

LABORATORY PROCEDURES CENTRAL LABORATORY GC-2

LANCE STUDY PROTOCOL ACH-TRZ-03

GC-2 MONITORING

Maisa Kiffer

Tamara Gagliardi

maisa.kiffer@gcdois.com.br

tamara.gagliardi@gcdois.com.br

Phone: (11) 3528-7406 - extensions No. 6919 / 6921

Fax: (11) 3528-7404

Opening Hours: Monday to Friday 8:30 AM - 6:00 PM

SUPPORT: questions about kits, queries, logistical matters, exams and results release

GENERAL INFORMATION ON VISITS WITH LABORATORY EXAMS

VISITS	Study Stage
V-3	Screening Visit
V-1	Standardization Visit
V1	Treatment Visit
V3	Treatment Visit

**SAMPLES SUBMISSION CONDITION on visits V-3, V-1, V1 and V3:
REFRIGERATED and FROZEN**

EXAMS BY VISIT










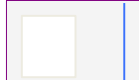

EXAMS	V-3	V-1	V1	V3
COMPLETE BLOOD COUNT AND PLATELETS	✓	✓	✓	✓
COAGULOGRAM (TP/TTPA)	✓	✓	✓	✓
SODIUM	✓	✓	✓	✓
POTASSIUM	✓	✓	✓	✓
SGOT	✓	✓	✓	✓
SGTP	✓	✓	✓	✓
ALKALINE PHOSPHATASE	✓	✓	✓	✓
TOTAL BILIRUBIN AND FRACTIONS	✓	✓	✓	✓
CREATININE	✓	✓	✓	✓
UREA	✓	✓	✓	✓
TOTAL PROTEINS AND FRACTIONS	✓	✓	✓	✓
CPK	✓	✓	✓	✓
CPK MB	✓	✓	✓	✓
PCR	✓	✓	✓	✓
APOLIPOPROTEIN B	✓	✓	✓	✓
GLUCOSE	✓	✓	✓	✓
HB1AC	✓	NA	NA	NA
TOTAL CHOLESTEROL AND FRACTIONS	✓	✓	✓	✓
TRIGLYCERIDES	✓	✓	✓	✓
TSH	✓	NA	NA	NA
TYPE 1 URINE	✓	NA	NA	✓
SERIAL BETA-HCG*	✓	✓	✓	✓

INSTRUCTIONS TO SUBJECTS AND GENERAL OBSERVATIONS








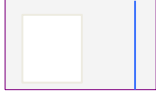

* **WE RECOMMEND 12-HOUR FASTING** in order to meet the recommended interval to perform the lipid panel.

EXAMS	INSTRUCTIONS TO RESEARCH SUBJECTS	ADDITIONAL GUIDELINES
BIOCHEMICAL PANEL, GLUCOSE	08 hour fast	Avoid physical exertion before collection
TOTAL CHOLESTEROL AND FRACTIONS, TRIGLYCERIDES, APOLIPOPROTEIN B	12 hour fast	Maintain your usual diet for at least 5 days
COAGULOGRAM	02 hour fast	Inform if you use medications, especially oral anticoagulants
TSH, CPK	03 hour fast	Do not practice intense physical activity in the three days prior to the exam
COMPLETE BLOOD COUNT AND PLATELETS	04 hour fast	Collection is not recommended after heavy physical activity.








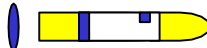

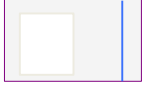

KIT SÃO PAULO COMPOSITION

Visits	Type Kit	Composition	Qty	Item
V-3 V3	Kit A	3.5 mL tube with EDTA	1	
		3.5 mL tube with Separator Gel	4	
		3.5 mL tube with Citrate	1	
		Needle vacuum (25 x 8 mm)	1	
		Holder and Blood Stop	1 / each	
		Transfer tube	1	
		80 mL Urine Vial	1	
		10 mL Conical Tube for Urine	1	
		Pasteur Pipette	2	
		Zip Bag	2	
		Identification Tags	2	
		Exam Request Form	2 counterparts	See page 13








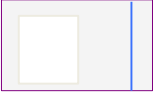

KIT SÃO PAULO COMPOSITION

Visits	Type Kit	Composition	Qty	Item
V-1 V1	Kit B	3.5 mL tube with EDTA	1	
		3.5 mL tube with Separator Gel	4	
		3.5 mL tube with Citrate	1	
		Needle vacuum (25 x 8 mm)	1	
		Holder and Blood Stop	1 / each	
		Transfer tube	1	
		Pasteur Pipette	1	
		Zip Bag	2	
		Identification Tags	2	
		Exam Request Form	2 counterparts	See page 13

KIT COMPOSITION OUT OF SÃO PAULO

Visits	Type Kit	Composition	Qty	Item
V-3 V3	Kit C	3.5 mL tube with EDTA	1	
		3.5 mL tube with Separator Gel	4	
		3.5 mL tube with Citrate	1	
		Needle vacuum (25 x 8 mm)	1	
		Holder and Blood Stop	1/each	
		Transfer tube	5	
		80 mL Urine Vial	1	
		10 mL Conical Tube for Urine	1	
		Pasteur Pipette	2	
		Zip Bag	2	
		Identification Tags	2	
		Exam Request Form	2 counterparts	See page 13

KIT COMPOSITION OUT OF SÃO PAULO

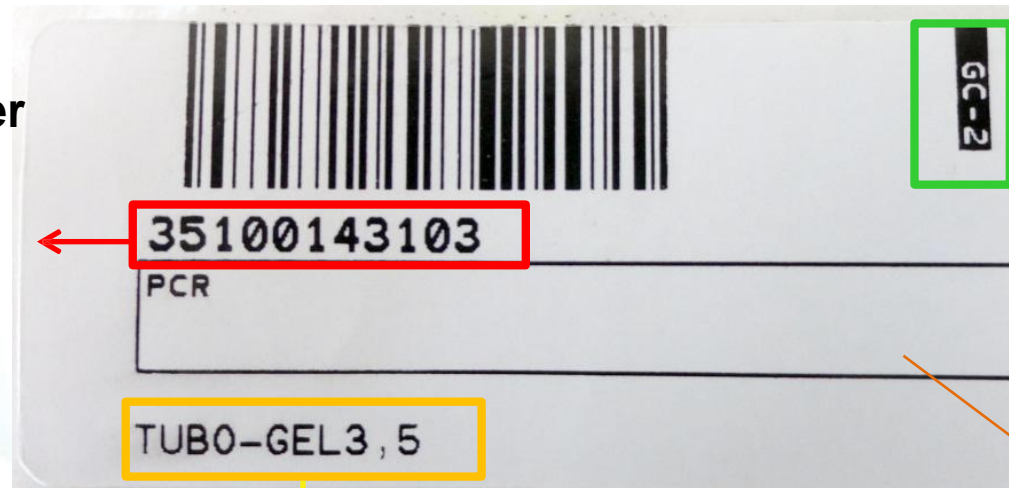
Visits	Type Kit	Composition	Qty	Item
V-1 V1	Kit D	3.5 mL tube with EDTA	1	
		3.5 mL tube with Separator Gel	4	
		3.5 mL tube with Citrate	1	
		Needle vacuum (25 x 8 mm)	1	
		Holder and Blood Stop	1 / each	
		Transfer tube	5	
		Pasteur Pipette	2	
		Zip Bag and Blood Stop	2	
		Identification Tags	2	
		Exam Request Form	2 counterparts	See page 13

GENERAL RECOMMENDATIONS FOR COLLECTION KITS

- ✓ Store the collection kits in an appropriate place, preferably with restricted access;
- ✓ Kits must be stored in a ventilated environment (**15-25°C**) and away from light;
- ✓ Frequently check the expiry dates of the kits and rotate the stock if necessary (prioritize the use of kits with a shorter expiry date);
- ✓ Deadline for replenishing kits (kit production and submission) at research centers: 15 days.
- ✓ Research center must inform GC-2 about the occurrence of losses, damage to kits or the existence of expired kits so that we can update the study kit inventory controlled by GC-2.

