LABORATORIO BIOQUIMICA MEDICA

CONTROL DE CALIDAD EXTERNO

CAP

Dra Yolanda P. Adamczuk

Curso: Cómo hacer control de calidad en Hemostasia

COFYBCF

15 de Junio de 2011

CAP (College of American Pathologist)

LAP (Laboratory Accreditation Program)

Objetivo: *Mejorar la calidad de los laboratorios en todos sus aspectos*

- Basado en rigurosos estándares de calidad
- Examina aspectos pre-analíticos, analíticos y post analíticos de la gestión de calidad del laboratorio
  - Manejo de las muestras
  - QCI
  - Equipamientos
  - QCE
  - Etc

CAP

- Basado en 4 ***STANDARDS***
  - **Standard I:** Calificaciones, responsabilidades y rol del Director del Laboratorio
  - **Standard II**: espacio físico y seguridad del laboratorio
  - **Standard III:** Manejo de la calidad (Quality management)
  - **Standard IV:** Requerimientos administrativos

CAP

- Más de 6600 lab acreditados en todo el mundo
- Entre ellos:
  - **Laboratorio Bioquímica Médica**
  - **Laboratorio del Hospital Italiano**

CAP: Checklists

- Es una lista detallada de los requerimientos que el inspector usa para determinar si el laboratorio cumple con los Standards de calidad
- Para el laboratorio es una guía para el desarrollo de reglas, procedimientos y procesos que ayudan a mejorar la calidad
- Son revisados periódicamente
- Existen para las distintas áreas del laboratorio, entre ellas *Hematology and Coagulation*

Inspecciones de CAP

- Cada 2 años en el laboratorio
- Durante el año intermedio entre las inspecciones, el laboratorio debe analizar los checklist, realizar una autoevaluación (SELFEVALUATION) y enviar un informe a CAP **(OBLIGATORIO)**

Proficiency Testing (PT)

- Sinónimo:
  - **External Quality Assessment (EQA)**
  - **QCE**

PT - CAP

- Monitorea el desempeño de un laboratorio a través de la comparación con sus pares
- Es obligatorio para los laboratorios acreditados
- Varios envíos al año de muestras de plasmas liofilizados incógnitas
- El programa compara cada laboratorio con aquellos que utilizan el mismo sistema instrumento/reactivo
- Las muestras deben procesarse en el laboratorio de la misma manera que las muestras de pacientes: misma metodología, mismo operador, etc
- Analitos que no estén enrolados en los PT de CAP: método alternativo para validar el desempeño al menos cada 6 meses

Cómo evalúa CAP los PT

- Selección del **Valor Target**
- **Peer group**: Por lo menos 9 resultados después de haber excluido los outlier
- Otras comparaciones estadísticas

Cómo evalúa CAP los PT

- Los resultados son agrupados de acuerdo al método utilizado para el análisis
- Se calculan varios estadísticos:
  - Media (promedio de los resultados reportados)
  - SD (medida de la variabilidad de los resultados de los participantes)
  - CV
  - Mediana
  - Límites de aceptabilidad
  - SDI (Standard Deviation Index):($Media_{Lab}$ – $Media_{Grupo}$)/SD: E expresado en términos de SDs de la media, con un signo aritmético indicando la dirección de la diferencia. Normaliza el resultado

Cómo evalúa CAP los PT

Analito	Valor Target	Criterio de evaluación
APTT	Peer Group	+/- 15%
Fibrinógeno	Peer Group	+/- 20 %
INR	Peer Group	+/- 20 %
TP	Peer Group	+/- 15%

Evaluación especial del INR: Si al menos el 80 % de los INRs reportados están entre +/- 10 % de los INRs calculados, el resultado es ACEPTABLE

Interpretación del desempeño

- Satisfactory: >/= 80 %
- Unsatisfactory: < 80 %

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

CAP Number: 6500601-01 **Kit#** 1
Institution: Laboratorio Bioquimica Medica
Attention: Dr. Mauricio Grosman PhD
City / State: Buenos Aires AR 1425

