



biokit

08186 Llíssà d'Amunt
Barcelona
Spain

Tel.:+ 34 93 860 90 00
Fax:+34 93 860 90 17
e-mail: biokit@biokit.com
www.biokit.com

Date: 08-02-2011 (edition)
17-02-2011 (revision)

Ref: 296/MKT/Q/50

SUBJECT **NEW quantex C3 (II)**



We are pleased to announce that our **quantex C3** reagent has been updated and improved by a new one, the **quantex C3 (II)**.

Biokit has invested a great deal of effort to get a new C3 reagent with the aim of offering a new generation of this product. This new reagent presents very important improvements.

Let's look at the most significant ones:

1. The new **quantex C3 (II)** is showing an excellent Limit of Quantitation (LoQ). This LoQ is 2.32 mg/dL using the ILab™ 600/650 instrument family.
2. The direct working range in the ILab™ 600/650 is between **5-500 mg/dL** and with rerun, the working range is between 5-2500 mg/dL.
3. The reagent on board stability is **30 days!!**
4. The calibration stability is **60 days!!**
5. This reagent can be used with the following samples menu: **serum, heparin plasma and EDTA plasma.**
6. Excellent agreement with the previous quantex C3 reagent using ILab™ 600/650 and Hitachi 917 analyzers.

Important notice: This new reagent will use the same Calibrators and Controls. However the new reagents (buffer and antiserum) must not be interchanged with the old ones.

Presentation & Codes

Reagent	OLD	NEW
Name & REF	<i>Quantex C3</i> <i>REF. 3000-2308</i>	<i>Quantex C3 (II)</i> <i>REF. 3000-2340</i>
Packaging	<i>C3 R1(Buffer): 1 x 60 mL</i> <i>C3 R2(Antiserum): 4 x 12 mL</i>	<i>C3 R1(Buffer): 1 x 58 mL</i> <i>C3 R2(Antiserum): 2 x 9.5 mL</i>
Calibrators	<i>Quantex PROTEINS standards REF. 3000-2128</i>	
Controls	<i>Quantex PROTEINS controls I/II</i>	<i>REF. 3000-2122</i>

Attached information

In this BKNews you can find some relevant information about this excellent new product:

- **PERFORMANCE SUMMARY OF QUANTEX C3 (II), INCLUDING:**
Limit of Detection, Limit of Quantitation, Linearity, Extended Linearity, Prozone, Precision, Reagent Comparison, Sample Matrix studies, Reagent “on board” stability, Calibration stability and a table comparing the new ILab™ 600/650 application settings with the old ones.
- New quantex C3 (II) Inserts
- ILab™ 600/650 application
- ILab™ 300, ILab™ 350/BQA and ILab™ 900/1800 applications
- CE certification
- Material Safety Data Sheet

For further information or other instrument applications contact:

Sandra Roselló Serrano
Product Manager (Quantex - Turbidimetric Assays)
Tel: +34 93 8609000
Fax: +34 93 8609017
e-mail: sandra.rosello@biokit.com

PERFORMANCE SUMMARY OF QUANTEX C3 (II) ON ILAB™ 600

1 CONTENTS

1 CONTENTS	1
2 INTRODUCTION	3
3 LIMIT OF DETECTION	3
3.1 Introduction.....	3
3.2 Results	4
3.3 Comments and Conclusions	4
4 LIMIT OF QUANTITATION, LINEARITY AND PROZONE	4
4.1 Limit of Quantitation	4
4.1.1 Introduction.....	4
4.1.2 Results	4
4.1.3 Comments and Conclusions	5
4.2 Linearity.....	5
4.2.1 Introduction.....	5
4.2.2 Results	5
4.2.3 Extended Linearity (with rerun).....	7
4.2.4 Comments and Conclusions	7
4.3 Prozone	7
4.3.1 Introduction.....	7
4.3.2 Results	8
4.3.3 Comments and Conclusions	9
4.4 Global Conclusions	9
5 PRECISION	9
5.1 Introduction	9
5.2 Results	9
5.3 Comments and Conclusions	10
6 REAGENT COMPARISON STUDIES	10
6.1 Introduction.....	10
6.2 Results	10
6.3 Comments and Conclusions	11
7 SAMPLE MATRIX STUDIES	11
7.1 Introduction	11
7.2 Results	11
7.3 Comments and Conclusions	12
8 INTERFERENCES AND CROSS-REACTIVITY	12
8.1 Introduction	12
8.2 Results	12
8.3 Comments and Conclusions	12
9 CALIBRATION AND REAGENT “ON BOARD” STABILITIES	13
9.1 Calibration stability.....	13

9.1.1 Introduction	13
9.1.2 Results	13
9.1.3 Comments and Conclusions	14
9.2 Reagent on board stability	14
9.2.1 Introduction	14
9.2.2 Results	14
9.2.3 Comments and Conclusions	14
10 SAMPLE CARRY-OVER	15
10.1 Introduction	15
10.2 Results	15
10.3 Comments and Conclusions	15
11 ILab™ 600/650 Application: Quantex C3 vs Quantex C3 (II).....	16

Quantex C3 (II) on the ILab™ 600. Summary of POP Results

2 INTRODUCTION

The *Quantex C3 (II)* is a turbidimetric assay intended for the quantitative *in vitro* determination of complement 3 (C3) in human serum or plasma. A sample containing complement 3 will aggregate when mixed with the reagent. The degree of aggregation is directly proportional to the complement 3 concentration in the sample and can be quantitated by measuring the increase of absorbance at 600 nm. Results are expressed in mg/dL or g/L of complement 3 based on the International Reference Material for Measurement of 14 Human Serum Proteins (CRM 470).

The new Quantex C3 (II) consists of two components, the buffer (R1) and the antisera reagent (R2), both ready to use.

This report presents the most relevant results of the Development Proof of Performance (PoP) experiments of the *Quantex C3 (II)* assay on the ILab™ 600 Instrument (Instrumentation Laboratory). All the data reported were obtained using one reagent batch, and a unique batch of calibrators and controls was also used.

Instrument or Application	ILab 600
Reaction mode	End up (33-17)
Calibration mode	Point to point
Calibration points	46-116-231-347-463
Sample volume	3 µl
Antiserum volume	75 µl
Buffer volume	190 µl
Water volume	10 µl
Rerun	1:5

3 LIMIT OF DETECTION

3.1 Introduction

The Limit of Detection (LoD) is defined as the mean reported value + 3SD (SD= Standard Deviation) for a sample free of the analyte (saline solution 0.9%).

The LoD has been determined analyzing 50 replicates of the saline solution (5 replicates, 2 runs per day, 5 days) and the calculation was done according to the following formula:

$$\text{LoD} = \text{Average}_{(50 \text{ replicates})} + 3 \text{ SD}$$

The LoD is the lowest actual amount of analyte in a sample that can be detected with a stated probability (usually 95%).

3.2 Results

The result obtained is shown below:

$$\text{LoD} = 0.3797$$

3.3 Comments and Conclusions

The detection limit of the Quantex C3 (II) could be defined as 0.38 mg/dL.

4 LIMIT OF QUANTITATION, LINEARITY AND PROZONE

4.1 Limit of Quantitation

4.1.1 Introduction

The Limit of Quantitation (LoQ) is defined as the minimum quantity of analyte that the method can reliably detect. Depending on the defined goal for error, the LoQ could be equal to the LoD (Limit of Detection) or higher, but never lower.

To assess the Limit of Quantitation, the calibrator level 2 (116 mg/dL) was diluted 1/10 with saline solution. Using this 1/10 dilution, from 10/10 to 0/10 dilutions were created using saline solution.

Each dilution was analyzed in quadruplicate and the mean reported value of each sample dilution calculated. The inaccuracy and the imprecision (CV) were also calculated.

Acceptance criteria: Maximum inaccuracy and imprecision will be 20%

4.1.2 Results

The results obtained are presented below:

Dilution	EV (mg/dL)	RV (mg/dL)	Inaccuracy (%)	Imprecision (%)
10/10	11.60	12.28	5.82	2.69
9/10	10.44	11.13	6.56	2.58
8/10	9.28	9.75	5.06	3.97
7/10	8.12	8.60	5.91	0.95
6/10	6.96	7.63	9.55	3.28
5/10	5.80	6.30	8.62	2.24
4/10	4.64	4.93	6.14	3.47
3/10	3.48	3.83	9.91	2.50
2/10	2.32	2.45	5.60	7.82
1/10	1.16	1.45	25.00	27.87
0/10	0.00	0.05	0.00	200.00

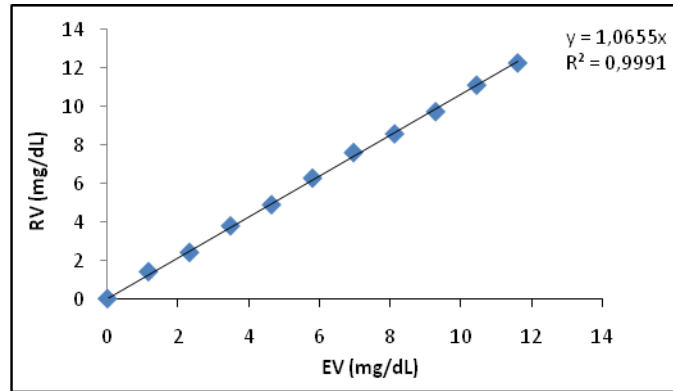
EV: Expected Values

RV: Reported Values (mean)

Inaccuracy (%) = $100 \times ((RV-EV)/EV)$

Imprecision (%) = CV

The EV versus the RV were plotted and linear regression statistics applied:



4.1.3 Comments and Conclusions

The Limit of Quantitation (LoQ) of the new Quantex C3 (II) could be established at 2.32 mg/dL, since it is the lowest concentration that meets the acceptance criteria.

Moreover, the LoQ (2.32 mg/dL) is higher than the LoD (0.38 mg/dL) as established.

4.2 Linearity

4.2.1 Introduction

The linearity of the assay has been determined using the following procedure: level 5 calibrator (463 mg/dL) and a serum sample were diluted with saline solution and analyzed in duplicate. The following dilutions were prepared: 100%, 50%, 25%, 12,5%, 6,25% and 0%.

The mean, SD, CV (%) and inaccuracy (%) were calculated.

4.2.2 Results

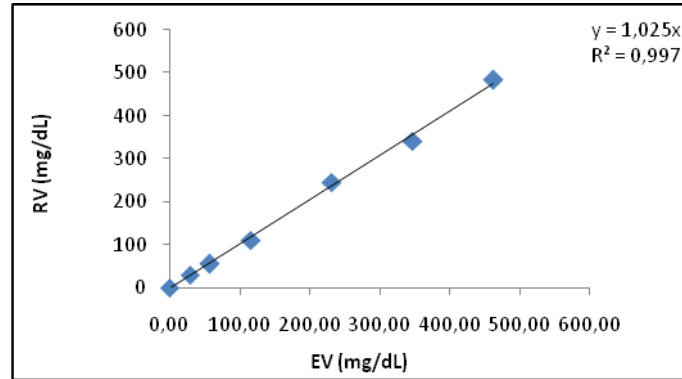
The results obtained are presented below:

- Level 5 standard

% Dilution	EV (mg/dL)	RV (mg/dL)			
		Mean	SD	CV (%)	Inaccuracy (%)
100	463.00	483.95	16.62	3.43	4.52
75	347.25	341.20	7.50	2.20	-1.74
50	231.50	246.05	4.88	1.98	6.29
25	115.75	111.55	1.06	0.95	-3.63
12.5	57.88	55.90	0.57	1.01	-3.41
6.25	28.94	29.50	0.14	0.48	1.94
0	0.00	0.00	0.14	0.00	0.00

EV: Expected Values
 RV: Reported Values (mean)
 Inaccuracy (%) = 100 x ((RV-EV)/EV)
 Imprecision (%)= CV

The EV versus the RV were plotted and the linear regression statistics is applied:

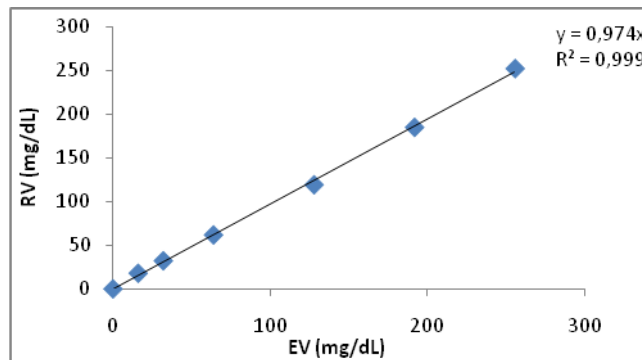


- Serum sample

% Dilution	EV	RV (mg/dL)			Inaccuracy (%)
		Mean	SD	CV (%)	
100	255.12	252.05	1.77	0.70	-1.203
75	191.34	184.85	2.76	1.49	-3.392
50	127.56	119.2	2.83	2.37	-6.554
25	63.78	61.85	1.34	2.17	-3.026
12.5	31.89	32.3	0.42	1.31	1.286
6.25	15.95	18	0.14	0.79	12.888
0	0.00	0.15	0.21	141.42	0.00

EV: Expected Values
 RV: Reported Values (mean)
 Inaccuracy (%) = $100 \times ((RV-EV)/EV)$
 Imprecision (%) = CV

The EV versus the RV were plotted and the linear regression statistics applied:



Acceptance criteria: Maximum inaccuracy and imprecision will be 20%

Reported value vs. Expected value:

Slope: 1.0 ± 0.05

Intercept: within $\pm 3\%$ of the mean X value

Correlation coefficient (r): >0.99

Specifications: Linearity between 5 and 500 mg/dL

4.2.3 Extended linearity (with rerun)

The level 4 calibrator (347 mg/dL) was run as a sample with and without the rerun capability of the instrument .

The rerun limit of the new Quantex C3 (II) application was changed to 300 mg/dL to assess the dilution function of the analyzer with the proposed dilution factor. The real recommended rerun limit with the new Quantex C3 (II) reagent will be 500 mg/dL.

The ILab™ 600/650 application for the Quantex C3 (II) reagent considers a 1/5 sample dilution (30µL of sample + 120µL of diluent) as a Sampling 2 condition, extending the linearity range up to 2500 mg/dL.

The mean, SD, CV and Inaccuracy were calculated and the results obtained compared.

Standard level 4	EV	RV (mg/dL)			
		Mean	SD	CV (%)	Inaccuracy (%)
without rerun	347.0	345.6	0.99	0.29	-0.403
with rerun	347.0	353.1	4.31	1.22	1.758

Acceptance criteria: Maximum inaccuracy and imprecision will be 20%

Specifications for Extended Linearity: between 5 and 2500 mg/dL

4.2.4 Comments and Conclusions

The dilutions analyzed show a linear plot and all the acceptance criteria are met.

4.3 Prozone

4.3.1 Introduction

The prozone or (high-dose) Hook effect is falsely low values on an immunoassay when a high amount of antigen affects the binding capacity of the antibody added. The purpose of a prozone study is to define the highest concentration still reporting above the upper limit of the linear range without falsely losing concentration. By definition, a sample reporting above the upper limit of the test range should be (auto) retested at a higher dilution and the result corrected by the dilution factor.

The prozone analysis was performed by increasing the amount of sample volume. The application was modified in order to increase the sample volume x5 (from 3µL to 15 µL), proportionally increasing the total concentration of the analyte in the reaction cell. To do this, the auto rerun capability of the analyzer was disabled.

The 5 calibrators and saline as a zero point (0 mg/dL, 46 mg/dL, 116 mg/dL, 231 mg/dL, 347 mg/dL, 463 mg/dL) were analyzed as samples in duplicate. Using this application, the simulated sample concentrations were 0 mg/dL, 230 mg/dL, 580 mg/dL, 1155 mg/dL, 1735 mg/dL and 2315 respectively.

The mean reported value for each sample dilution and the inaccuracy were calculated.

Acceptance criteria for Prozone: The “NO prozone” claim will be set at the highest concentration checked that still reports above the upper limit of the test range.

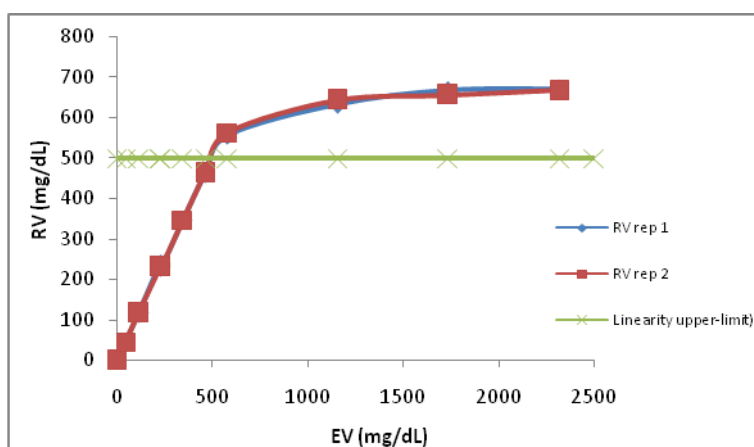
4.3.2 Results

The results obtained (without the auto rerun capability) are presented below:

	3 μ L application	15 μ L application		
	EV (mg/dL)	EV (mg/dL)	RV (mg/dL)	Innaccuracy
saline	0	0	0.35	0.00
std 1	46	230	235.45	2.37
std 2	116	580	560.15	-3.42
std 3	231	1155	639.1	-44.67
std 4	347	1735	661.75	-61.86
std 5	463	2315	668.45	-71.13

The EV (assigned calibrator values) versus the $RV_{\text{replicate 1}}$ and $RV_{\text{replicate 2}}$ were plotted. The upper limit range proposed (500 mg/dL) is marked on the graph:

EV	RV replicate 1	RV replicate 2
0	0	0
46	46	46
116	116	116
231	231	231
347	347	347
463	463	463
0	0.7	0
230	239.7	231.2
580	557.9	562.4
1155	634.1	644.1
1735	667.3	656.2
2315	669.9	667



4.3.3 Comments and Conclusions

The new Quantex C3 (II) reagent presents no inhibitory prozone until 580 mg/dL, being higher than the upper limit of linearity proposed.

4.4 Global Conclusions

The Upper and Lower limits of the test range have been defined using the LoQ, linearity and prozone results. The Lower limit assigned is 5 mg/dL, but the LoQ value is 2.32 mg/dL. The lower limit of the new Quantex C3 (II) reagent is significantly lower than the previous Quantex C3 reagent (25 mg/dL).

The upper limit assigned is 500 mg/dL and it has been assigned using the results obtained from the prozone analysis. The EV value of 580 mg/dL is the highest concentration that has an acceptable inaccuracy value. Concentrations higher than 500 mg/dL (upper limit) have to be re-analyzed using the auto rerun capability of the analyzer.

Thus, we can conclude that the linearity range for the new Quantex C3 (II) on ILab™ 600 instruments is:

- 5 mg/dL to 500 mg/dL without the automatic rerun capability
- 5 mg/dL to 2500 mg/dL with the automatic rerun capability

5 PRECISION

5.1 Introduction

A 5-day precision study was carried out. Saline solution and two Control levels (CI and CII) were analyzed in quintuplicate in 2 runs per day for 5 days (total n = 50).

The ranges listed below for Control I and Control II were established using the current Quantex C3.

	Mean (mg/dL)	Range (mg/dL)
Control I	83	66-100
Control II	198	159-238

5.2 Results

Within run, between run, between day, and total SD and CV have been calculated and are summarized in the following table.

	Control I	Control II
Grand Mean (mg/dL)	80.56	192.99
Within-Run Variance	1.21	7.30
Within-Run SD	1.10	2.70
Within-Run CV	1.37%	1.40%
Between-Run Variance	0.29	1.23
Corrected Between-run Variance	0.05	-0.23
Between-Run CV	0.28%	0%
Between-Day Variance	2.64	5.19
Corrected Between-Day Variance	2.49	4.58
Between-Day CV	1.96%	1.11%
Total SD	1.82	3.29
Total CV	2.25%	1.70%

Specifications:

- Within run CV: < 3%**
- Total CV: < 5%**

5.3 Comments and Conclusions

Both control levels met the specifications, so the precision of the new Quantex C3 (II) reagent used in an ILab™ 600 analyzer is excellent.

6 REAGENT COMPARISON STUDIES

6.1 Introduction

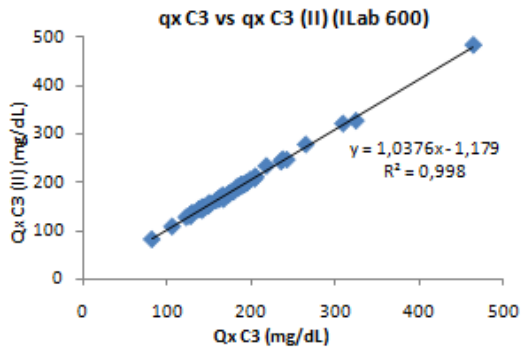
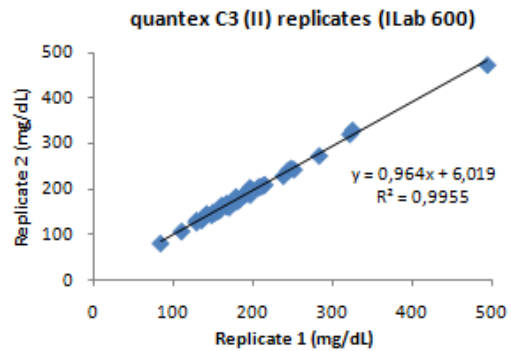
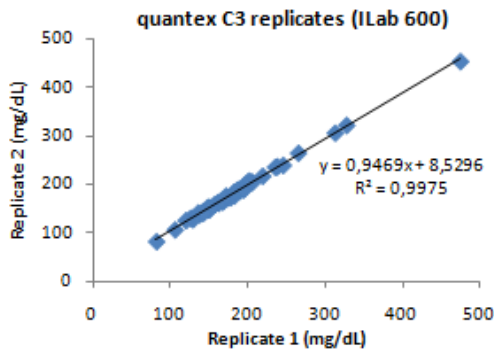
The Reagent Comparison studies consisted of the analysis of different anonymous samples with the Quantex C3 (II) reagent in comparison with the current Quantex C3 reagent using the same instrument ILab™ 600. The samples used in these studies were from patients in Hospital de Sant Pau (Barcelona). Around 50 random serum samples covering all the analytical range were analyzed in duplicate using a ILab™ 600 and 67 serum samples were analyzed using a Hitachi 917.

Acceptance criteria:

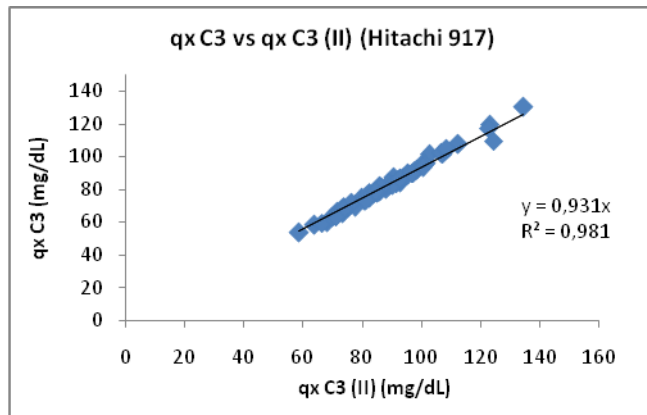
- Slope: 1.0 ± 0.1**
- Intercept: within ± 10% of the mean X value**
- Correlation Coefficient (r): ≥ 0.950**

6.2 Results

The results of the comparison of samples between the Quantex C3 (II) and the current Quantex C3 on the ILab™ 600 and Hitachi 917 analyzers are presented below. The scatter plots show the correlation line and the linear regression statistics. A table shows the comparison statistics.



Reference	C3 Replicate 1	C3 (II) Replicate 1	qx C3
Test	C3 Replicate 2	C3 (II) Replicate 2	qx C3 (II)
Intercept	8,530	6,019	-1,179
Slope	0,947	0,964	1,038
r statistic	0,999	0,998	0,999
r ²	0,998	0,996	0,998
Mean Y	182,2	188,1	188,5
Mean X	183,4	188,9	182,8
Min X	82,1	83,2	82,0
Max X	475,1	493,6	463,9
n	50	50	50
Sxy	3,0	4,2	2,8



6.3 Comments and Conclusions

Comparison of the Quantex C3 and the new Quantex C3 (II) reagents meets the acceptance criteria in both analyzers.

7 SAMPLE MATRIX STUDIES

7.1 Introduction

The comparability between different types of sample matrixes was carried out using serum, heparin plasma and EDTA plasma.

53 samples were used to analyze the correlation between serum and heparin plasma and 67 samples were used to analyze the correlation between serum and EDTA plasma.

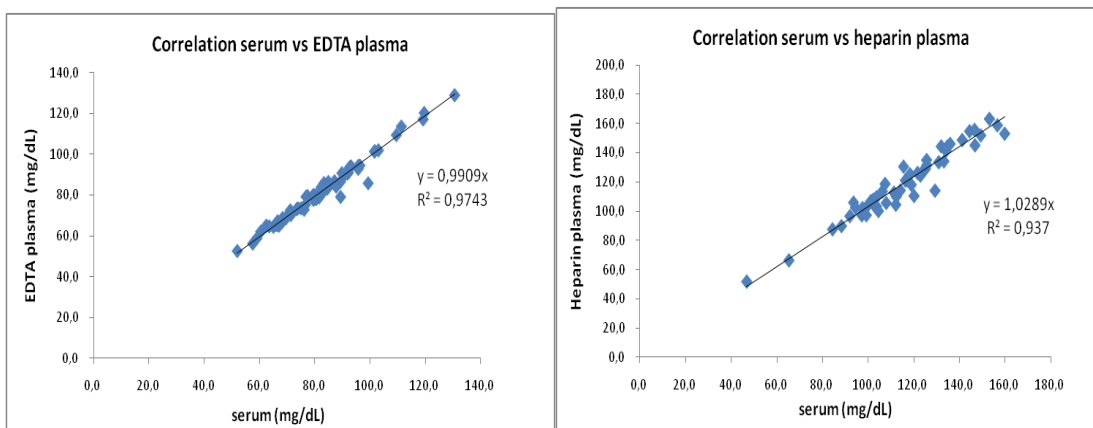
The correlation coefficient, slope, and intercept of the comparison of each matrix (heparin plasma or EDTA plasma) vs. reference (serum) were all calculated.

Specifications for the sample matrix studies were:

Slope: 1 ± 0.1

Correlation coefficient (r): ≥ 0.90 .

7.2 Results



7.3 Comments and Conclusions

All the specifications are met, thus we can conclude that the different matrixes are equivalent and can be used with the new Quantex 3 (II) reagent).

8 INTERFERENCES AND CROSS-REACTIVITY

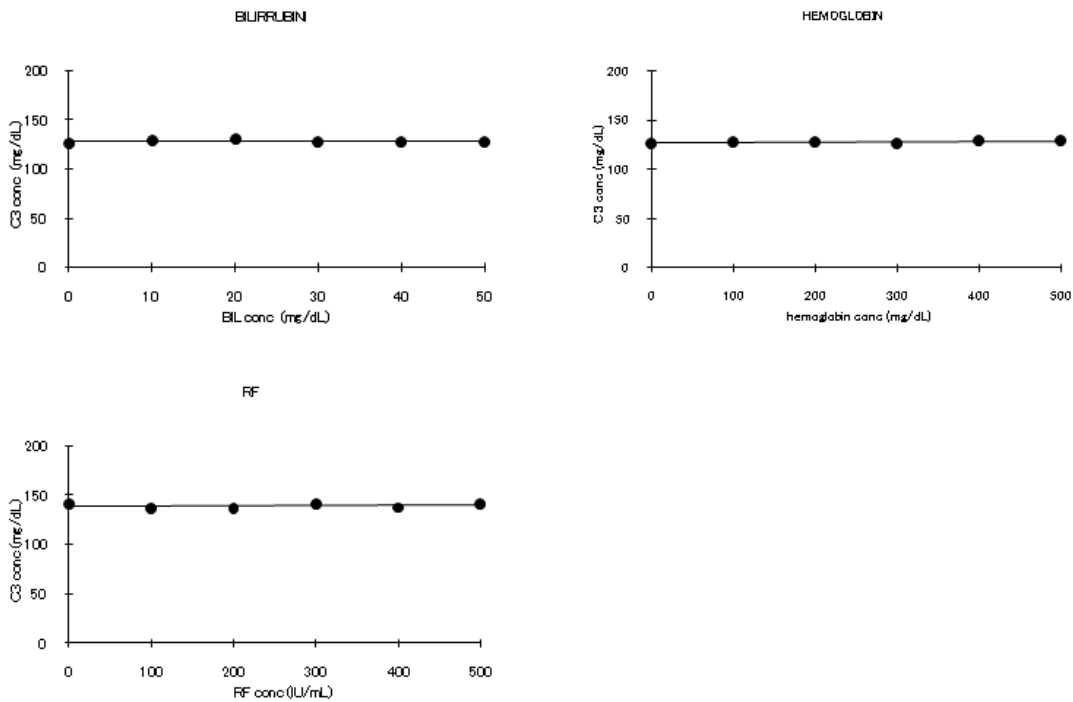
8.1 Studies at the maximum interfering substance concentration

Bilirubin, rheumatoid factors, hemoglobin and lipids were analyzed to determine potential interfering substances.

Each commercial interfering substance was added to pooled serums at different concentrations.

8.2 Results

The following graphs show the results for each potential interfering substance.



8.3 Comments and Conclusions

No significant interferences were found for bilirubin up to concentrations of 50 mg/dL, RF up to concentrations of 500 IU/ml and hemoglobin up to concentrations of 500 mg/dL.

9 CALIBRATION AND REAGENT “ON BOARD” STABILITIES

9.1 Calibration stability

9.1.1 Introduction

The instrument was calibrated on day 0 and several control days were fixed (day 10, 14, 42, 60).

The Delta absorbances obtained for each Calibrator level in all the calibrations performed throughout the study were compared with the calibration data for day 0.

Acceptance criteria: Maximum inaccuracy will be 20%

9.1.2 Results

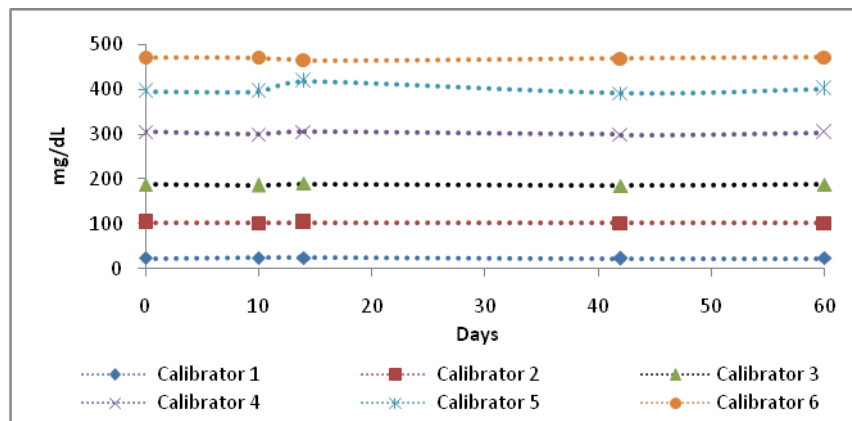
The calibration values are shown below:

Date	Day	$\Delta\text{Abs} (\times 10^3)$					
		Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4	Calibrator 5	Calibrator 6
17/09/2010	0	23.93	102.79	188.41	304.66	395.53	470.74
27/09/2010	10	24.16	101.99	186.81	299.49	394.66	470.04
01/10/2010	14	24.28	103.09	189.74	305.57	417.38	464.51
29/10/2010	42	23.74	101.92	185.19	298.94	391.17	467.65
16/11/2010	60	23.84	101.47	187.22	303.42	400.56	470.68

These values were compared with the mean calibration values at day 0.

% Inaccuracy	Calibrator 1	Calibrator 2	Calibrator 3	Calibrator 4	Calibrator 5	Calibrator 6
day 10 vs day 0	0.940	-0.778	-0.849	-1.697	-0.220	-0.149
day 14 vs day 0	1.454	0.292	0.706	0.299	5.524	-1.323
day 42 vs day 0	-0.819	-0.846	-1.709	-1.878	-1.102	-0.656
day 60 vs day 0	-0.389	-1.284	-0.632	-0.407	1.272	-0.013

The data represented in graph form is shown below:



9.1.3 Comments and Conclusions

With the new Quantex C3 (II) reagent calibration stability can be assured for at least 60 days.

9.2 On board reagent stability

9.2.1 Introduction

On day 0, reagents were uncapped and placed on-board in the reagents tray of the instrument (Hitachi 917). The vials remaining inside the analyzer until the on-board stability study concluded and the vials had not been recapped.

The reagent tray must be covered to avoid evaporation of the reagent and contamination and the instrument has to be “on” throughout the duration of the study.

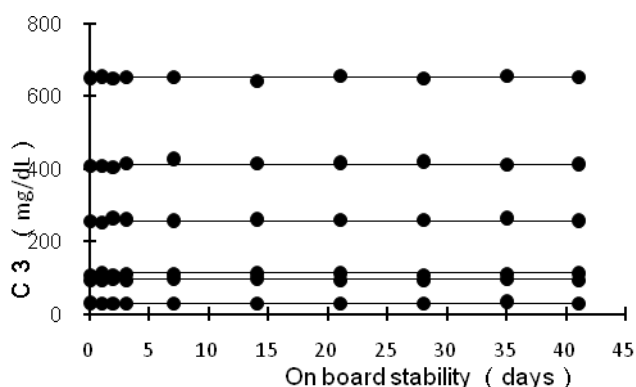
9.2.2 Results

The mean of each duplicate was calculated and statistic calculations applied (mean, SD, CV).

The results obtained are presented below:

Days	Sample 1 (mg/dL)	Sample 2 (mg/dL)	Sample 3 (mg/dL)	Sample 4 (mg/dL)	Sample 5 (mg/dL)	Sample 6 (mg/dL)
0	93	256	28	107	408	647
1	94	252	29	109	408	651
2	95	262	29	108	404	649
3	94	259	30	110	415	653
7	96	255	30	111	425	653
14	95	258	30	109	415	642
21	94	259	30	110	414	657
28	94	259	29	108	418	649
35	97	262	32	111	412	657
41	93	254	29	109	410	654
N	10	10	10	10	10	10
MEAN	94	258	29	109	413	651
SD	1.20	3.29	0.98	1.33	5.83	4.51
CV(%)	1.27	1.28	3.34	1.22	1.41	0.69

The results were also plotted:



9.2.3 Comments and Conclusions

The results show that the on board stability of the reagent is at least 40 days in the instrument used.

10 SAMPLE CARRY-OVER

10.1 Introduction

Sample carry-over is defined as the percentage of a particular sample that is carried over to the immediately next sample analyzed.

The following sequence was analyzed two fold:

L, L, L, H, H, L, L, H, H, L, L, H, H, L, L

L: control I (low control)

H: control II (high control)

The sample carry-over is calculated according to the following equation:

$$\% \text{ carry-over} = ((R-M)/H_z) \times 100$$

Where:

M is the mean of the reported values (3 per run) of the low control placed in positions 1-3

R is the mean of the reported values (3 per run) of the control placed in positions 6, 10 and 14 (just after the high control).

H_z is the concentration for the high control.

10.2 Results

The following table summarises the sample carry-over experiment and shows the calculated result (%).

Sequence		Run 1	Run 2
1	L	45,2	45,3
2	L	45,1	45
3	L	45,9	45,8
4	H	312,7	336,7
5	H	326,9	319,7
6	L	45,8	46,7
7	L	45	45,7
8	H	340,3	326,7
9	H	339,4	337,4
10	L	46,1	46
11	L	46,2	46,1
12	H	334,3	338,7
13	H	334,7	321,1
14	L	46	45,7
15	L	45,9	46

M = 45,38

R = 46,05

H_z = 330,72

% Carry-over = 0,20

10.3 Comments and Conclusions

The estimated carry-over for a sample is 0.20%. This value is not significant compared to the lower limit of linearity for the reagent.

Quantex C3 versus Quantex C3 (II). iLab™ 600/650 Test Parameters

	QUANTEX C3	QUANTEX C3 (II)
Photometric Test Parameters		
Test №	**	77
Test Name, Test Code	C3, C3	C3 (II), C3 (II)
Sample Type	Serum	Serum
Reporting Unit, Decimal Points	mg/dL, 1	mg/dL, 1
Reaction Cycle	Standard	Standard
Twin Analysis	OFF	OFF
Methodology Type, Measuring Point	End point, 17/33	End point, 17/33
Photometric Methodology	1 Wavelength	1 Wavelength
Primary/Secondary Wavelength	340	600
Sampling Conditions		
Sampling 1 Sample vol.	3	3
Sample/Diluent vol.	0/0	0/0
Sampling 2 Sample vol.	3	3
Sample/Diluent vol.	30/120	30/120
Sampling 3 Sample vol.	9	9
Sample/Diluent vol.	0/0	0/0
Sampling 4	***	***
Diluent Code	Saline	Saline
Diluent Warning Limit	***	**
First Run	Sampling 1	Sampling 1
Below/Above Normal Range	***	***
Panic L	***	***
Panic H	Sampling 2	Sampling 2
Non Linear	**	**
Prozone	N/A	N/A
HIGH!, ABS	Sampling 2	Sampling 2
Reagent volumes		
R1 Code	77781	02771
Rgt/Dil. Vol., Stirring	190/0, yes Buffer	190/0, ON Buffer
Low Vol. Warning Limit	***	***
Stability (days)	**	**
R2 Code	01772	02772
Rgt/Dil. Vol., Stirring	190/10, yes Reagent	75/10, ON Reagent
Low Vol. Warning Limit	***	***
Stability (days)	**	**
Ranges and Evaluation Criteria		
Normal Range-Male	**	*
Normal Range-Female	**	*
Normal Range-Other	**	*
Valid Range	0-490	0-500*
Hemolysis/Icterus/Lipemia Limit *** **	***	***
Reaction Slope	Positive	Positive
Absorbance Limit	Above, 3200	Above, 3200
Prozone Limit	N/A	N/A
Non Linear Limit	N/A	N/A
Slope/Intercept correction	1/0	1/0
Qualitative Report	OFF	OFF
Calibration Conditions		
Calibration	5 points, point to point, 2 Reps	5 points, point to point, 2 Reps
Stability (days)	30	60
Calibrator, Concentrations Std.	PROTEINS std. *	PROTEINS std. ****
R-Blank Limit (mAbs)	150	150
Cal. Reps Range (%)	***	***
Min. Cal. Response (mAbs)	***	***
Cal. Factor Change (%)	***	***
M-Point Curve Fit (%)	N/A	N/A
Auto R-Blank by Bottle	ON	ON

* Operator definable, see the insert. ** Operator definable. *** Optional.
 **** Lot dependent. See concentration on standard value data sheet. N/A Not applicable to this test

quantex C3 (II)

3000-2340

READ HIGHLIGHTED CHANGES

1 x 58 ml C3 (II) R1 (Buffer)
2 x 9.5 ml C3 (II) R2 (Reagent)**Intended Use**

The reagents **quantex C3 (II)** are intended for the quantitative determination of complement 3 (C3) in human serum or plasma using the ILab™ Chemistry Systems. Check with your distributor or with the Technical Department of BIOKIT, S.A. for other available applications. Refer to the Clinical Chemistry publication "Effects of Disease on Clinical Laboratory Tests"¹ for a summary of causes of increased or decreased complement 3 concentration.

Summary/Principle

Turbidimetric assay.²

A sample containing complement 3 will aggregate when mixed with the reagent. The degree of aggregation is directly proportional to the complement 3 concentration in the sample and can be quantitated by measuring the increase of absorbance at 600 nm. Results are expressed in mg/dl or g/l of complement 3 based on the International Reference Material for Measurement of 14 Human Serum Proteins (CRM 470).³

Reagents

- C3 (II) R1 (Buffer):
Phosphate Buffer 30 mM pH 8.0.
- C3 (II) R2 (Reagent):
Goat serum anti-human complement 3 in phosphate buffer 10 mM.

All reagents contain < 0.1% sodium azide.

Precautions

The **quantex** reagents are intended for IN VITRO diagnostic use.

For professional use only.

Sodium azide may react with lead or copper pipes and plumbing creating highly explosive metal azides. Flush drains with water thoroughly after disposing of the remains of reagents.

Because no test method can offer complete assurance of the absence of infectious agents, this product should be handled with caution.⁴

Dispose all used materials in a suitable biohazardous waste container.

Reagent preparation

- C3 (II) R1 (Buffer) : Ready to use. Place container in reagent tray.
- C3 (II) R2 (Reagent): Ready to use. Place container in reagent tray.

If necessary, transfer the material to the adequate container.

Reagent storage and stability

Reagents from unopened vials are stable until the expiration date shown on the vial when stored at 2-8°C. