SEROCON EQA PROGRAMS PROTOCOL

1. PURPOSE

This protocol aims to define the general framework of the EQA programs organized by SEROCON.

2. SCOPE

It covers the methods, evaluations, and reporting that may be used in the organized EQA programs.

3. PARTICIPANT CRITERIA

- All medical laboratories that wish to demonstrate their competence to regulatory authorities, accreditation bodies, or their customers may participate in the EQA programs.
- The minimum number of participants is set at 5. For rounds with fewer than 5 participants, additional information will be provided to the participants.
- In cases where any relevant party requests that the proficiency test results, be provided directly by the proficiency test organizer, participants will be informed of this arrangement prior to participation.

4. APPLICATION TO PROGRAMS

- Participants who wish to apply for SEROCON EQA programs can initiate their application by sending an email to info@serocon.com or by calling +90 850 303 6644.
- The Customer Relations Officer collects the participation requests and communicates with the clients to provide the necessary guidance and information.
- Participants are directed to the SEROCON PORTAL via www.serocon.com to complete their program registration.
- The initial registration is completed using the user manual available on the portal or with the assistance of the Customer Relations Officer.
- The created registration is reviewed and approved by the system administrators, completing the application process.

5. EQA Programs and Their Contents

The contents of the EQA programs are presented in Annex 1

6. Sample Preparation and Shipment

In our EQA programs, all samples are prepared by our expert team at SEROCON facilities in accordance with the ISO 13485 standard. Samples are delivered to participants either by hand or via courier under cold chain conditions. Confirmation of full receipt of the samples is obtained from all participants through the SEROCON PORTAL

7. Quality Control and Traceability

In our EQA programs, the necessary quality control procedures are fully applied to the prepared samples in accordance with the ISO 13485 standard. Samples are regularly checked throughout the process, from the procurement of components to their shipment to participants. To ensure traceability, the produced samples are marked with a unique LOT number. Samples that do not meet quality control criteria are destroyed.

The compliance of the prepared samples with proficiency testing standards is ensured through homogeneity and stability analyses. These analyses are conducted by subcontracted laboratories that meet ISO 15189 standards. The analyzed samples are checked according to ISO 13528 Annex B, and only those approved for compliance are sent to participants.

8. Confidentiality

SEROCON highly respects participant confidentiality. All information provided by participants to the proficiency test organizer is considered confidential. To ensure the privacy of all users, system access is granted only through a username and password known to the user.

• To protect participant data, SEROCON assigns a unique code to each participant for data control in the EQA programs, and personnel responsible for data processing work only with these codes. The codes assigned for each EQA program differ, making them difficult to predict.

• Only the Coordinator can view the institution-code matching.

• SEROCON is responsible, in accordance with legal obligations, for the management of all information obtained or generated during the execution of its activities.

• If a legally authorized authority requests that the proficiency test results be sent to them, participants will be informed in advance in accordance with ISO 17043.

• If legally authorized authorities request that proficiency test results be provided directly by the proficiency test organizer, the affected participants will be informed in writing by the Coordinator.

In accordance with the Personal Data Protection Law No. 6698, all participants are provided with an information notice and informed of the measures taken to protect their data at the time of registration.

9. SEROCON Portal Usage and Result Entry

Access to the SEROCON PORTAL is made via the "Portal Login" button located at the top left corner of the www.serocon.com website, which directs users to the portal's secure area. All users can access all necessary documents on this page, including the "SEROCON Portal User Manual." First-time users complete their registration in the program with guidance from the Customer Relations Officer.

Results for opened EQA programs must be entered through the SEROCON PORTAL by the last day of the program month. Attention should be paid to units and system alerts during result entry. The system is designed to minimize incorrect data entry. It does not allow result entries outside the ranges specified in Article 5 or entries marked with "<>". Participants who wish to enter results marked with "<>" can input the relevant value into the system without the "<>" symbols.

10. Result Evaluation and Statistical Design

All statistical calculations used are performed at a 95% confidence interval.

10.1. Determination of Outlier Values

In evaluations, data sets are subjected to an outlier test according to the Chauvenet method.

