle (flashback), IMPROVACUTER® Multi Sample Needle

Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 3, 2015
Received: February 23, 2016

Dear Dianna Hong:

This letter corrects our substantially equivalent letter of June 7, 2016.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

DE GRUYTER

Clin Chem Lab Med 2014; aop

Cevdet Zungun, Fatma Meriç Yilmaz*, Elif Guney Boru and Canan Topcuoglu

Comparison of Improvacuter™ Tubes with BD Vacutainer™ tubes for various hormones in the aspects of stability and influence of gel separators

DOI 10.1515/cccc-2014-0583
Received June 2, 2014; accepted July 21, 2014

Abstract

Background: Validation of blood collection tubes are important to determine the role of different collection tubes which influence the assurance of laboratory results. We compared two different tubes (Improvacuter™ and Becton Dickinson (BD) Vacutainer™) and investigated the effect of gel and storage time in comparison with each other.

Methods: We compared the results of nine immunoassays performed on UniCel® DxI 800 using blood samples collected in BD Vacutainer SST II Advance tubes, Improvacuter Gel and Clot Activator tubes, BD Vacutainer Clot Activator tubes and Improvacuter tubes. Analytes were measured in all tubes on 3 consecutive days to study the effect of long-term storage. Evaluation of clinical significance was performed based on total allowable error.

Results: Estradiol and testosterone concentrations obtained from Improvacuter Gel and Clot Activator tubes and BD Vacutainer SST II Advance tubes remained below

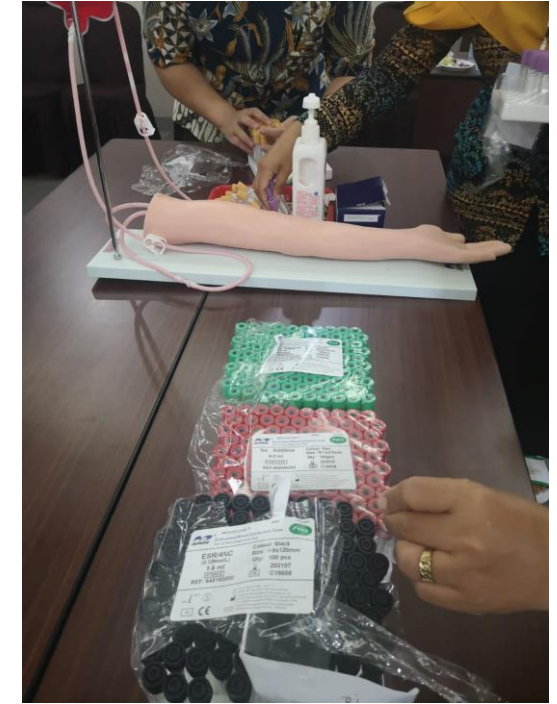
gel containing tubes for estradiol and testosterone are not recommended on UniCel® DxI 800 according to our results. The change in the analyte concentrations over 48 h remained within the TE_a limits for the studied analytes. Improve tubes gave similar results to BD tubes.

Keywords: BD Vacutainer; gel separator tube; hormone assay; improvacuter; stability.

Introduction

In order to minimize preanalytical errors due to prolonged contact of serum with blood cells, Clinical and Laboratory Standards Institute (CLSI) recommends performing the analysis within 2 h following blood collection [1]. The use of serum separator gels has found acceptance among clinical laboratories since they were manufactured and introduced approximately 40 years ago by Becton, Dickinson and Company (BD, Franklin Lakes, NJ, USA). The separator gel formation which is made from polymeric material provides some benefits due to its specific density [2]. The





- Pelatihan Flebotomi untuk meningkatkan keahlian dan keterampilan dari para analis maupun perawat dalam pengambilan sampel
- Mengurangi faktor kesalahan teknis dan kegagalan pengambilan sampel

