Quality System

External Quality Assessment

AIM of QUALITY SYSTEM

The aim of QUALITY SYSTEM

- A valid instrument for the self-evaluation of diagnostic quality in laboratories.

- Validation of the internal quality control is assured by the periodical external quality control.

- Comparison between laboratories placed on the same territory increase the quality of the analitycal proficiency.

- Integration between internal and external control allows constant "Total Quality" improvement.

SCHEMES

CLINICAL CHEMISTRY

Albumin	Ck Nac	Iron (Fe)	Magnesium (Mg)
Alfa Amylase	Chloride	Gamma GT	Phosphate
ALP AMP	HDL Cholesterol	Glucose	Potassium (K)
Bicarbonates	LDL Cholesterol	GOT (AST)	Sodium (Na)
Biliar Acids	Total Cholesterol	GPT (ALT)	Total Proteins
Direct Bilirubin	Cholinesterase	LDH	Triglycerides
Total Bilirubin	Copper (Cu)	Lipase	Urea
Calcium (Ca)	Creatinine	Lithium (Li)	Uric Acid

IMMUNOLOGY

Alfafetoprotein	Ferritin	Prolactine
AntiTyreoglobuline Antibody	Folic Acid	PSA Free
CA 125	FSH	PSA Total
CA 15-3	FT3	Testosteron
CA 19-9	FT4	Tireoglobuline
Carbamazepine	HCG	TMAB
CEA	IgE	TPO
Corthisole	LH	TSH
Digoxin	Progesteron	T3
Estradiol		T4

COAGULATION

PT Quick Time
APTT
Antithrombin III
Fibrinogen

ELECTROPHORESIS

Albumin
Alpha 1 Globuline
Alpha 2 Globuline
Beta Globulin
Gamma Globulin

HEMATOLOGY

WBC/GB
RBC/GR
HGB/HBG
HCT
MCV/VMG
MCH/TCMH
RDW/IDR-CV
PLT/PLQ

SEROLOGY

Chlamydia IgG	HbcAb IgM	HIV 1 - 2
Chlamydia IgM	HBeAb	Rubella IgG
Cytomegalovirus IgG	HBeAg	Rubella IgM
Cytomegalovirus IgM	HBsAb	Syphilis IgG
Ebstein-Barr VCA IgG	HBsAg	Syphilis IgM
Ebstein-Barr VCA IgM	HCV	Toxoplasma IgG
HIV	Helicobacter Pylori IgG	Toxoplasma IgM
HAV IgG	Herpes virus I IgG	Troponema Pallidum IgG
HAV IgM	Herpes virus II IgG	Troponema Pallidum IgM
HbcAb		

SPECIFIC PROTEINS

Alpha 1 Glicoprotein
Antistreptolisine O
C3
C4
C Reactive Protein
IgA
IgG
IgM
Reumathoid Factor
Transferrin

URINE

Ascorbic Acid	Specific Weight
Albumine	pH
Bilirubine	Proteins
Ketone	Blood
Glucose	Urobilirogen
Leucocyte	MicroAlbumine
Nitrite	

DRUGS OF ABUSE

Amphetamine	Ecstasy
Metamphetamine	Morphine
Opiates	Brupernophine
Methadone	THC
Barbiturate	Benzodiazepine
Cocaine	

CARDIAC MARKERS

CK - Tot	pro-BNP
CK - MB	BNP
Hs CRP	TnI
HCY	TnT
Myo	

MICROBIOLOGY

HBA1C

ESR

FOB

HEMATOLOGY SMEAR

URINE SEDIMENTATION

PROGRAM OPTIONS

LEVELS

ASSAYS

SHIPMENT

Programs	Assay per year	Vial per assay	Shipment per year
CLINICAL CHEMISTRY	4	2 (2 levels)	1
	12	1	1
	4	1	1
COAGULATION	4	2 (2 levels)	1
	12	1	1
	4	1	1
IMMUNOLOGY	4	2 (2 levels)	1
	12	1	1
	4	1	1
ELECTROPHORESIS	4	1	1
SPECIFIC PROTEINS	4	1	1