Kit ID: 23129089
Kit Mailed: 9/13/2010
Original Evaluation: 10/14/2010

EVALUATION
ORIGINAL

CGL-C 2010 Coagulation, Limited

CAP

CAP #: 6500601 **Subspecialty :** Hematology

Regulated Analyte	Proficiency Event 2010 1			Proficiency Event 2010 2			Proficiency Event 2010 3			Current Event Performance Interpretation	Cumulative CLIA '88 Performance Interpretation	
	Test Event	Score	%	Test Event	Score	%	Test Event	Score	%			
Cell ID/Flow Differential	FH9-A	5/5	100	FH9-B	5/5	100				Pending	Successful	<4>
Erythrocyte Count	FH9-A	5/5	100	FH9-B	5/5	100				Pending	Successful	<4>
Hematocrit	FH9-A	5/5	100	FH9-B	5/5	100				Pending	Successful	<4>
Hemoglobin	FH9-A	5/5	100	FH9-B	5/5	100				Pending	Successful	<4>
Leukocyte Count	FH9-A	5/5	100	FH9-B	5/5	100				Pending	Successful	<4>
Platelet Count	FH9-A	5/5	100	FH9-B	5/5	100				Pending	Successful	<4>
PTT	CGL-A	5/5	100	CGL-B	5/5	100	CGL-C	5/5	100	Satisfactory	Successful	
Prothrombin Time	CGL-A	5/5	100	CGL-B	5/5	100	CGL-C	5/5	100	Satisfactory	Successful	
Hematology		**40/40**	**100**		**40/40**	**100**		**10/10**	**100**	**Satisfactory**	**Successful**	

<4> Scorecard performance pending future evaluation or may not be applicable due to discontinued testing or use of a waived method.

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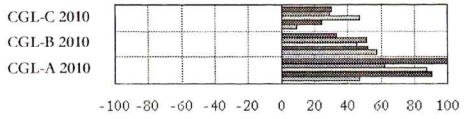
EVALUATION
ORIGINAL

CGL-C 2010 Coagulation, Limited

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	S.D.I	Limits of Acceptability Lower	Limits of Acceptability Upper	Your Grade
Activated PTT, quant	**CGL-11**	64	61.0	5.8	21	+0.5	51	71	Acceptable
Seconds	**CGL-12**	87	83.3	7.0	21	+0.5	70	96	Acceptable
DIAG STAGO STA-PTT A	**CGL-13**	65	60.4	4.8	21	+0.9	51	70	Acceptable
DIAG STAGO ST4,STRT4/8	**CGL-14**	34	32.7	2.6	22	+0.5	27	38	Acceptable
	CGL-15	61	60.1	6.0	22	+0.1	51	70	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation



Test Method	Specimen	Your Result	Good Response	Acceptable Response	Your Grade
Activated PTT, qual	**CGL-11**	PROLONGED			[26]
	CGL-12	PROLONGED			[26]
	CGL-13	PROLONGED			[26]
	CGL-14	NOT PROLONGED			[26]
	CGL-15	PROLONGED			[26]

The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

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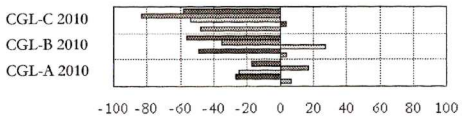
EVALUATION
ORIGINAL

CGL-C 2010 Coagulation, Limited

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	Limits of Acceptability S.D.I	Lower	Upper	Your Grade
PT, quant	**CGL-11**	33.2	36.45	2.17	31	-1.5	30.9	42.0	Acceptable
Seconds	**CGL-12**	53.1	60.82	4.79	31	-1.6	51.6	70.0	Acceptable
DIAG STAGO NEO CI PLUS	**CGL-13**	33.1	36.04	2.60	32	-1.1	30.6	41.5	Acceptable
DIAG STAGO ST4,STRT4/8	**CGL-14**	12.9	12.82	0.54	33	+0.2	10.8	14.8	Acceptable
	CGL-15	33.5	36.19	2.07	32	-1.3	30.7	41.7	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation

Survey -100----------Mean----------+100

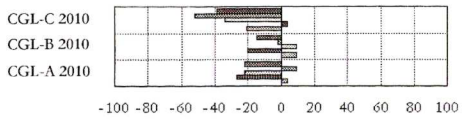


Test Method	Specimen	Your Result	Good Response	Acceptable Response	Your Grade
PT, qual	**CGL-11**	PROLONGED			[26]
	CGL-12	PROLONGED			[26]
	CGL-13	PROLONGED			[26]
	CGL-14	NOT PROLONGED			[26]
	CGL-15	PROLONGED			[26]