TUBE IDENTIFICATION

Tube **bar code number**
(same as the request
form)



GC-2 Identification
Central Laboratory

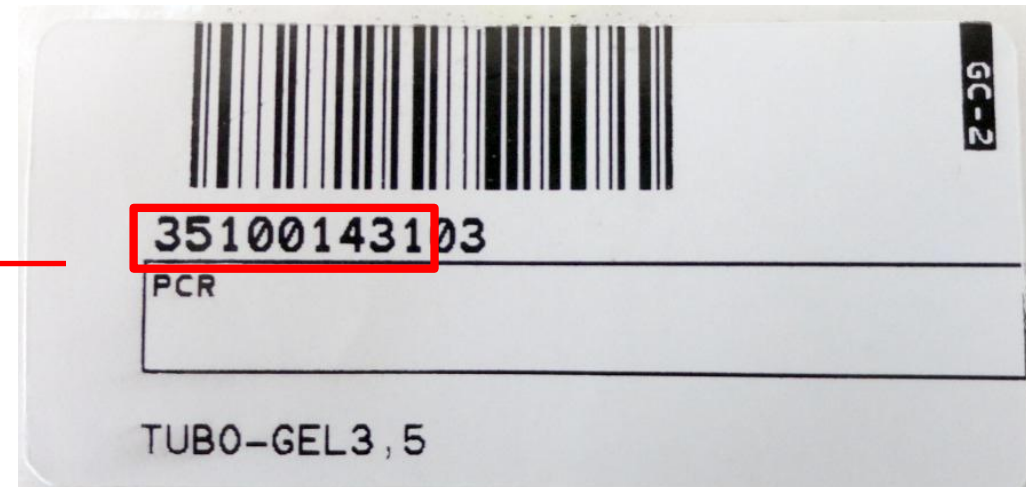
Tube and volume identification

Abbreviations of
analytes/exams
contained in the
tube

TUBE LABELING

PLEASE REVIEW THE LABELING
OF THE TUBES AND VIALS.

The first 9 digits must be the same on all labels of the components of the research subject kit



- If divergences are detected in the **first 9 digits** of the tube/vial labels vs. **the first 9 digits** of the code shown in the right field of the requirement form, please **DISPOSE** of these labels and use the labels for manual filling that are available in the kit and immediately inform GC-2 before submitting the material.
- **Labels** attached to tubes/vials must match the pre-specified numbers on the requirement form = **IMPORTANT VERIFICATION** to avoid changing tubes between different research subjects
- **TUBES WITH NO IDENTIFICATION LABEL CANNOT BE ANALYZED.**

LABORATORY REQUIREMENT FORM

Avenida Nações Unidas, 12.399
Edifício Landmark - 12º andar - conj 125
CEP 04578-000, São Paulo - SP
Tel: +55 11 3512-6911
Fax: +55 11 3512-6911

GC2

3612
*3612

Biquetas: 351-001554-01 351-001407-11
351-001554-01 351-001407-11
351-001554-01 351-001407-12
351-001554-01 351-001407-13
351-001554-01 351-001407-14
351-001554-01 351-001407-15

FORMULÁRIO DE REQUISIÇÃO LABORATORIAL

Iniciais Paciente :

Data de Nascimento : ____ / ____ / ____
Dia Mês Ano

Nº de Triagem : _____

Nº de Randomização : _____

Data da Coleta : ____ / ____ / ____
Dia Mês Ano

Horário : ____ : ____ (24 horas)
HH MM

Sexo : Feminino Masculino

Visita

VT1 VISITA EXTRA: LACIDO URICO
 ALBUMINA
 AMILASE
 ANTI HBS
 CLORO
 HEMOGRAMA

Amostras Enviadas

Preenchido pelo Centro					Preenchimento GC-2
Condição Envio	Quantidade	Tubos enviados:	Kit Customizado	Lista de Verificação	Nº de Tubos
Refrigerado	2	Tubo com gel separador 3,5	<input type="checkbox"/>	<input type="checkbox"/>	
Refrigerado	1	Tubo Edta 3,5 ml	<input type="checkbox"/>	<input type="checkbox"/>	

Para maiores informações, ler as instruções no Manual de Procedimentos Laboratoriais

Comentários Adicionais:

Preenchido por: _____ Assinatura: _____ em _____

PRIMEIRA VIA: Envie junto com as amostras para GC-2

SEGUNDA VIA: Arque no Centro de Pesquisa

CAUTIONS

1. Use **UPPERCASE** letters with legible handwriting.
2. Complete all fields with no exception - highlighted in **RED**.
3. In case of **RETEST**, select the necessary exams
4. If the **BHCG** test is not necessary, justify it in the NOTE field (e.g. Not Applicable - NA)
5. The form must be signed and dated (according to GCP - Good Clinical Practices) in the field highlighted in **GREEN**
6. In case of an error in filling out the form, **NEVER** erase or use correction fluid. Cross it out, put your initials and date, then enter the correct information on the side.
7. Send the original copy of the completed form along with the samples to the Central Laboratory.
8. Keep the 2nd counterpart completed in the research center files.


COLLECTION ORDER

Order for the collection of the sample tubes

*Clinical and Laboratory Standards Institute (CLSI-Former NCCLS)
recommendations – 2003 – H3-A5 - §8.10.2*










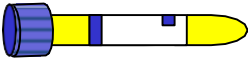
1st 
Blue
CITRATE TUBE

2nd 
Yellow
TUBE WITH SEPARATOR GEL

3rd 
Purple
TUBE EDTA

SAMPLE PANEL

V-3 and V3 – COLLECTION - São Paulo

	BLOOD COUNT (HB1AC in V-3)	BIOCHEMISTRY	BHCG (V-3 and V3) TSH (only V-3)	COAGULOGRAM	URINE 1
Collection Material	 1 EDTA Tube – 3.5 mL	 3 Tubes with separator gel – 3.5 mL	 1 Tube with separator gel – 3.5 mL	 1 Citrate Tube – 3.5 mL	 80 mL urine vial
Submission Material	TOTAL BLOOD	TOTAL BLOOD	TOTAL BLOOD	PLASMA	URINE
Submission Condition	REFRIGERATED	REFRIGERATED	REFRIGERATED	FROZEN	REFRIGERATED
Material sent to the Central Laboratory GC-2	 1 EDTA Tube – 3.5 mL	 3 Tubes with separator gel – 3.5 mL	 1 Tube with separator gel – 3.5 mL	 1 Transfer tube – 5 mL	 10 mL conical tube