It is calculated using the following formula, and each value is compared with the critical value obtained from the Chauvenet critical table.

$$D_{MAX} = \frac{|x - \bar{x}|}{s_x}$$

- D_{max}= Maximum Allowable Deviation
- X= Each Value
- $\bar{x}$= Mean
- s_x= Standard Deviation of the Data Set

10.2. Calculation of the Assigned Value

10.2.1 Mean

It is obtained by dividing the sum of all values in the data set by the total number of data points.

$$Mean = \frac{1}{n}\sum_{0}^{n} x_i$$

- n= Total Number of Data Points
- x_i= Each Data Point

10.2.2 Robust Methods

10.2.2.1. Median

For data groups with n < 15 and containing less than 20% outliers, the median is used as the assigned value.

$$med_{(x)} = \begin{cases} x_{(n/2)} & n\ Odd\ Number \\ \dfrac{3_{(n/2)} + 5_{(1+n/2)}}{2} & n\ Even\ Number \end{cases}$$

- $Med_{(x)}$ = x Median of the Values
- All data are arranged in ascending order (x_n being the largest value)
- n= Total Number of Data Points
- x_i= Each Data Point

10.2.2.2. Hampel method

The Hampel method is used when n < 15 and the proportion of outliers exceeds 20% (maximum 50%). The mean is calculated using the web application provided in ISO 13528, reference 37,

"http://quodata.de/en/web-services/QHampel.html" (ISO 13528 reference 37)

10.3. Uncertainty of the Assigned Value

The measurement uncertainty of the assigned value is calculated using the following formulas.

Except for Robust methods,

$$u_{xpt} = \frac{\theta_{pt}}{\sqrt{n}}$$

- u_{xpt} = Assigned Value Uncertainty
- n = Number of Participants
- θ_{pt} = Standard Deviation (Dispersion)

In Robust methods;

$$u_{xpt} = 1{,}25x\frac{\theta_{pt}}{\sqrt{n}}$$

- u_{xpt} = Assigned Value Uncertainty
- n = Number of Participants
- θ_{pt} = Standard Deviation (Dispersion)

10.4. Calculation of the Cycle Standard Deviation

10.4.1 Standard Deviation

After the results from participants are evaluated using outlier tests, for data groups without outliers and with n > 12, the standard deviation is used as the dispersion value.

$$Standart\ Deviation\ (sample) = \sqrt{\frac{1}{n-1}\sum_{1}^{n}(xi - \bar{x})^2}$$

- n= Total Number of Data Points
- x_i= Each Data Point
- $\bar{x}$= Mean

10.4.2 Robust Methods

10.4.2.1. MADe Method

For data groups with n < 15 and containing less than 20% outliers, MADe is used as the assigned value.

$$d_i = |x_i - med_{(x)}|$$

$$MADe_{(x)} = 1{,}483x\text{med}_{(di)}$$

- $Med_{(x)}$ = x Median of the Values
- d_i Absolute Differences of All Values from the Median
- x_i=Each Data Point

- $med_{(di)}$ Median of the Obtained Absolute Differences

10.4.2.2. Qn Method

The Q_n method is used when n < 15 and the proportion of outliers exceeds 20% (maximum 50%). The mean is calculated using the web application provided in ISO 13528, reference 37,

"http://quodata.de/en/web-services/QHampel.html" (ISO 13528 reference 37)

10.4.2.3. Algorithm A

Algorithm A is a statistical method used to determine both location and dispersion. In theory, it adjusts data deviating from a normal distribution by converging them (k = 1.5), thereby modifying the position of the location and spread. It is formulated as follows.

$$x^* = \text{median of } x_i \ (i = 1, 2, ..., p)$$

$$s^* = 1{,}483 \ median \ of \ |x_i - x^*| \ \text{ with } (i = 1, 2, ..., p)$$

$$\delta = 1{,}5s^*$$

$$x_i^* = \begin{cases} x^* - \delta & when \quad x_i < x^* - \delta \\ x^* + \delta & when \quad x_i > x^* + \delta \\ x_i & otherwise \quad same \end{cases}$$

$$x^* = \sum_{i=1}^{p} x_i^* / p$$

$$s^* = 1{,}134 \sqrt{\sum_{i=1}^{p} (x_i^* - x^*)^2 / (p-1)}$$

The same operations in the relevant formulas are applied repeatedly (iteration). Iterations are stopped if the last two iterations match to 5 significant figures, with a minimum of 46 iterations. For example, if the values for x and s in the 22nd iteration are 1.0252 and 0.0025012, and in the 23rd iteration they are again 1.0252 and 0.0025012, the iterations are stopped, and the values of x* and s* are determined.