Test / Unit of Measure / Peer Group	Specimen	Your Result	Mean	S.D.	No. of Labs	Limits of Acceptability S.D.I	Lower	Upper	Your Grade
INR, quant	**CGL-11**	3.4	3.72	0.26	30	-1.2	2.9	4.5	Acceptable
	CGL-12	6.3	7.07	0.62	29	-1.2	5.6	8.5	Acceptable
DIAG STAGO NEO CI PLUS	**CGL-13**	3.4	3.66	0.29	31	-0.9	2.9	4.4	Acceptable
DIAG STAGO ST4,STRT4/8	**CGL-14**	1.0	0.99	0.05	30	+0.3	0.7	1.2	Acceptable
	CGL-15	3.5	3.66	0.22	31	-0.7	2.9	4.4	Acceptable

Plot of the Relative Distance of Your Results from Target as Percentages of allowed Deviation

Survey -100----------Mean----------+100



The College of American Pathologists recommends that the result of this interlaboratory comparison not be used as a sole criterion for judging the performance of any individual clinical laboratory.

International Normalized Ratio

CGL-11

REAGENT/INSTRUMENT	NO. LABS	MEAN	S.D.	C.V.	MEDIAN	LOW VALUE	HIGH VALUE
DADE/SIEMENS THROMB C +							
SIEMENS/SYSMEX CA-SERIES	35	2.93	0.22	7.5	2.9	2.6	3.5
DIAG STAGO NEO CI PLUS							
DIAG STAGO ST4,STRT4/8	30	3.72	0.26	7.1	3.7	3.3	4.1
DIAG STAGO STA COMPACT	869	3.42	0.18	5.2	3.4	2.9	3.9
DIAG STAGO STA SATELLITE	22	3.50	0.34	9.6	3.4	3.1	4.4
DIAG STAGO STA-R/EVOLUTN	197	3.31	0.14	4.3	3.3	2.9	3.7
SIEMENS/SYSMEX CA-SERIES	6	-	-	-	3.3	3.0	3.6
DIAG STAGO NEO CI							
DIAG STAGO STA COMPACT	9	-	-	-	3.2	3.0	3.6
HEMOSIL PT-FIB HS PLUS							
IL ACL 7000 & UNDER	87	3.21	0.20	6.2	3.2	2.7	3.8
IL ACL 8/9/10K, ELITE/PRO	7	-	-	-	3.2	2.9	3.4
HEMOSIL PT-FIB							
IL ACL 7000 & UNDER	108	3.10	0.25	7.9	3.1	2.5	3.7
IL ACL 8/9/10K, ELITE/PRO	79	3.01	0.18	6.1	3.0	2.6	3.5
IL ACL FUTURA/ADVANCE	40	3.02	0.20	6.7	3.0	2.6	3.5
HEMOSIL RECOMBIPLASTIN							
IL ACL TOP SERIES	5	-	-	-	2.9	2.7	3.1
HEMOSIL RECOMBIPLSTN 2G							
DIAG STAGO STA COMPACT	14	2.75	0.16	5.8	2.8	2.5	3.0
IL ACL 7000 & UNDER	20	2.80	0.29	10.5	2.8	2.3	3.4
IL ACL 8/9/10K, ELITE/PRO	267	2.85	0.18	6.4	2.9	2.3	3.4
IL ACL FUTURA/ADVANCE	162	2.89	0.16	5.4	2.9	2.5	3.3
IL ACL TOP SERIES	268	2.80	0.15	5.5	2.8	2.4	3.2
SIEMENS/SYSMEX CA-SERIES	14	3.08	0.11	3.6	3.1	2.9	3.3
SIEMENS INNOVIN							
DIAG STAGO STA COMPACT	36	2.77	0.13	4.6	2.8	2.5	3.0
DIAG STAGO STA-R/EVOLUTN	6	-	-	-	2.8	2.7	7.6
SIEMENS BCS, BCS XP	186	2.88	0.13	4.7	2.9	2.5	3.2
SIEMENS/SYSMEX CA-SERIES	1490	2.70	0.13	4.9	2.7	2.3	3.1
SYSMEX CA-SERIES (JP)	5	-	-	-	2.6	2.3	3.0
SIEMENS THROMBOREL S							
SIEMENS BCS, BCS XP	15	3.07	0.21	6.8	3.0	2.7	3.4
SIEMENS/SYSMEX CA-SERIES	36	3.04	0.19	6.4	3.1	2.7	3.4
SYSMEX CA-SERIES (JP)	11	3.09	0.14	4.7	3.1	2.8	3.3
TRINITY TRINICLOT EXCEL S							
TRINITY AMAX DESTINY (M) ◆	28	2.79	0.16	5.9	2.8	2.4	3.1
TRINITY TRINICLOT HTF							
TRINITY AMAX DESTINY (M) ◆	20	3.05	0.17	5.7	3.1	2.7	3.4
TRINITY COAGAMATE MTX	44	2.96	0.15	5.2	3.0	2.6	3.3
TRINITY MDA SERIES	27	3.06	0.16	5.3	3.1	2.7	3.3