SAMPLE PANEL

V-1 and V1 – COLLECTION - São Paulo

BLOOD COUNT

BIOCHEMISTRY

BHCG

COAGULOGRAM

Collection Material



1 EDTA Tube – 3.5 mL



3 Tubes with separator gel
– 3.5 mL



1 Tube with separator gel – 3.5 mL



1 Citrate Tube – 3.5 mL

Submission Material

TOTAL BLOOD

TOTAL BLOOD

TOTAL BLOOD

PLASMA

Submission Condition

REFRIGERATED

REFRIGERATED

REFRIGERATE
D

FROZEN

Material sent to the Central Laboratory GC-2



1 EDTA Tube – 3.5 mL



3 Tubes with separator gel
– 3.5 mL












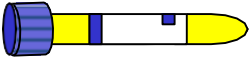
1 Tube with separator gel
– 3.5 mL



1 Transfer tube
– 5 mL









SAMPLE PANEL

V-3 and V3 – COLLECTION - Out of São Paulo

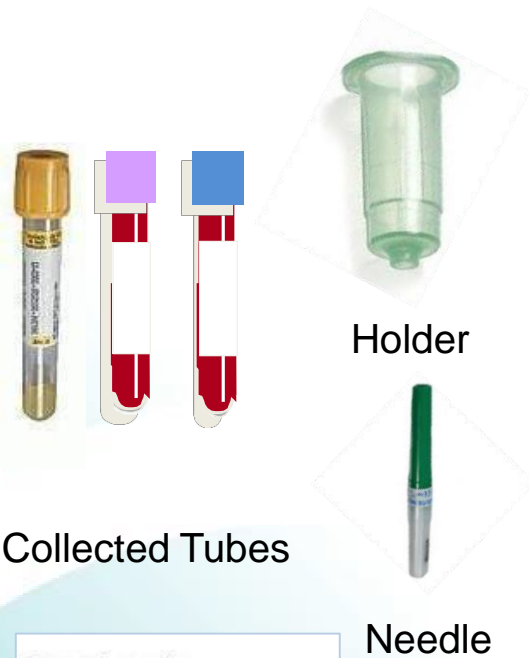
	BLOOD COUNT (HB1AC in V-3)	BIOCHEMISTRY	BHCG and TSH TSH (only V-3)	COAGULOGRAM	URINE 1
Collection Material	 1 EDTA Tube – 3.5 mL	 3 Tubes with separator gel – 3.5 mL	 1 Tube with separator gel – 3.5 mL	 1 Citrate Tube – 3.5 mL	 80 mL urine vial
Submission Material	TOTAL BLOOD	SERUM	SERUM	PLASMA	URINE
Submission Condition	REFRIGERATED	REFRIGERATED	REFRIGERATED	FROZEN	REFRIGERATED
Material sent to the Central Laboratory GC-2	 1 EDTA Tube – 3.5 mL	 3 Transfer tubes – 5 mL	 1 Transfer tube – 5 mL	 1 Transfer tube – 5 mL	 10 mL conical tube

SAMPLE PANEL

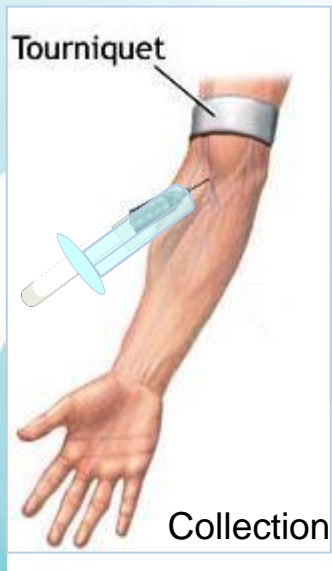
V-1 and V1 – COLLECTION - Out of São Paulo

	BLOOD COUNT	BIOCHEMISTRY	BHCG	COAGULOGRAM
Collection Material	 1 EDTA Tube – 3.5 mL	 3 Tubes with separator gel – 3.5 mL	 1 Tube with separator gel – 3.5 mL	 1 Citrate Tube – 3.5 mL
Submission Material	TOTAL BLOOD	SERUM	SERUM	PLASMA
Submission Condition	REFRIGERATED	REFRIGERATED	REFRIGERATED	FROZEN
Material sent to the Central Laboratory GC-2	 1 EDTA Tube – 3.5 mL	 3 Transfer tubes – 5 mL	 1 Transfer tube – 5 mL	 1 Transfer tube – 5 mL

GENERAL VACUUM COLLECTION INSTRUCTIONS

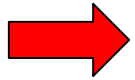


- Universal precautions must be taken whenever working with blood or any biological fluid.
- Always have at hand all the collection material necessary for the procedure.
- Accommodate the subject in a comfortable position (sitting or lying down).
- The collection must be made by direct vein puncture, for minimal venous occlusion, choose the antecubital vein (as shown in the figure beside).
- Connect the tube under vacuum and ensure complete sample aspiration.
- Carefully remove the needle and compress immediately with dry gauze or cotton wool, for about 1 minute and then place the blood stop.
- After finishing the collection, dispose of the needle in an appropriate container for waste.



STANDARD SAMPLE TREATMENT PROCEDURES SÃO PAULO

Visits V-3, V-1, V1 and V3



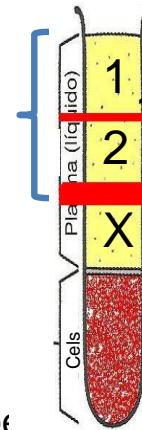
Collect blood samples in the following order



1 Citrate Tube – 3.5 mL



- Homogenize the tube carefully by inversion, about 5 to 8 times
- Centrifuge **within 2 hours after collection** for minutes at 1500g
- Visually divide the plasma into 03 parts as shown in the figure.
- **CAREFULLY** transfer the **two upper parts** of the plasma (about 1 mL), not resuspending the liquid. Leave the third part of the plasma in the tube
- Freeze the sample (-20°C) until the time of submission (submit it **frozen** - require dry ice).



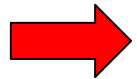
Frozen
Samples



1 Transfer tubes
– 5 mL

STANDARD SAMPLE TREATMENT PROCEDURES SÃO PAULO

Visits V-3, V-1, V1 and V3



Collect blood samples in the following order



4 Tubes with separator gel – 3.5 mL



- Place in an upright position to clot for 15-30 minutes.
- Centrifuge immediately at 1500xg for 15 minutes
- Keep the sample refrigerated until submission time.



4 Tubes with separator gel – 3.5mL



1 EDTA Tube – 3.5 mL



- Immediately after collection**, the blood sample tube with EDTA (purple cap) needs to be gently inverted 8-10 times to obtain a complete mixture with the anticoagulant. It is extremely important that this step is carried out.



1 EDTA Tube – 3.5 mL

Refrigerated
Samples

STANDARD SAMPLE TREATMENT PROCEDURES SÃO PAULO

Visits V-3 and V3



80 mL urine vial



- Collect the first urine in the morning or after 4 hours without urinating.
- Discard the first jet and collect the middle jet
- Guide the subject to clean the genitals with water and mild soap.
- Transfer 10mL to the conical tube with the aid of a pasteur pipette
- Keep the sample refrigerated until submission time.

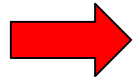


1 Conical tube – 10 mL

Refrigerated
Samples

STANDARD SAMPLE TREATMENT PROCEDURES OUT OF SÃO PAULO

Visits V-3, V-1, V1 and V3



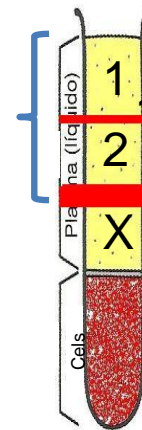
Collect blood samples in the following order



1 Citrate Tube – 3.5 mL



- Homogenize the tube carefully by inversion, about 5 to 8 times
- Centrifuge **within 2 hours after collection** for minutes at 1500g
- Visually divide the plasma into 03 parts as shown in the figure.
- **CAREFULLY** transfer the **two upper parts** of the plasma (about 1 mL), not resuspending the liquid. Leave the third part of the plasma in the tube.
- Freeze the sample (-20°C) until the time of submission (submit it **frozen** - require dry ice).