Customers

- St. Carolous Hospital
- Red Cross (PMI)
- Pramita Laboratorium Klinik
- Biotest Laboratorium Klinik
- Tirta Medical Center
- Sahid Sahirman Hospital
- RS Patria IKKT
- RS Yarsi, Jakarta
- Laboratorium Klinik Daya Medika
- Omni Hospital
- RSAU Hasan Toto
- Abdul Moeloek Hospital
- RS Hermina Group
- RS PGI Cikini
- RS Ciputra Group
- Kalgen Innolab
- Mayapada Clinic, dll
- dan yang berikutnya **ANDA**

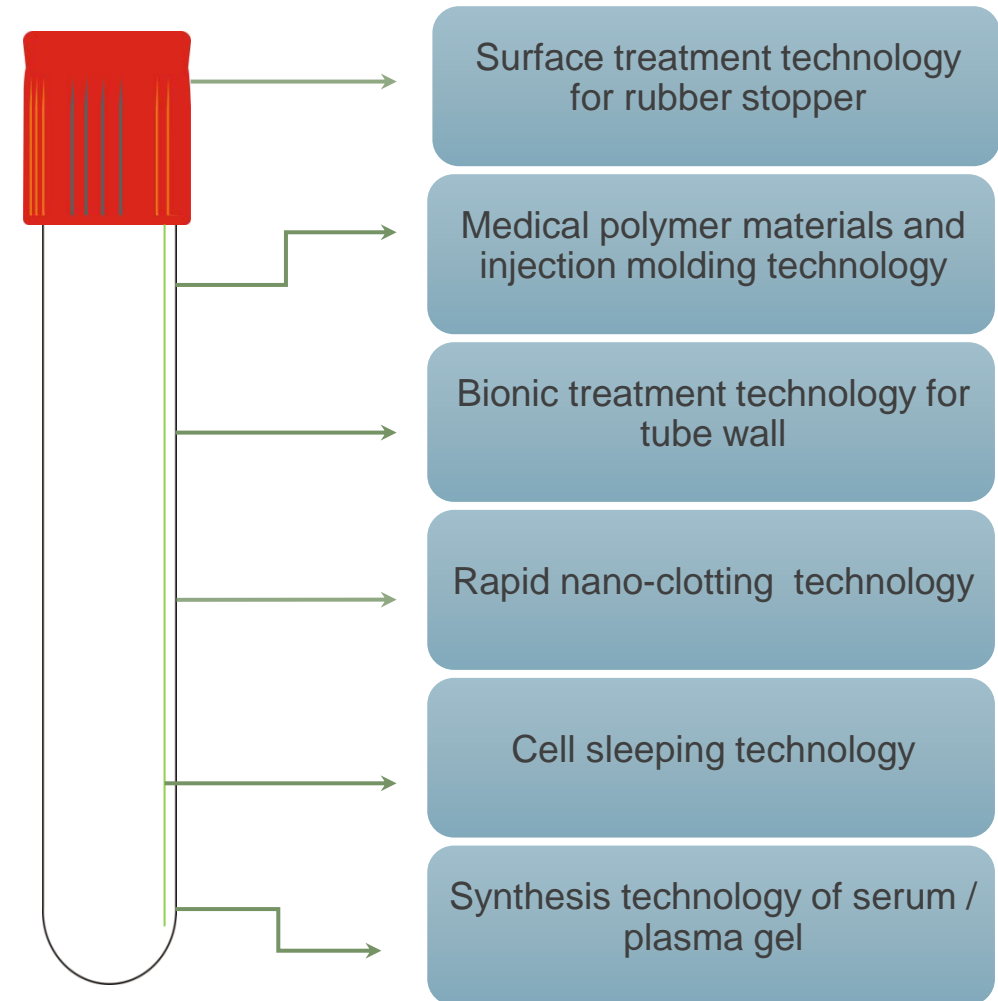


TERIMA KASIH





Info lebih lanjut :
Tommy
0812-9108-0077



<https://forms.gle/v1egmmY1VCF5tjhv6>