◆ = MECHANICAL

International Normalized Ratio

CGL-12

REAGENT/INSTRUMENT	NO. LABS	MEAN	S.D.	C.V.	MEDIAN	LOW VALUE	HIGH VALUE
DADE/SIEMENS THROMB C +							
SIEMENS/SYSMEX CA-SERIES	35	5.24	0.49	9.3	5.2	4.4	6.6
DIAG STAGO NEO CI PLUS							
DIAG STAGO ST4,STRT4/8	29	7.07	0.62	8.8	7.1	6.1	8.4
DIAG STAGO STA COMPACT	864	6.28	0.39	6.2	6.2	5.2	7.5
DIAG STAGO STA SATELLITE	22	6.60	0.74	11.2	6.4	5.8	8.5
DIAG STAGO STA-R/EVOLUTN	196	5.93	0.32	5.4	5.9	5.2	6.8
SIEMENS/SYSMEX CA-SERIES	6	-	-	-	6.1	5.7	6.9
DIAG STAGO NEO CI							
DIAG STAGO STA COMPACT	9	-	-	-	6.0	5.3	6.8
HEMOSIL PT-FIB HS PLUS							
IL ACL 7000 & UNDER	88	5.46	0.37	6.7	5.4	4.7	6.4
IL ACL 8/9/10K, ELITE/PRO	7	-	-	-	5.1	4.9	5.9
HEMOSIL PT-FIB							
IL ACL 7000 & UNDER	106	5.37	0.51	9.6	5.4	3.8	6.7
IL ACL 8/9/10K, ELITE/PRO	80	5.15	0.40	7.7	5.1	4.0	6.0
IL ACL FUTURA/ADVANCE	40	5.32	0.48	9.1	5.3	4.3	6.4
HEMOSIL RECOMBIPLASTIN							
IL ACL TOP SERIES	5	-	-	-	4.4	4.3	4.7
HEMOSIL RECOMBIPLSTN 2G							
DIAG STAGO STA COMPACT	14	4.33	0.33	7.7	4.3	3.8	4.9
IL ACL 7000 & UNDER	20	4.41	0.47	10.6	4.5	3.6	5.4
IL ACL 8/9/10K, ELITE/PRO	265	4.53	0.29	6.5	4.6	3.7	5.4
IL ACL FUTURA/ADVANCE	164	4.53	0.28	6.2	4.5	3.7	5.2
IL ACL TOP SERIES	266	4.42	0.28	6.4	4.4	3.6	5.2
SIEMENS/SYSMEX CA-SERIES	16	4.82	0.30	6.2	4.8	4.2	5.5
SIEMENS INNOVIN							
DIAG STAGO STA COMPACT	35	4.12	0.19	4.6	4.1	3.8	4.6
DIAG STAGO STA-R/EVOLUTN	6	-	-	-	4.0	3.8	4.4
SIEMENS BCS, BCS XP	186	4.36	0.22	5.0	4.4	3.7	5.0
SIEMENS/SYSMEX CA-SERIES	1485	4.14	0.22	5.2	4.1	3.5	4.8
SYSMEX CA-SERIES (JP)	5	-	-	-	3.8	3.5	4.6
SIEMENS THROMBOREL S							
SIEMENS BCS, BCS XP	14	5.01	0.41	8.2	5.0	4.4	5.9
SIEMENS/SYSMEX CA-SERIES	35	4.99	0.38	7.6	4.9	4.4	5.7
SYSMEX CA-SERIES (JP)	11	5.09	0.31	6.2	5.0	4.5	5.7
TRINITY TRINICLOT EXCEL S							
TRINITY AMAX DESTINY (M) ◆	28	4.77	0.36	7.6	4.8	3.8	5.4
TRINITY TRINICLOT HTF							
TRINITY AMAX DESTINY (M) ◆	20	5.00	0.29	5.7	5.1	4.3	5.4
TRINITY COAGAMATE MTX	43	5.06	0.27	5.4	5.0	4.4	5.7
TRINITY MDA SERIES	27	5.11	0.30	6.0	5.2	4.4	5.5

◆ = MECHANICAL

LABORATORIO BIOQUIMICA MEDICA

SHIPMENT: 2010 CGL-C
CAP NUMBER: 6500601-01 01
INSTITUTION: Laboratorio Bioquimica Medica Main
ATTENTION: Dr. Mauricio Grosman PhD
CITY/STATE: Buenos Aires, Argentina

College of American Pathologists - Limited Coagulation Survey
CGL-C 2010

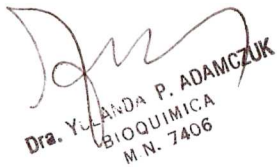
INR CALCULATION SUMMARY

KIT ID: 23129089
EVALUATION DATE: 10/20/2010

EVALUATION OF INR RESULT VALUES

Reported ISI: 1.31
Reported Mean Reference Range PT: 13.0

SPECIMEN	YOUR LABORATORY'S REPORTED PT	YOUR LABORATORY'S REPORTED INR	CALCULATED INR	LIMITS OF ACCEPTABILITY LOWER	UPPER
CGL-11	33.2	3.4	3.4	3.2	3.6
CGL-12	53.1	6.3	6.3	6.1	6.5
CGL-13	33.1	3.4	3.4	3.2	3.6
CGL-14	12.9	1.0	1.0	0.8	1.2
CGL-15	33.5	3.5	3.5	3.3	3.7



Acceptable performance.

Lab Director or Designee

Nov | 2010

Date

LABORATORIO BIOQUIMICA MEDICA

Acciones correctivas en caso de PTs insatisfactorios

Laboratory Accreditation Program
Proficiency Testing Exception Summary (PTES) Response Form

PT exception for: Kit: PT Provider: PT Analyte Group:
Exception Type:

1. How did your laboratory investigate the problem?

2. What was the cause of the PT exception?

3. What specific corrective action have you taken to prevent recurrence?

4. What evidence do you have that the problem was successfully corrected?

5. What category fits your analysis (see next page for common causes of unacceptable results):

- ☐ Methodological Problem
- ☐ Technical Problem
- ☐ Clerical error
- ☐ No explanation after explanation
- ☐ Problem with PT materials
- ☐ Other

6. Attach a copy of your evaluated results for this analyte or subspecialty.

7. Medical Director's Signature: _____

Request ID:
LAP Number:
AU ID:
Generated Date:

For Office Use: Analyte Code - PTES Commissioner -

Common Causes of Unacceptable Results

Methodologic Problems

- Instrument problem identified
- Instrument repaired or replaced
- Faulty standard or other reagent
- Incorrect calibration
- Other method problem

Technical Problems

- Misinterpretation/misidentification
- Dilution error or incorrect pipetting
- Time delay between reconstitution and analysis
- Calculation error
- Run accepted in nonlinear range
- Run accepted even though controls were out of range
- Sample mix-up
- Other technical problem

Clinical Errors

- Transcription error
- Transposition error

Problems with PT Materials

- Hemolyzed specimen
- Bacterial contamination
- Perceived survey bias
- Poor growth in culture
- Unstable PT material
- Matrix effect incompatible with method
- No comparable peer group
- Acceptable range too low
- Late shipment

No explanation after investigation

Use this choice only when a thorough investigation has yielded no satisfactory explanation.

Ref: Arch Pathol Lab Med 1987;111:1011

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Qué PTs ofrece CAP para Hemostasia

www.cap.org

13 Coagulation

13 Coagulation

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