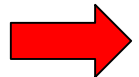
Frozen
Samples



1 Transfer tubes – 5 mL

STANDARD SAMPLE TREATMENT PROCEDURES OUT OF SÃO PAULO

Visits V-3, V-1, V1 and V3



Collect blood samples in the following order



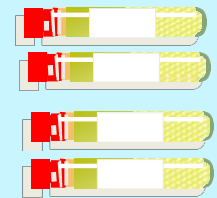
4 Tubes with separator gel – 3.5 mL



- Place in an upright position to clot for 15-30 minutes.
- Centrifuge immediately at 1500xg for 15 minutes
- Transfer the serum to the transfer tube with the help of a pasteur pipette
- Keep the sample refrigerated (4-8°) until submission time.



Refrigerated
Samples



4 Transfer tubes – 5 mL



1 EDTA Tube – 3.5 mL



- Immediately after collection**, the blood sample tube with EDTA (purple cap) needs to be gently inverted 8-10 times to obtain a complete mixture with the anticoagulant. It is extremely important that this step is carried out.
- Keep the sample refrigerated (refrigerator 4-8°) until the submission time.



1 EDTA Tube – 3.5 mL

STANDARD SAMPLE TREATMENT PROCEDURES OUT OF SÃO PAULO

Visits V-3 and V3



80 mL urine vial



- Collect the first urine in the morning or collect after 4 hours without urinating.
- Discard the first jet and collect the middle jet
- Guide the subject to clean the genitals with water and mild soap.
- Transfer 10mL to the conical tube with the aid of a pasteur pipette
- Keep the sample refrigerated until submission time.



Refrigerated
Samples



1 Conical tube – 10 mL

SAMPLE CENTRIFUGATION

Centrifugation at 1500 x g for 15 min

ATTENTION: It is important that the tubes are equally balanced in the centrifuge:

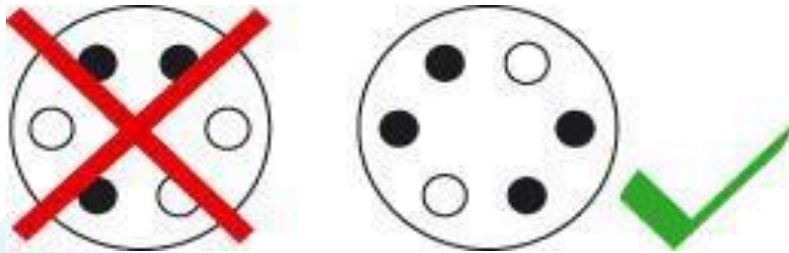


Table referring to g = 1500 (Radius vs. Velocity)

RADIUS (cm)	VELOC. (rpm)	RADIUS (cm)	VELOC. (rpm)
7	4 300 at 4 400	17	2 800 at 2 900
8	4 000 at 4 100	18	2 700 at 2 800
9	3 800 at 3 900	19	2 600 at 2 700
10	3 600 at 3 700	20	2 500 at 2 600
11	3 400 at 3 500	21	2 500 at 2 600
12	3 300 at 3 400	22	2 400 at 2 500
13	3 200 at 3 300	23	2 400 at 2 500
14	3 000 at 3 100	24	2 300 at 2 400
15	2 900 at 3 000	25	2 300 at 2 400
16	2 800 at 2 900	26	2 200 at 2 300

NOTE

If the centrifuge available at the center is not able to carry out the necessary RPMs, as calculated in "FORMULA 1", proceed as follows:

- 1) Calculate the maximum force (No. of g) that the centrifuge can apply, using FORMULA 2.
- 2) Substitute this value in FORMULA 3 to determine the amount of time needed in the centrifuge of the center.

Formula 1

$RPM = 1000 \times \text{square root} [(N.\text{of } g) / (11.18) \times \text{radius}(\text{cm})]$

Formula 2

$g = 11.18 [(RPM/1000)^2 \times \text{radius} (\text{cm})]$

Formula 3

Time (centrifuge of the center) =

$$\frac{(\text{Time required} \times \text{No. of } g \text{ required})}{\text{No. of } g \text{ of the centrifugation of the center}}$$

KIT REQUIREMENT

Formulário de Solicitação de Kits

Enviar por Fax: (11) 3528 7404 ou email: monitoria@gcdois.com.br

 Complete com letra legível utilizando caneta esferográfica preta

DATA DE HOJE:
CENTRO DE PESQUISA:
INVESTIGADOR:
SOLICITANTE
TELEFONE:
PROTOCOLO:
PATROCINADOR:

KITS SOLICITADOS PELO CENTRO					KITS AUTORIZADOS PELO PATROCINADOR (se aplicável)	
NOME DA VISITA	QT.	MOTIVO				QT. AUTORIZADA
		REABASTECIMENTO	EXPIRADO	PERDIDO	OUTROS	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

ATENÇÃO: PRAZO DE ENTREGA DE 15 DIAS

MATERIAL DE TRANSPORTE	QUANTIDADE SOLICITADA PELO CENTRO	QUANTIDADE AUTORIZADA PELO PATROCINADOR (se aplicável)
<input type="checkbox"/> CAIXAS REFRIGERADAS UN3373		
<input type="checkbox"/> GELO REUTILIZAVEL		

DOCUMENTOS	QUANTIDADE
<input type="checkbox"/> FORMULÁRIO DE REQUISIÇÃO DE EXAMES	
<input type="checkbox"/> AWB	
<input type="checkbox"/> DECLARAÇÃO DE TRANSPORTE	
<input type="checkbox"/> OUTROS:	

ATUALIZAÇÃO DO ENDEREÇO DE ENVIO (SE NECESSÁRIO):

APENAS PARA ESTE ENVIO - ENDEREÇO: _____

ALTERAÇÃO PERMANENTE DO ENDEREÇO DE ENVIO: _____

OBSERVAÇÃO: _____

Av. Nações Unidas, 12.3996 conj. 125A – Ed. Landmark
04578-000 - São Paulo – SP
Tel. (11) 3528-7406 | Fax. (11) 3528-7404

Send to FAX: 3528-7404

or

Via email described on slide 02

Contact GC-2 monitoring 15 days in advance to supply with new kits if necessary.

KITS DELIVERY TIME AFTER REQUIREMENT: NO MORE THAN 15 BUSINESS DAYS

REUSABLE ICE HANDLING INSTRUCTIONS



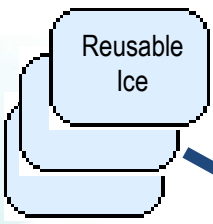
Manufacturer Description:
Rigid Reusable Ice (Gela Kent - GK) – 200mL

Specifications:
Rigid ice
Technical data
Volume: 200mL.
Ice size: 12x7x3cm..
Ice composition: non-toxic acrylic thickener, polyethylene.
Manufacturer: Gela Kent - GK produtos térmicos e hospitalares Ltda.

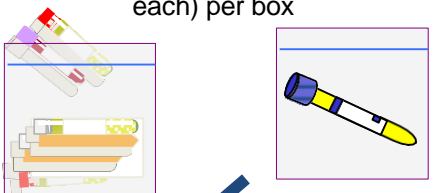
- ✓ Keep the reusable ice in the freezer.
- ✓ 3 reusable ice packs will be used per box (3 liters).
- ✓ Accommodate one (1) ice at the bottom of the box and one (1) ice on each side (total = 3).
- ✓ **WARNING: do not place the collection tubes in direct contact with the reusable ice. Always **protect** it using paper towels or plastic bags.**

PACKAGING INSTRUCTIONS FOR REFRIGERATED SAMPLES

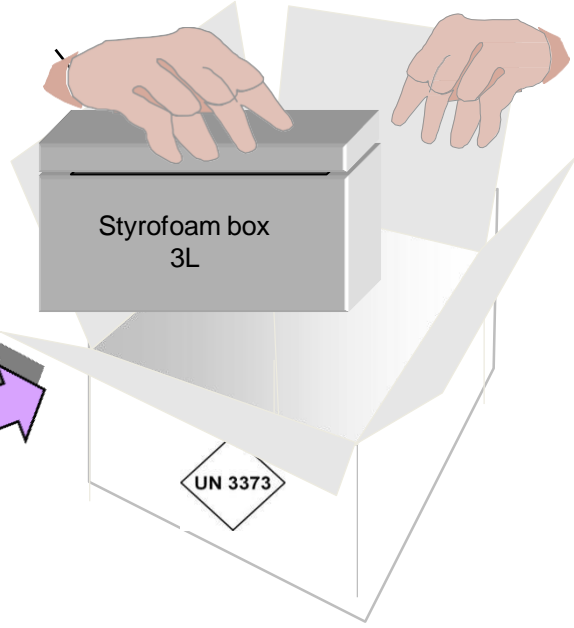
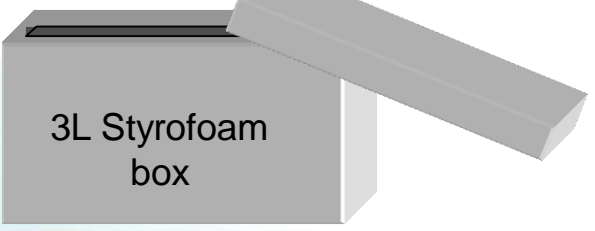
1st Insert the three reusable ice units on the bottom and sides of the box



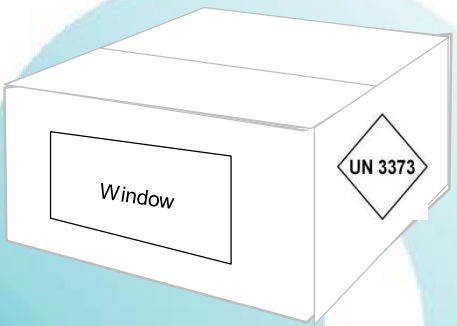
2nd Insert the zip bags with the samples, maximum 4 zip bags (no more than 5 tubes each) per box



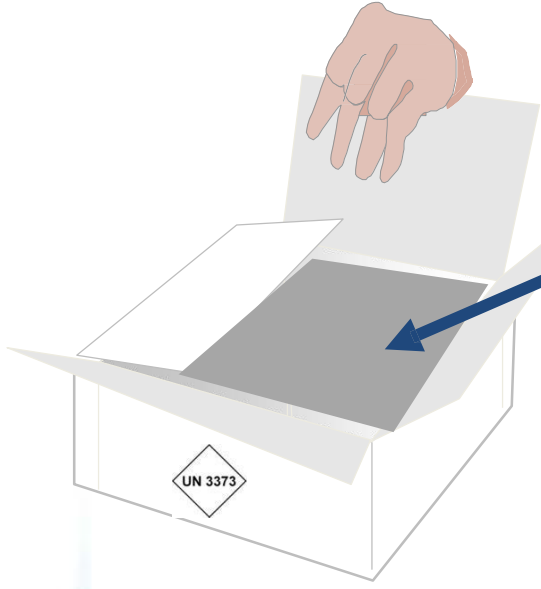
Note that urine must be sent in a zip bag separate from the tubes



UN 3373



4th Attach the AWB/Transport Statement to the "window" on the outside of the cardboard box



3rd Place one counterpart of each Request Form for each sample of subject sent, between the styrofoam box and the cardboard box

GC-2
 Avenida Magalhães Mendes, 12.350
 Edifício Lactobios - 12080-900 São Paulo - SP
 Unidade: Hematólogia Coagulada
 Fone: 11 3123-2197

Center X
 XXXXXXXXXXXXXXXXXXXXXXX
 XXXXXXXXXXXXXXXXXXXXXXX
 XXXXXXXXXXXXXXXXXXXXXXX
 XXXXXXXXXXXXXXXXXXXXXXX
 XXXXXXXXXXXXXXX

FORM OF REQUIREMENT OF EXAM

Initials: Date of Collection: ____/____/____
 Screening No.: TR _____ Collection time: ____:____:____ (24 hours)
 Randomization No.: _____ Fasting: yes no
 Date of Birth: ____/____/____ Weight: _____ Height: _____
 Gender: Female Male HCG is required? yes no
 Note: _____