Programs	Assay per year	Vial per assay	Shipment per year
URINE	4	1	4
URINE + SEDIMENTATION	4	1 + FILE	4
SEDIMENTATION	4	FILE	4
HEMATOLOGY	4	1	4
HEMATOLOGY + SMEAR	4	1 + FILE	4
SMEAR	4	FILE	4
SEROLOGY	4	1	4
BACTERIOLOGY	4	1	4
HBA1C	4	1	4
DRUG OF ABUSE	4	1	4
FECAL OCCULT BLOOD	4	1	4
ESR	4	1	4
CARDIAC MARKER	4	1	4
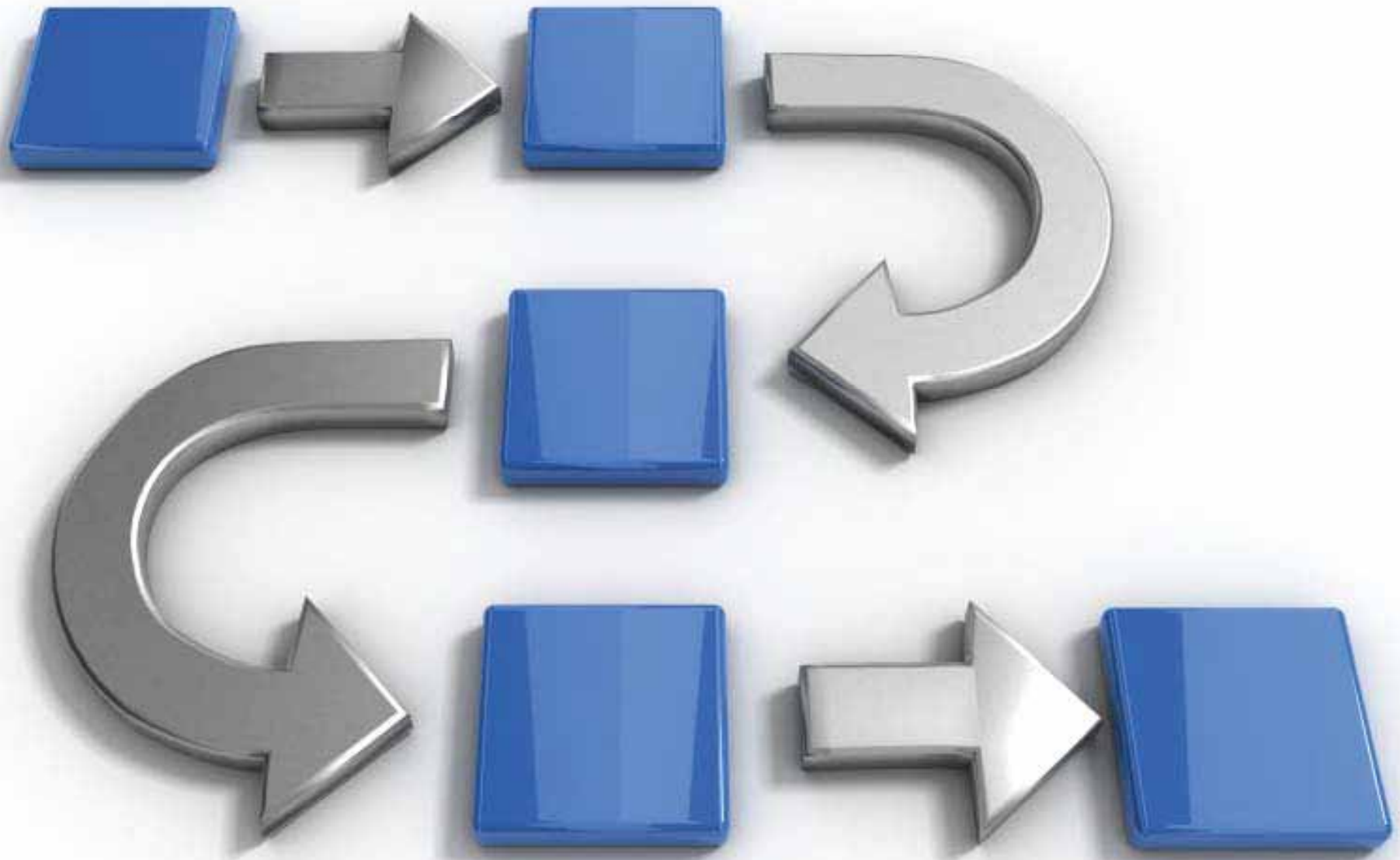
STEPS OF QUALITY SYSTEM

- Each laboratory receives samples of different analytes with unknown concentration; specimen with a long expiry date are delivered once per year