10.5. Performance Criteria

In reporting, the evaluations obtained are expressed as SDI (Standard Deviation Index).

10.5.1 Z Score

The Z score indicates how close a participant's value is to the assigned value.

$$Z = \frac{x_i - x_{pt}}{\theta_{pt}}$$

10.5.2 Z' Score

The Z' (Z prime) score is used when the uncertainty of the assigned value exceeds 30% of the standard deviation.

$$Z' = \frac{x_i - x_{pt}}{\sqrt{\theta_{pt} + u_{xpt}}}$$

10.5.3 Evaluation of Scores

Z and Z' scores use the same criteria for evaluation.

- ✓ $|z| \leq 2{,}0$ Acceptable
- ✓ $2{,}0 < |z| < 3{,}0$ Questionable
- ✓ $|z| \geq 3{,}0$ Unacceptable

In addition, according to TÜRKAK P704;

$|z| \leq 2.0$ Pass

2.0 <|z| It is reported as insufficient performance.

In qualitative programs, the participant's value is compared with the assigned value, and values equivalent to the assigned value are reported as acceptable.

10.6. Coefficient of Variation (%CV)

The coefficient of variation indicates the percentage variation of the standard deviation relative to the mean and is used in the assessment of repeatability, as it standardizes variability.

$$\%CV = \frac{\theta_{pt}}{x_{pt}} x100$$

10.7. Accuracy Coefficient (%Bias)

It is the difference between the mean value obtained from a series of measurements and the true or accepted reference value. Bias indicates systematic error.

$$\%Bias = \frac{x_i - x_{pt}}{x_{pt}}$$

11. REPORTING

Reports are made available for user review after the 2nd week of the month following each round. All reports are automatically generated through the SEROCON PORTAL and individually for each user. Prepared reports are communicated to participants via the portal.

Participants are given 7 calendar days to review their reports. Any objections must be submitted in writing via email to info@serocon.com or through the Solution Center on the SEROCON PORTAL. When appropriate for the objectives of the proficiency testing program, SEROCON provides expert commentary on participants' performance in accordance with the provisions of TS EN ISO/IEC 17043, clause 7.4.2.

The following guidelines should be observed in the SEROCON PORTAL, from result entry to reporting;

- ✓ Results must be entered into the SEROCON Portal via www.serocon.com using a username and password no later than the last day of the relevant month.
- ✓ When entering results, each institution must use the program opened for its own device and method.
- ✓ For participants to track their performance, values from previous rounds in which they participated are provided for each parameter using Levey-Jennings charts during sample analysis periods.
- ✓ In case of a device change during the program, SEROCON must be informed so that the necessary adjustments can be made.
- ✓ Due to a device change, participants should leave the old device data as of the change date and enter new data according to the newly defined program arrangement.
- ✓ Result entry in the SEROCON PORTAL is restricted to prevent errors and avoid large deviations. Results that should be entered with the "<>" symbol must be entered without the symbol. The system does not allow entry of results outside the limit values defined in Section 5 for each parameter.
- ✓ All reports and data are stored in accordance with the record control procedure.

12. Complaints and Objections

Customer complaints and objections can be submitted directly to the Customer Relations Unit either verbally (by phone) or in writing (via email, website, or the SEROCON Portal Solution Center), or by filling out the Contact Form on the website. All written and verbal complaints are evaluated. Upon receiving a complaint, the Customer Relations Unit promptly informs the complainant that the issue has been received and will be reviewed as soon as possible.

When a complaint or objection is received, it is investigated to determine whether it is related to the proficiency testing service. If confirmed, the complaint/objection is addressed. The result of the complaint/objection is communicated to the customer in writing (email).

If the complaint concerns proficiency test samples, investigations are conducted regarding the distributed samples. In case defective samples are identified, the customer is informed, the samples are recalled, and replacement samples are sent. Subsequent procedures are conducted according to the Nonconforming Work Procedure. Participants may raise objections regarding the samples

within 7 days of receipt. Feedback on actions taken and corrective measures is provided to the participant and, if applicable, to other participants affected by the nonconformity.

The period for objections to reports is 7 days. If errors are identified after re-evaluation of the reports, the reports are withdrawn and revised reports are issued. Feedback regarding the measures taken is communicated to the participant and, if applicable, to other participants affected by the nonconformity.

13. CONTACT

SEROCON R&D BIOTECHNOLOGY HEALTH CHEMICALS INDUSTRY AND TRADE INC
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Annex 1

Clinical Chemistry CC4 and CC12				
Sample Property	Lyophilized Serum	**Working Notes**		CC4: 1x4 1 Sample Every 3-Month Period CC12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
*Sodium	mmol/L	115	200	
*Potassium	mmol/L	2.0	8.0	
*Chloride	mmol/L	75	130	
*Total Protein	g/dL	4,50	10,00	
*HDL Cholesterol	mg/dL	15	100	
LDL Cholesterol	mg/dL	70	190	
*Total Bilirubin	mg/dL	0.1	10	
*AST (SGOT)	U/L	5	300	
*Triglycerides	mg/dL	40	500	
*LDH	U/L	40	700	
CK	U/L	40	700	
CK-MB Activity	U/L	5	200	
Iron	mg/dL	30	400	
*Total Cholesterol	mg/dL	90	400	
Phosphorus	mg/dL	2	20	
*ALP	U/L	20	300	
*ALT (SGPT)	U/L	4	300	
Total Iron-Binding Capacity	mg/dL	180	1000	
UIBC	mg/dL	150	600	
Amylase	U/L	20	600	
Magnesium	mg/dL	1.0	6.0	
Direct Bilirubin	mg/dL	0.1	2	
Lipase	U/L	10	400	
*Glucose	mg/dL	40	500	
*Albumin	g/dL	2.0	6.0	
*Urea	mg/dL	10	400	
GGT	U/L	10	400	
*Calcium	mg/dL	4.5	14	
*Creatinine	mg/dL	0.5	10	
Uric Acid	mg/dL	1	100	
"*" The marked parameters are within the scope of accreditation.				

Diabetes GH4 and GH12				
Sample Property	Lyophilized Serum	**Working Notes**		GH4: 1x4 1 Sample Every 3-Month Period GH12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
*HbA1c	%	4	15	
"*" The marked parameters are within the scope of accreditation.				

PREPARED BY	REVIEWED/APPROVED BY
Quality Manager	Coordinator

Tumor Markers TM4 and TM12				
Sample Property	Lyophilized Serum	**Working Notes**		TM4: 1x4 1 Sample Every 3-Month Period TM12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
AFP	ng/mL	0.1	200	
CA 125	U/mL	5	400	
CA 15-3	U/mL	5	400	
CA 19-9	U/mL	5	400	
*PSA (Total)	ng/mL	1	20	
Free PSA	ng/mL	0.1	20	
*CEA	ng/mL	1	100	
"*" The marked parameters are within the scope of accreditation.				

IMMUNOASSAY IMM4 and IMM12				
Sample Property	Lyophilized Serum	**Working Notes**		IMM4: 1x4 1 Sample Every 3-Month Period IMM12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Anti-TG	IU/mL	10	2000	
Anti-TPO	IU/mL	10	2000	
*Ferritin	ng/mL	10	600	
Folic Acid	ng/mL	1	20	
FSH	mIU/mL	1	200	
*FreeT3	pg/mL	1.5	12	
*FreeT4	ng/dL	0.5	12	
*HCG (Beta)	mIU/mL	5	5000	
Estradiol	pg/mL	5	4000	
Insulin	mIU/mL	2	1000	
LH	mIU/mL	1.0	80	
Progesterone	ng/mL	0.1	20	
Prolactin	ng/mL	1	100	
Testosterone	ng/dL	20	800	
*Vitamin B12	pg/mL	90	1200	
*TSH	mIU/L	0.2	20	
Vitamin D	ng/mL	4	200	
PTH	pg/mL	10	200	
"*" The marked parameters are within the scope of accreditation.				

IMMUNOASSAY-S IMM-S4				
Sample Property	Lyophilized Serum	**Working Notes**		IMM-S4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Cortisol	mg/dL	3	96	
DHEA-SO4	mg/dL	50	850	
Calcitonin	pg/mL	1	1000	
Anti-CCP	U/mL	0.5	100	
17-OH ProgesteronE	ng/dL	20	1200	
IGF-1	ng/mL	20	250	
IGFBP3	ng/mL	20	600	
Erythropoietin	mIU/mL	1	200	
C – Peptit	ng/mL	1	20	
Growth Hormone	ng/mL	0.1	30	
Free Testosterone	ng/mL	0.1	30	
Androstenedione	ng/mL	0.1	10	
Thyroglobulin	ng/mL	0.1	200	
ACTH	pg/mL	5	200	
SHBG	nmol/L	5	200	

Coagulation CGL4 and CGL12				
Sample Property	Lyophilized Plasma	**Working Notes**		CGL4: 1x4 1 Sample Every 3-Month Period CGL12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
*PT (INR)	Second	7	50	
*aPTT	Second	20	200	
Fibrinogen	g/L	0.6	6	
"*" The marked parameters are within the scope of accreditation.				

Coagulation-DDIM CGL4 and CGL12				
Sample Property	Lyophilized Plasma	**Working Notes**		CGL4: 1x4 1 Sample Every 3-Month Period CGL12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
*D-Dimer	mg/L FEU	0,05	5000	
"*" The marked parameters are within the scope of accreditation.				

Coagulation-S CGL-S4				
Sample Property	Lyophilized Plasma	**Working Notes**		CGL-S4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Antithrombin III	%	50	150	
D-Dimer	mg/L FEU	200	2000	
Thrombin Time	Second	10	30	
Protein S	%	50	200	
Protein C	%	50	200	
Factor 2	%	40	200	
Factor 5	%	40	200	
Factor 8	%	40	200	
Factor 9	%	40	200	
Factor 10	%	40	200	
Factor 11	%	40	200	
Factor 12	%	40	200	
vWF	%	40	250	
Activated Protein C Resistance	-	0.6	11,00	
Lupus Anticoagulant	Second	20	60	

Plasma Proteins PP4				
Sample Property	Lyophilized Serum	**Working Notes**		PP4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
ASO	U/L	10	500	
*CRP	mg/L	0	100	
hs-CRP	mg/L	0	100	
RF	U/mL	5	150	
IgA	g/L	0	8	
IgM	g/L	0	8	
IgG	g/L	0	8	
IgE	U/mL	10	1000	
C3	g/L	0.1	4	
C4	g/L	0.1	4	
"*" The marked parameters are within the scope of accreditation.				

Plasma Proteins-S PP-S4				
Sample Property	Lyophilized Serum	**Working Notes**		PP-S4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
IgG1	mg/dL	50	1200	
IgG2	mg/dL	5	600	
IgG3	mg/dL	5	200	
IgG4	mg/dL	1	150	
Prealbumin	mg/dL	10	200	
Alpha-1-Acid Glycoprotein	mg/dL	10	400	
Transferrin	mg/dL	10	600	
Haptoglobulin	mg/dL	5	200	
Ceruloplasmin	mg/dL	5	200	
C1 Esterase Inhibitor	g/L	0.1	0.6	
Alpha-1-Antitrypsin	mg/dL	50	1200	
Alpha-2-Macroglobulin	mg/dL	50	1200	
Apolipoprotein A1	mg/dL	50	400	
Apolipoprotein B	mg/dL	50	400	
Free ve Total Kappa	mg/L	1	50	
Free ve Total Lambda	mg/L	1	50	
Beta-2-Microglobulin	mg/L	0.5	3	
Cystatin C	mg/L	0.2	6	

Immunosuppressive Drug ISD4				
Sample Property	Lyophilized Serum	**Working Notes**		ISD4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Tacrolimus	ng/mL	1	300	
Cyclosporine	ng/mL	1	1000	
Sirolimus	ng/mL	1	30	
Everolimus	ng/mL	1	20	

Urine Toxicology UT4				
Sample Property	Lyophilized Urine	**Working Notes**		UT4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Amphetamine(AMP)	ng/ml	-	3000	
Barbiturates(BAR)	ng/mL	-	1500	
Buprenorphine (BUP)	ng/mL	-	150	
Benzodiazepines (BZD)	ng/mL	-	1500	
Cocaine (COC)	ng/mL	-	4000	
Methamphetamine(MET)	ng/mL	-	3000	
Morphine/Opiates(MOR/OPI)	ng/mL	-	8000	
Methadone(MTD)	ng/mL	-	1500	
SPICE I(SPC I)	ng/mL	-	250	
SPICE II (SPC II)	ng/mL	-	250	
SPICE II(SPC II-10)	ng/mL	-	250	
Marijuana/Hashish(THC)	ng/mL	-	250	
MDMA (Ecstasy) (XTC)	ng/mL	-	1500	

Cardiac Markers CM4 VE CM12				
Sample Property	Lyophilized Serum	**Working Notes**		CM4: 1x4 1 Sample Every 3-Month Period CM12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
hs Troponin I	ng/L	0.001	10000	
Mass CK-MB	ng/ml	0.1	50	
hs Troponin T	ng/L	0.001	10000	
Troponin I	ng/mL	0.001	30	
Troponin T	ng/mL	1	11	
HCG (Beta)	mIU/mL	5	5000	

Cardiac Markers-S CM-S4				
Sample Property	Lyophilized Serum	**Working Notes**		CM-S4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Myoglobin	ng/mL	0.1	1000	
BNP	pg/mL	1	1000	
NT-ProBNP	pg/mL	1	1000	

Prenatal Screening PS4				
Sample Property	Lyophilized Serum	**Working Notes**		PS4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
AFP	ng/mL	0.1	200	
Free Estriol (E3)	ng/mL	0.15	500	
Beta HCG	mIU/mL	5	200000	
PAPP-A	IU/L	0.1	100	
Free Beta HCG	ng/mL	5	200	
Inhibin A	pg/mL	2	200	

Procalcitonin PCT4				
Sample Property	Lyophilized Serum	**Working Notes**		PCT4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Procalcitonin	ug/L	0.2	200	

Serum Protein Electrophoresis SPE4				
Sample Property	Lyophilized Serum	**Working Notes**		SPE4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Albumin	%	10	80	
α1	%	1	30	
α2	%	1	30	
Beta	%	10	80	
Gamma Globulin	%	10	80	

Thalassemia TLS4 and TLS12				
Sample Property	Lyophilized Hemolysate	**Working Notes**		TLS4: 1x4 1 Sample Every 3-Month Period TLS12: 1X12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Hemoglobin A0	%	30	99	
Hemoglobin A2	%	0.1	7	

Therapeutic Drug Level Monitoring TDM4				
Sample Property	Lyophilized Serum	**Working Notes**		TDM4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Digoxin	ng/mL	0.1	10	
Phenytoin	mg/L	1	30	
Phenobarbital	mg/L	1	50	
Carbamazepine	mg/L	1	100	
Lithium	mEq/L	0.2	3	
Salicylate	mmol/L	1	100	
Theophylline	mg/L	1	30	

Ethanol-Ammonia EA4 and EA12				
Sample Property	Liquid Sample	**Working Notes**		EA4: 1x4 1 Sample Every 3-Month Period EA12: 1x12 1 Sample Per Month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Ethanol	mg/dL	5	1000	
Ammonia	umol/L	5	500	

HEMATOLOGY HM4 VE HM12				
Sample Property	Whole blood	**Working Notes**		HM4: 1x4 1 Sample Every 3-Month Period HM12: 1x12 1 sample per month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Hematocrit (HCT)	%	15	90	
Hemoglobin (HGB)	g/dL	5	18	
MCH	pg	15	50	
MCHC	g/dL	15	40	
MCV	fL	35	200	
MPV	fL	4	20	
Platelet (PLT)	K/uL	50	1000	
PDW	fL	5	30	
Leukocyte (WBC)	K/uL	1	30	
Erythrocyte (RBC)	10e6/uL	1.0	12	

Urine Chemistry UC4				
Sample Property	Urine Sample	**Working Notes**		UC4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Creatinine	mg/dl	5	200	
Microprotein	mg/dl	1	100	
Microalbumin	mg/dl	0.1	600	
Calcium	mg/dl	2	30	
Sodium	mEq/L	50	400	
Potassium	mEq/L	10	200	
Chloride	mEq/L	40	700	
Urea	mg/dl	300	5000	
Uric Acid	mg/dl	5	100	
Glucose	mg/dl	5	600	
Magnesium	mg/dL	5	50	

IMMUNOHEMATOLOGY IH4				
Sample Property	Manual: Erythrocyte Suspension (ES), Plasma Automatic: Whole Blood	**Working Notes**		IH4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Forward Blood Grouping (PATIENT ES)	-	-	-	
Forward Blood Grouping (DONOR ES)	-	-	-	
Reverse Blood Grouping (PATIENT Plasma)	-	-	-	
Reverse Blood Grouping (DONOR Plasma)	-	-	-	
RH Factor (PATIENT)	-	-	-	
RH Factor (DONOR)	-	-	-	
Crossmatch	-	-	-	
Direct Coombs	-	-	-	
Indirect Coombs	-	-	-	

Blood Gases BG4 and BG12				
Sample Property	Ready to use solution	**Working Notes**		BG4: 1x4 1 Sample Every 3-Month Period BG12: 1x12 1 sample per month
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
pCO2	mmHg	15	90	
pH	-log(H)	6.5	7,5	
pO2	mmHg	15	190	
Calcium	mmol/L	0.5	6	
Chloride	mmol/L	70	140	
Glucose	mg/dL	30	500	
Lactate	mmol/L	0	15	
Potassium	mmol/L	3	6	
Sodium	mmol/L	100	180	

Erythrocyte Sedimentation Rate ESR4				
Sample Property	Whole blood	**Working Notes**		ESR4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Erythrocyte Sedimentation Rate	mm/hour	***4***	100	

Complete Urine Analysis UA4/US4				
Sample Property	Urine sample	**Working Notes**		UA4 ve US4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Erythrocyte	-	-	-	
Bilirubin	-	-	-	
Urobilinogen	-	-	-	
Ketone	-	-	-	
Nitrite	-	-	-	
Glucose	-	-	-	
pH	-log(H)	-	-	
Specific Gravity	-	-	-	
Leukocyte	-	-	-	
Microscopy Erythrocyte	Piece	-	-	
Microscopy Leukocyte	Piece	-	-	
Microscopy Epithelial Cells	Piece	-	-	
Microscopy Crystals	Piece	-	-	
Protein	-	-	-	

Sample Property	Liquid Sample / Serum Sample	Working Notes		TRC4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
Toxoplasma IgM	-	-	-	
Toxoplasma IgG	-	-	-	
Rubella IgM	-	-	-	
Rubella IgG	-	-	-	
CMV IgG	-	-	-	
CMV IgM	-	-	-	

Viral Marker VM4				
Sample Property	Liquid Sample / Serum Sample	**Working Notes**		VM4: 1x4 1 Sample Every 3-Month Period
Parameter Name	**Unit**	**Working Range**		**Special/Restrictive Condition**
		Lower Limit	**Upper Limit**	
VM1 Panel				
HbsAg	-	-	-	
Anti-HBs	-	-	-	
Anti-HIV	-	-	-	
Anti-HCV	-	-	-	
HBeAg	-	-	-	
Syphilis (VDRL)	-	-	-	
VM2 Panel				
Anti-HBc Total	-	-	-	
Anti HAV IgM	-	-	-	
Anti-HAV Total/IgG	-	-	-	
Anti HBe	-	-	-	
Anti HBcM	-	-	-	
EBV VCA IgG	-	-	-	
EBV VCA IgM	-	-	-	
EBV EBNA IgG		-	-	

Glucometre GC4 and GC12				
Sample Property **Parameter Name**	Whole Blood	**Working Notes**		GC4: 1x4 1 Sample Every 3-Month Period GC12: 1x12 1 sample per month
Sample Property	**Unit**	**Working Range**		**Working Notes**
		Lower Limit	**Upper Limit**	
Glukoz	mg/dL	30	500	-