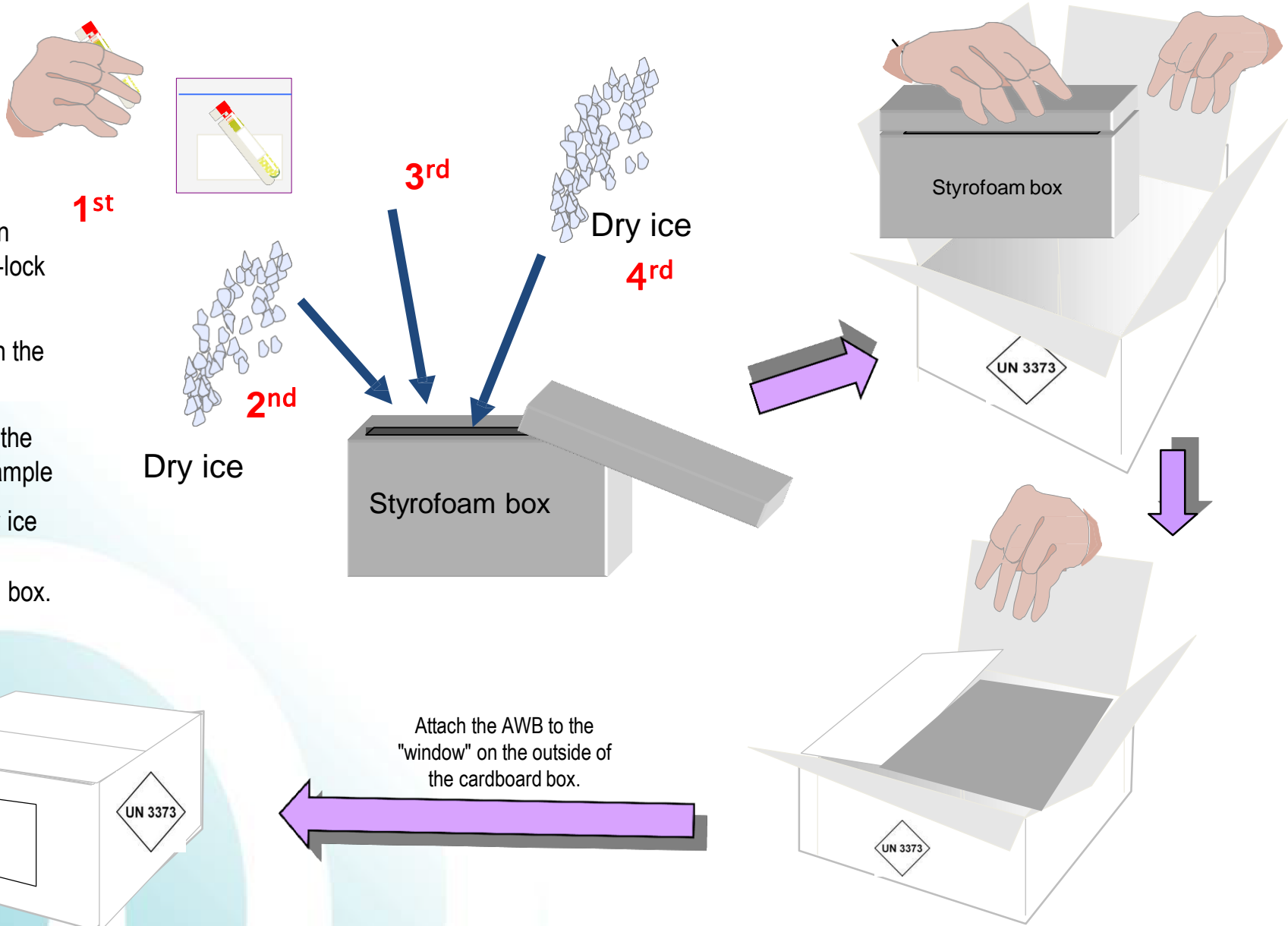
Visit
 Visit V6 Other: Visit: _____

Submitted Samples				Completed by GC-2	
Submission Condition	Quantity	Submitted Tubes	Verification List	Number of Tubes Returned	Initials
Refrigerated	1	EDTA Tube - 2.0 mL - Purple Cap	<input type="checkbox"/>		
Refrigerated	2	Transfer Tube - 5.0 mL - Red Cap	<input type="checkbox"/>		
Refrigerated	2	Fluoride Tubes - 5.0 mL - Gray Cap	<input type="checkbox"/>		
Refrigerated	1	Citrate Tube - 10 mL	<input type="checkbox"/>		

For more details, check the laboratory procedures manual.
 Additional Data: _____
 Completed by: _____ Signature: _____ Date: ____/____/____
 Filled by: _____ Signature: _____ Date: ____/____/____
FIRST COUNTERPART: Send along with the refrigerated samples to the laboratory.
SECOND COUNTERPART: File at the Clinical Research Center.

ACH-TRV-03(03/09)_FINAL VERSION 1.0 - 3/22/2011

PACKAGING INSTRUCTIONS FOR FROZEN SAMPLES





Declaração

Declaramos para os devidos fins, que estamos transportando através da SPS Logística mercadoria abaixo descrita, somente para Análises / Pesquisa Clínica; sem fins comerciais, razão porque não se sujeita à emissão de Nota Fiscal, mercadoria esta que se destina à Cidade de São Paulo, Estado de São Paulo.

DESCRIÇÃO DO CONTEÚDO: Espécime para Diagnóstico Não Infeccioso (Biological Substance - Category B UN3373)

Espécime para diagnóstico material humano, sendo transportado para propósitos de diagnóstico ou investigação clínica (UN3373). As embalagens utilizadas seguem as determinações da instrução de embalagem 650, sendo que os materiais acondicionados não apresentam qualquer perigo de contágio.

Em caso de acidente, quebra ou vazamento informar ao destinatário pelo telefone (11) XXX-XXXX

Responsável Destinatário: Sr. XXXX - Laboratório XXXXX.

Condição de Material gelo seco refrigerado ambiente

Peso Bruto :

Quantidade de ml: _____

Estudo:

REMETENTE:

Nome da Instituição :

Investigador ou Responsável :

Endereço :

Cep:

País :

DESTINATÁRIO:

Nome da Instituição :

Responsável :

Endereço :

Estado e Cidade :

País : Brasil

Telefone : (11)

FINALIDADE: Análise Clínica Laboratorial

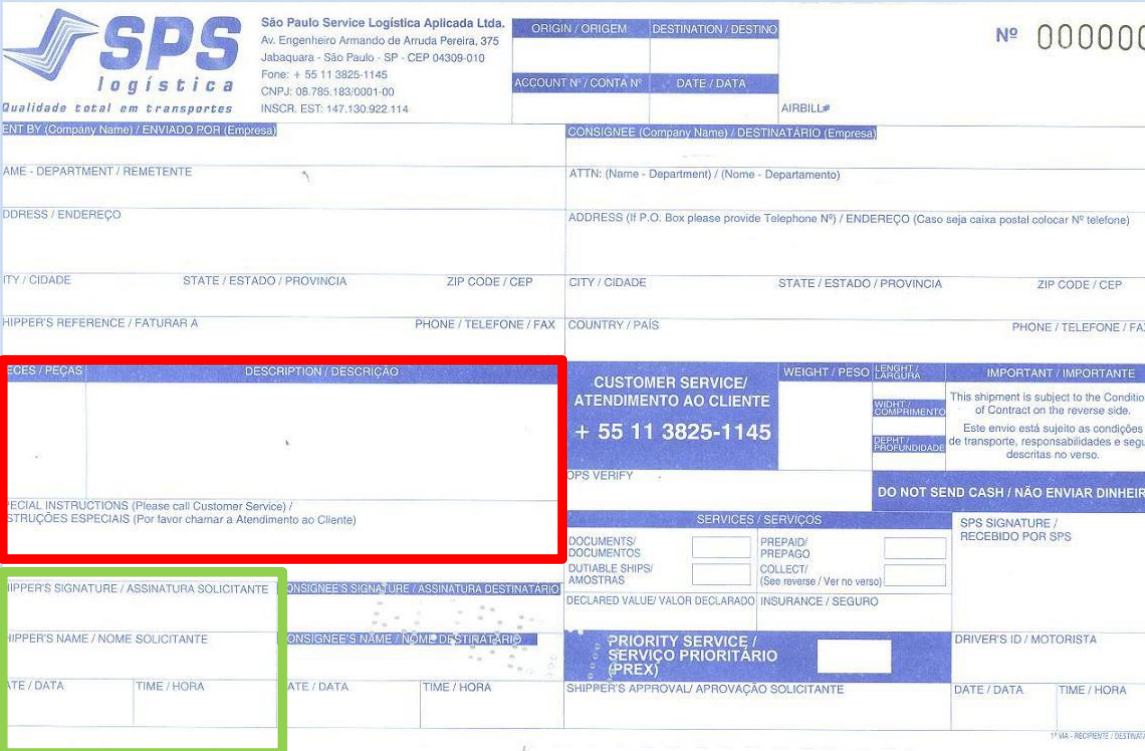
Certo de haveremos atendido, as solicitações desta Companhia, conforme descrito no Manual da IATA, edição 2009, seção 2.9 itens 11-01 e 11-06.

Nome do Responsável / RG: _____ / CPF: _____ / TEL: _____

- ✓ The Transport Statement will be sent to the center together with AWB.
- ✓ The center must send one copy of the transport statement for each set of boxes (refrigerated + frozen)
- ✓ Properly **fill out, sign and stamp** this statement on the day the samples are submitted.
- ✓ If in doubt, contact GC-2.

STANDARD PROCEDURE FOR SAMPLE SUBMISSION

Use only one AWB (sample submission document), even if you have more than one shipping box. Complete the AWB (in “volumes”) with the total number of boxes.



Persons responsible for packaging and shipping samples and dangerous goods (such as dry ice) must receive IATA (International Air Transport Association) training/certification.

- Send e-mail to **SPS Logística Aplicada** (contacts below) and schedule sample collection at least **24 hours** in advance, preferably;

- Inform the Courier:

- Study name
- Investigator's name
- Center code
- Center address and person present at the time of pick-up.

- Complete the **total number of boxes** and the **condition of transport** (refrigerated/frozen) in the part highlighted in **red**.

- Sign and date where indicated (part in **green**)

- Keep a copy of AWB on your files.

COURIER: SPS LOGÍSTICA APLICADA

Marco Aurélio Pastor

marco.pastor@spsla.com.br

Anderson Silva

anderson.silva@spsla.com.br

Anderson Leão

anderson.leao@spsla.com.br

Andrea Santos

andrea.santos@spsla.com.br

Phone: (11) 3825 1145 / (11) 7848 4840

Opening Hours: Monday to Friday 8:00 AM - 6:00 PM

ATTENTION: Always include all contacts in the scheduling email

RESULTS DELIVERY TIME:

Upon receipt of the samples at the Laboratory, the results will be sent in:

✓ ***2 days***

ACCESS MODE:

- **Access all reports made available on the GC-2WEB PORTAL using a specific center user and password that will be provided at the beginning of the study.**

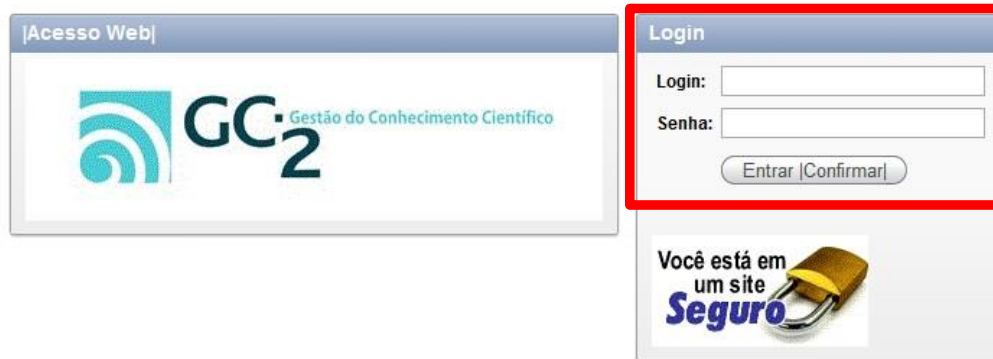
<http://www.gcdois.com.br/resultado>

- **PI and/or delegated persons should review the laboratory report.**



➤ ACCESS AND DOWNLOAD OF LABORATORY REPORTS:

1. Access the GC-2 portal (<http://www.gcdois.com.br/resultado>)
2. Insert **LOGIN** and **PASSWORD** in the specific fields (IN RED)



[Acesso Web]

GC₂ Gestão do Conhecimento Científico

Login

Login:

Senha:

Entrar | Confirmar

Você está em um site Seguro

3. On the home page, select the protocol and click Search. All results available for viewing and downloading (pdf) will be shown.



Bem Vindo | Laudos | Alterar Senha

Lista de Laudos

Protocolo Centro de Pesquisa

Pesquisar

dados não encontrados

LABORATORY REPORTS

- ✓ KEEP A FILE IN THE CENTER
- ✓ INDIVIDUAL REPORT BY VISIT
- ✓ DOES NOT HAVE ALERTS (FLAGS)
- ✓ AVAILABLE VIA PORTAL GC2

INFORMAÇÃO CONFIDENCIAL					
LAUDO DE EXAME					
<p>www.gc2ols.com.br</p> <p>Protocolo: _____ Data Coleta: 05/12/2012 Patrocinador: _____ Hora Coleta: 15:00 Centro: _____ Data Emissão: _____ Investigador: _____ Cod Lab: _____</p>					
ALBUMINA					
Método: Cinético Colorimétrico					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
	4,0	3.2 a 4.8	g/dL	Normal	
Liberação: Norma Ohki Nakaguma (CRF 14.978)					
AMILASE					
Método: Cinético Ellenedo IFCC					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
	90	30 a 118	U/L	Normal	
Liberação: Norma Ohki Nakaguma (CRF 14.978)					
ACIDO URICO					
Método: ENZIMÁTICO-URICASE					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
	5,9	3.5 a 7.2	mg/dL	Normal	
Liberação: Norma Ohki Nakaguma (CRF 14.978)					
BHCG					
Método: ELFA					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
	5,00	< 5,00 mUI/mL: Correlacionam-se com a ausência de gravidez. De 5,00 a 50,00 mUI/mL: São duvidosos e sugerem repetição após uma semana. > 50,00 mUI/mL: Correlacionam-se, geralmente com gravidez.			
Liberação: Norma Ohki Nakaguma (CRF 14.978)					
BILIRRUBINA TOTAL E FRAÇÕES					
Método: OXIDACAO COM VANADATO					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
BILIRRUBINA INDIRETA	0,9	0 a .8	mg/dL	Alto	
BILIRRUBINA TOTAL	1,2	0 a 1.2	mg/dL	Normal	
BILIRRUBINA DIRETA	0,3	0 a .4	mg/dL	Normal	
Liberação: Norma Ohki Nakaguma (CRF 14.978)					
CÁLCIO					
Método: COLORIMÉTRICO					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
	8,8	8.3 a 10.6	mg/dL	Normal	
Liberação: Norma Ohki Nakaguma (CRF 14.978)					
CLORO					
Método: ISE - POTENCIOMÉTRICO INDIRETO					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
	105	99 a 109	mEq/L	Normal	
Liberação: Norma Ohki Nakaguma (CRF 14.978)					
COLESTEROL TOTAL					
Método: ENZIMÁTICO					
Material: SORO					
	Resultado	Valor Referência	Unidade	Flag	Delta Flag
	200	Desejáveis: < 200 mg/dL Limitrofes: 200 a 239 mg/dL Altos: > 239 mg/dL	mg/dL		
Liberação: Norma Ohki Nakaguma (CRF 14.978)					

QUERIES RESOLVING AND SUBMISSION



QUERIES:

- Pending or inconsistent information
- Improper biological material
- Protocol deviation (visits)



If there is no return from the center...



- **Requirements**

- ✓ Do not forget to send the exam requirement form with the samples
- ✓ Always complete the laboratory requirement (Lack of information or divergent information can result in laboratory queries and delays)

- **Ask your questions**

- ✓ Refer to the GC-2 Laboratory Procedures Manual or contact GC-2 (slide 02) whenever there are questions about laboratory procedures.

- **Collection**

- ✓ If a sample has not been collected, **RECORD** on the requirement form **(Additional Comments)**.

In case of doubts about:

- ✓ Interpretation of results;
- ✓ Exams correlation;
- ✓ Analysis of interings and pre-analytical variables;
- ✓ Analytical Methodologies.

The investigator may contact our medical team through the following channels:

Dr. Carlos Kiffer	Dr. Gustavo Campana
medico@gcdois.com.br	
Phone: (11) 3528 7406	



REFERENCE VALUES STUDY LANCE

Version 1.0 (29/Nov/2012)

EXAM	AGE (years)/ Period	FEMALE	MALE	UNIT
Erythrocytes	> 17 years	3.9 to 5.0	4.3 to 5.7	millions/mm ³
Hemoglobin		12.0 to 15.5	13.5 to 17.5	g/dL
Hematocrit		35 to 45	39 to 50	%
V.C.M.		82 to 98	81 to 95	fl
H.C.M.		26 to 34	26 to 34	pg
C.H.C.M.		31 to 36	31 to 36	g/dL
RDW		11.9 to 15.5	11.9 to 15.5	%
Platelets		150,000 to 450,000	150,000 to 450,000	mm ³
Leukocytes		3,500 to 10,500	3,500 to 10,500	mm ³
Myelocytes		0	0	mm ³
Metamyelocytes		0	0	mm ³
Band Neutrophils		no more than 840	no more than 840	mm ³
Segment. Neutrophils		1,700 to 8,000	1,700 to 8,000	mm ³
Eosinophils		50 to 500	50 to 500	mm ³
Basophils		0 to 100	0 to 100	mm ³
Lymphocytes		900 to 2,900	900 to 2,900	mm ³
Monocytes	300 to 900	300 to 900	mm ³	
Atypical Lymphocytes	0	0	/mm ³	
Glycated Hemoglobin	0 to 18 years	4 to 6% non-diabetic patients to control Diabetes Mellitus: Pubertal range: less than or equal to 8.0% Pubertal range < 8.5% Final phase of puberty and young adults < 7.0%	4 to 6% non-diabetic patients to control Diabetes Mellitus: Pubertal range: less than or equal to 8.0% Pubertal range < 8.5% Final phase of puberty and young adults < 7.0%	%
	>18 years	4 to 6%	4 to 6%	%
Prothrombin Activity and Time		Prothrombin Time: 70 to 110% Prothrombin Activity: 0.90 to 1.20	Prothrombin Time: 70 to 110% Prothrombin Activity: 0.90 to 1.20	Seconds %
Activated Partial Thromboplastin Time		Less than 42 seconds patient/control ratio: lower than 1.25	Less than 42 seconds patient/control ratio: lower than 1.25	Seconds

REFERENCE VALUES STUDY LANCE

Version 1.0 (29/Nov/2012)

EXAM	AGE (years)/ Period	BIOCHEMISTRY		
		FEMALE	MALE	UNIT
Sodium		136 to 146	136 to 146	mEq/L
Potassium		3.5 to 5.5	3.5 to 5.5	mEq/L
Urea		10 to 50	10 to 50	mg/dL
Creatinine	> 13 years	0.60 to 1.10	0.70 to 1.30	mg/dL
Blood sugar		Normal: 70 to 99 Glucose intolerant: 100 to 125 Mellitus: Above 125 mg/dl (in at least 2 samples collected on different days)	Normal: 70 to 99 Glucose intolerant: 100 to 125 Mellitus: Above 125 mg/dl (at least 2 samples collected on different days)	mg/dL
SGOT (AST)		No more than 37	No more than 39	U/L
SGTP (ALT)		No more than 45	No more than 49	U/L
Total Bilirubin		No more than 1.2	No more than 1.2	mg/dL
Direct		No more than 0.4	No more than 0.4	
Indirect		No more than 0.8	No more than 0.8	
Alkaline phosphatase		No more than 129	No more than 129	U/L
Total Protein		5.7 to 8.2	5.7 to 8.2	g/dL
Globulin		1.7 to 3.5	1.7 to 3.5	g/dL
Albumin		3.2 to 4.8	3.2 to 4.8	g/dL
A/G Ratio		0.9 to 2.0	0.9 to 2.0	NA
CPK		33 to 211	33 to 211	U/L
CK-MB		< 25	< 25	U/L
C Reactive Protein		inflammatory diseases in the acute phase: > 10.0 For coronary risk assessment: low risk: <1.00 mild: 1.00 to 3.00 high risk: > 3.00	inflammatory diseases: acute phase: > 10.0 For coronary risk assessment: low risk: <1.00 mild: 1.00 to 3.00 high risk: > 3.00	mg/L
Apolipoprotein B		51 to 171	56 to 162	mg/dL
Total Cholesterol		Desirable: < 200 Limit: 200 to 239 High: > 239	Desirable: < 200 Limit: 200 to 239 High: > 239	mg/dL
HDL		≥ 40	≥ 40	mg/dL
VLDL		Less than 30	Less than 30	mg/dL
LDL		Desirable: < 100 Borderline: 100 to 129 High borderline: 130 to 159 High: 160 to 189 Very high: > 189	Desirable: < 100 Borderline: 100 to 129 High borderline: 130 to 159 High: 160 to 189 Very high: > 189	mg/dL
Triglycerides		Desirable: < 150 Borderline: 150 to 199 High: 200 to 499 Very high: > 500	Desirable: < 150 Borderline: 150 to 199 High: 200 to 499 Very high: > 500	mg/dL

REFERENCE VALUES STUDY LANCE

Version 1.0 (29/Nov/2012)

HORMONE				
EXAM	AGE (years)/ Period	FEMALE	MALE	UNIT
TSH	12 to 20 years	0.510 to 4.300	0.510 to 4.300	uUI/mL
	21 to 120 years	0.270 to 4.200	0.270 to 4.200	uUI/mL
B-HCG		<p>< 2: Correlate with the absence of pregnancy From 2 to 25: They are doubtful and suggest repetition after one week. > 25: Correlate, usually with pregnancy Menopause (over 40 years): Less than or equal to 7</p>	NA	mUI/mL
URINE				
EXAM	AGE (years)/ Period	FEMALE	MALE	UNIT
Type 1 Urine COLOR Ph DENSITY Abnormal Elements Proteins Glucose Ketone Bodies Bilirubin Urobilinogen Quantitative Sediment Exam Red Blood Cells White Blood Cells Cylinders Crystals		<p>0.5 to 8.0 1.010 to 1.030</p> <p>Negative Negative Negative Negative</p> <p>> or = at 2.0 mg/dL</p> <p>no more than 10000/ml no more than 20000/ml absent absent</p>	<p>0.5 to 8.0 1.010 to 1.030</p> <p>Negative Negative Negative Negative</p> <p>> or = at 2.0 mg/dL</p> <p>no more than 10000/ml no more than 20000/ml absent absent</p>	<p>mg/dL</p> <p>mL mL</p>

SCHEDULE OF HOLIDAYS FOR SAMPLING

GC-2 Courier, Laboratory and Monitoring services **will not work** during national holidays and bridges, mentioned in the table below.

✓ The Center should not schedule patients for the dates mentioned.

✓ On the day before the holiday, try to schedule the collection at a time that ensures that the sample arrives at the laboratory during business hours.

✓ The research centers will be re-alerted by GC-2 about the proximity of the referred holidays.

HOLIDAY	2013	2014
New Year	January 01 (Tue) December 31 (Day off)	January 01 (Wed)
Anniversary of São Paulo	January 25 (Wed)	January 25 (Sat)
Carnaval	February 11 and 12 (Mon/Tue)	March 03 and 04 (Mon/Tue)
Easter	March 29 (Fri)	April 18 (Fri)
Tiradentes	April 21 (Sun)	April 21 (Mon)
Labor Day	May 01 (Wed)	May 01 (Thu)
Corpus Christi	May 30 (Thu) May 31 (Day off - Fri)	June 19 (Thu) June 20 (Day off - Fri)
Constituição de 1932	July 09 (Tue) Day off 8 (Mon)	July 09 (Wed)
Brazil's Independence Day	September 07 (Sat)	September 07 (Sun)
Nossa Sra. Aparecida	October 12 (Sat)	October 12 (Sun)
All Souls' Day	November 02 (Sat)	November 02 (Sun)
Brazil's Proclamation of the Republic	November 15 (Fri)	November 15 (Sat)
Black Awareness Day	November 20 (Wed)	November 20 (Thu) November 21 (Day off – Sex)
Christmas	December 25 (Wed)	December 25 (Thu)