- Operators have to analyze the sample and send the results **on web site**

STEPS OF QUALITY SYSTEM

- Data will be statistically elaborated by the **University of Urbino**; Values of each laboratory will be compared between them, allowing to have informations about results , methods, instruments and reagents

- The laboratories will receive **reports** easy to read and understand; a graph combine the results from all partecipants in the survey

QS WEB SITE

QS WEB SITE allows direct access to a dedicated page for each customer with the following features:

-Entry results
-Download reports
-Profile edit
-License status

Quality System

New | Save | Delete | Print | Export | Logout

Home | DataEntry ⌄ | Comunications ⌄ | Results Area ⌄ | Settings ⌄

Welcome P0001

16/11/2011 WELCOME IN QUALITY SYSTEM

Web Portal for Quality System EQA

Typology exams in state 'OPEN'							
#	TYPOLOGY	ID_USER	DATA_CREATE	DATA_MODIFIED	STATE_ENG	PERIODICITY	DATE_FROM	DATE_TO
select	CHEMISTRY 1 LEVELS	P0001	10/11/2011 17.56.27		OPEN	MONTHLY	OCTOBER	OCTOBER

User: P0001
App: v1.4.1

New | Save | Delete | Print | Export | Logout

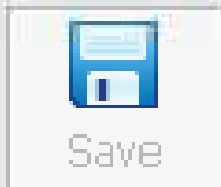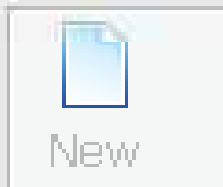Home | DataEntry | Comunications | Results Area | Settings

New test for JANUARY 2011 CHEMISTRY 2 LEVELS

Lot choosed: **3LOTT**

Data entry status: OPEN

Data Entry

#	Analite	Method	U.M	Instrument	Value1	Value2	V.Min	V.Max
Update Cancel	ALBUMIN	BROMOCRES	G/DL					
Edit	ALP		U/L					
Edit	ALT		U/L					
Edit	AMYLASE		U/L					
Edit	AST		U/L					
Edit	BICARBONATE		MMOL/L					
Edit	BILE ACIDS		UMOL/L					
Edit	CALCIUM		MG/DL					
Edit	CHLORIDE		MMOL/L					
Edit	CHOLINESTERASE		U/L					
Edit	CK NAK		U/L					
Edit	COPPER		UG/DL					
Edit	CREATININE		MG/DL					

Instrument dropdown:
- A15/A25 BIOSYSTEM
- ABBOTT ARCHITECT SERIES
- ABX PENTRA 400
- AEROSET
- AIRONE 200RA CRONY
- ARCO BIOTECNICA, CLASSIC MENARINI
- AUTOLAB

New

Save

Delete

Print

Export

Logout
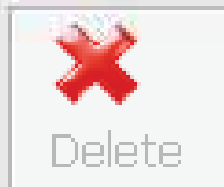
...omunications

Results Area

Settings

Download reports

Clinical Chemistry

cycle: March 2011
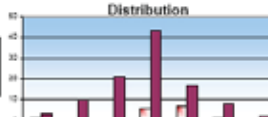
Analyte: Alfa Amylase
Unit: U/L

Method: CNPG3/Benzylidene
BPS Liquid -
PNPG7/Ethylidene

Statistic of Total Data

Distribution

MEAN	76,57
MODE	70,00
MEAN N.	78,61

S.D.	14,0
C.V. %	18,30
S.D. N.	15,8
C.V. N. %	20,07

Participant   ZR23

Found Value 84   80,2548 Normalized Value

P.S.P.

Diff. %	9,71
Z-Score	0,53
N. Diff. %	2,09

Personal Score Performance

License state P0001

		Programs		
ID_USER	NAME_ENG	FROM_DATE	TO_DATE	ENABLED
P0001	CHEMISTRY 1 LEVELS	01/11/2011 0.00.00	30/11/2012 0.00.00	True
P0001	CHEMISTRY 2 LEVELS	01/11/2011 0.00.00	30/11/2012 0.00.00	True
P0001	SEROLOGY	01/11/2011 0.00.00	30/11/2012 0.00.00	True
P0001	CARDIAC MARKERS	01/11/2011 0.00.00	30/11/2012 0.00.00	True
P0001	IMMUNOLOGY 2 LEVELS	01/11/2011 0.00.00	30/11/2012 0.00.00	True
P0001	HEMATOLOGY	01/11/2011 0.00.00	30/11/2012 0.00.00	True

Settings profile P0001

User ID: P0001

Password: xxxxx

Email: lorenzo.bernucci@biogroupme

Language: English

Theme: Plastic Blue

STATISTICAL ELABORATION

STATISTICAL ELABORATION

Data submitted are checked by Bio- Group
Medical System's Quality Control
Department and further statistically analyzed
in collaboration with the
University of Urbino
Medical Statistic Department.

University of Urbino

STATISTICAL ELABORATION

Result of the statistical analysis are send to participants in order to verify quality data, opening discussions on eventually correlated problems.

The laboratory operator, checking the results on a graph, will be soon able to establish

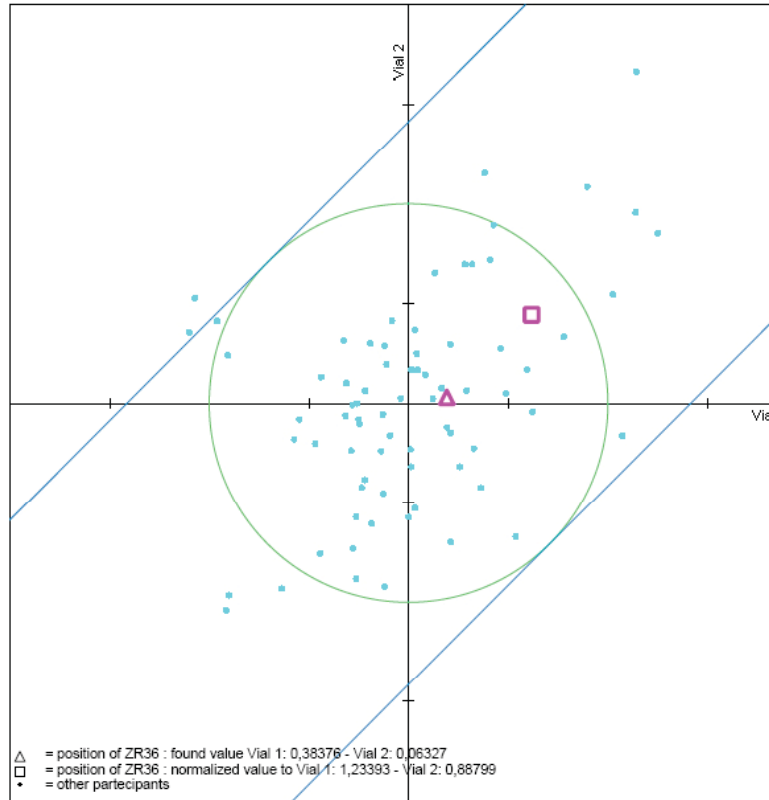the course of quality for each analyte.

Quality System COAGULATION

Analytical and Statistic Values	Vial 1	Vial 2
Middle Value	221,4	157,04
Standard Deviation	55,92	38,02
Variation Coefficient	25,26	24,21
Measured Value	**242,**	**159,**
Normalized Value	**290,4**	**190,8**
Diverging %	31,16	21,5
Standard Diverging	1,23	0,89
Instrument data MANUAL		
Middle Value	218,47	219,43
Standard Deviation	22,71	78,48
Variation Coefficient	10,39	35,76
Diverging %	32,92	-13,05
Standard Diverging	0,33	-0,13

Customer: **ZR36**
Test n: **MARCH 2011**
Item: **- Fibrinogen**
Unit of Measurement: **mg/dL**
Number participants: **79**

Methods: Clauss Method

Notes:

△ = position of ZR36 : found value Vial 1: 0,38376 - Vial 2: 0,06327
□ = position of ZR36 : normalized value to Vial 1: 1,23393 - Vial 2: 0,88799
• = other partecipants

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Quality System IMMUNOLOGY tab 2

Analytical and Statistic Values	Vial 1	Vial 2
Middle Value	108,01	57,89
Standard Deviation	17,94	9,83
Variation Coefficient	16,61	16,98
Measured Value	**92,2**	**57,4**
Normalized Value	**92,2**	**57,4**
Diverging %	-14,64	-0,85
Standard Diverging	-0,88	-0,05
Instrument data STATFAX 303+		
Middle Value	108,32	58,51
Standard Deviation	21,6	11,9
Variation Coefficient	19,94	20,35
Diverging %	-14,88	-1,89
Standard Diverging	-0,15	-0,02

Customer: **ZR06**
Test n: **MARCH 2011**
Item: **- Estradiol -**
Unit of Measurement: **pg/mL**
Number participants: **44**

Methods: ELISA

Notes:

□ = position of ZR06 : normalized value to Vial 1: -0,88128 - Vial 2: -0,05
• = other partecipants

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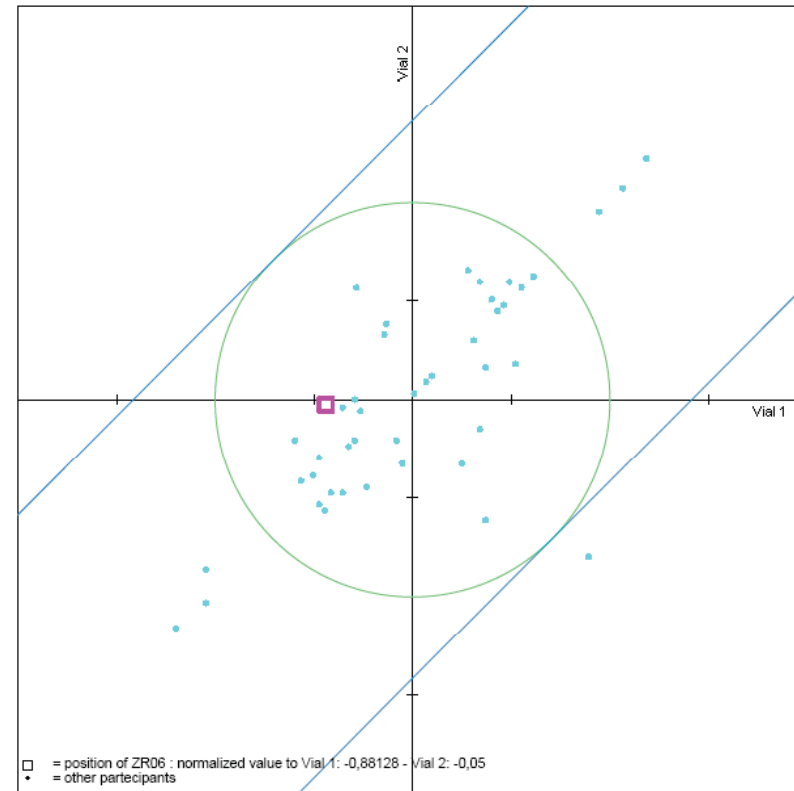
CLINICAL CHEMISTRY 1 LEVEL

Analite:	**ALP**		Cycle:	SEPTEMBER 2012
Unit:	U/L		Sample N.:	25984-09
Total data:	480		Instrument:	BT PRODUCTS BT35I
Group data:	312		Method:	DGKC

Statistics of Total Data
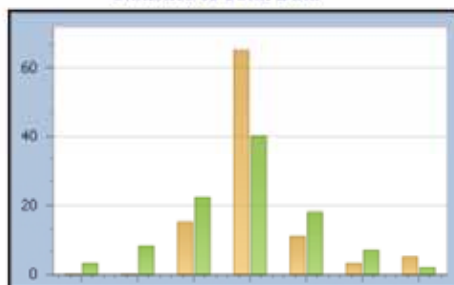
Mean:	63,65
Median:	63,00
Mode:	66,00
Mean N:	66,86

S.D:	23,12
MAD:	18,00
C.V %:	36,32
S.D.N:	23,95
C.V.N %:	35,81

PARTECIPANT: ZKB101

Found Value:	51,39	Normalized Value:	51,39
Diff. %:	-19,26	N Diff. %:	-23,13
Z-Score:	-0,53	N. Z-Score:	-0,64
MI:	-0,46		

Personal Score Performance: 90,19

+/-2 Warning Limit
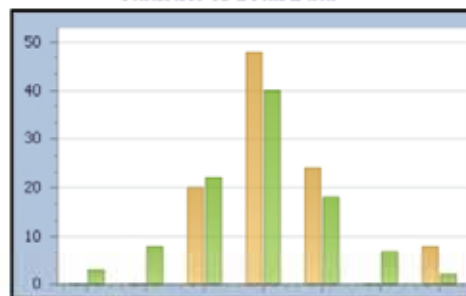+/-3 Action Limit

P.S.P

DISPERSION
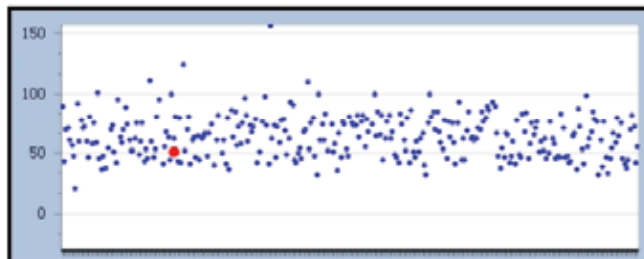
Bio-Group MEDICAL SYSTEM Srl   eMail: eqs@biogroupmedicalsystem.com
Campiano 9/b – 61010 Talamello (ITALY) - Tel. +39 0541 920686 - Fax. +39 0541 922130

COAGULATION 1 LEVEL

Cycle:	SEPTEMBER 2012
Sample N.:	310107-09
Instrument:	MANUAL OPTIC
Method:	CALCIC THROMBOPLASTIN

Statistics of Total Data

S.D:	2,79
MAD:	2,35
C.V %:	11,23
S.D.N:	3,95
C.V.N %:	15,49

PARTECIPANT: ZGN046

Normalized Value:	22,90
N Diff. %:	-10,24
N. Z-Score:	-0,66

Personal Score Performance: 85,04

+/-2 Warning Limit
+/-3 Action Limit

DISPERSION

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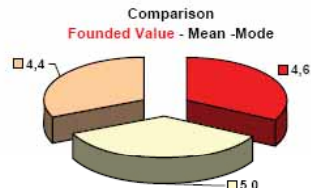
Haematology

cycle: July 2011

Analyte: RBC Concentration: 10^6/microliter

Statistical Data

Mean value:	5,0
Standard Deviation:	0,87
Coeff. of variation:	17,5
Mode value:	4,4

Comparison
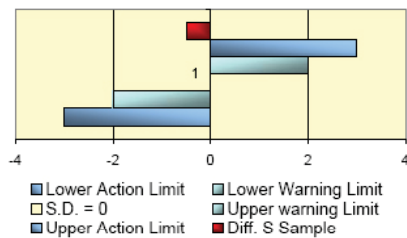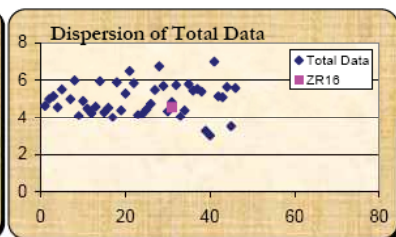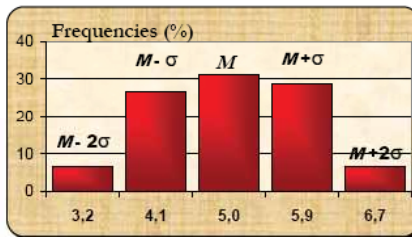Founded Value - Mean -Mode

□ 4,4 ■ 4,6 □ 5,0

Participant: **ZR16**

Founded Value: **4,57**
Diff. in %: -8,339276
Diff. S: -0,476881

Warning Limit: +/- 2 S
Action Limit: +/- 3 S

Standard Deviation

□ Lower Action Limit □ Lower Warning Limit
□ S.D. = 0 □ Upper warning Limit
□ Upper Action Limit ■ Diff. S Sample

Next Target: *Center Your Target*

Frequencies (%)

M- 2σ   M- σ   M   M+σ   M+2σ
3,2   4,1   5,0   5,9   6,7

Dispersion of Total Data
◆ Total Data
■ ZR16

rev.04 LP68

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Loc. Campiano n°9/b - 61010 Talamello (ITALY) Tel.+39-0541 920686   Fax +39-0541 922130
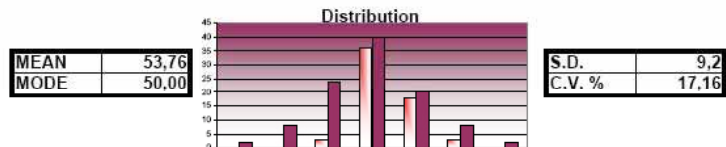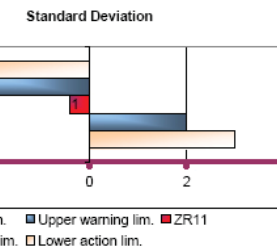

ESR

Analyte: ESR 1 hr.
Unit: mm/hr.

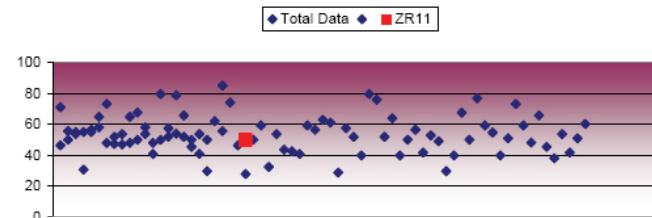cycle: July 2011

Method: Manual

Statistic of Total Data

Distribution

MEAN	53,76		S.D.	9,2
MODE	50,00		C.V. %	17,16

Participant **ZR11**

Found Value **50**

Diff. % -7,00
Z-score -0,41
Next Target *Center your Target*

Standard Deviation

□ Upper action lim. □ Upper warning lim. ■ ZR11
□ Lower warning lim. □ Lower action lim.

Dispersion

◆ Total Data ◆ ■ ZR11

L.P.1955

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Campiano 9/b - 61010 Talamello (ITALY) Tel. +39-0541 920686   Fax +39-0541 922130

Microbiology

cycle: July 2011

Participant: **ZR03**

FOUNDED STOCK

*Pseudomonas Aeruginosa*

EXPECTED STOCK

Pseudomonas Aeruginosa

ANTIBIOGRAM

tested	ZR03	S	I	R
Amikacin AK		95	0	5
Amoxicillin-Clavulanic Acid AUG		0	7	93
Ampicillin AMP		5	0	95
Cefepime FEP		89	7	4
Cefotaxime CTX		17	13	70
Ceftazidime CAZ	S	88	9	4
Ceftriaxone CRO		59	17	24
Cefuroxime CXM		4	0	96
Ciprofloxacin CIP		95	3	2
Co-Trimoxazole SXT		10	0	90
Fosfomycin FOS		78	9	13
Gentamicin CN		92	5	3
Imipenem IMI	S	93	5	2
Levofloxacin LEV		81	4	15
Meropenem MRP	S	96	4	0
Nitrofurantoin F		9	0	91
Norfloxacin NOR		82	0	18
Piperacillin/Tazobactam TZP	S	89	4	7
Piperacillin PRL	S	92	3	6
Tobramycin TOB		95	5	0

S — Meropenem MRP

I — Ceftriaxone CRO

R — Cefuroxime CXM

Total results in %

Frequencies in %

Legend: □ % ■ ZR03

Categories: Negative, Klebsiella oxytoca, Serratia liquefaciens, Pseudomonas Cepacia, Pseudomonas Aeruginosa, Pseudomonas SPP, Citrobacter SPP, Shigella SPP, Aeromonas salmonicida, Escherichia Coli

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URINALYSIS

cycle: July 2011

Participant: **ZR06**

Total participants: 280

Results	% Negative	% Positive	ZR06
Ascorbic acid			
Bilirubin	100	0	NEGATIVO
Ketones	100	0	NEGATIVO
Glucose	100	0	NEGATIVO
Leucocytes	100	0	NEGATIVO
Nitrite	100	0	NEGATIVO
Protein	100	0	NEGATIVO
Blood	100	0	NEGATIVO
Urobilinogen	100	0	NEGATIVO
pH (pH 5=negative)	0	100	POSITIVO
SG (SG 1.000= negative)	0	100	POSITIVO
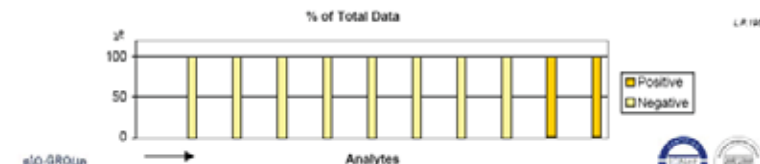
% of Total Data

Legend: □ Positive □ Negative

Analytes

Quality is the set of characteristics for a product or a service that allows to satisfy fixed and implicit needs.

Quality System

Clinical Laboratories have to **work under specific quality rules** and control the analytical phase with a quality program and examine the whole analytical process by **taking part to an External Quality Program.**

CONCLUSION

The implementation of **QUALITY SYSTEM** in laboratory will raise quality to a **high standard of excellence.**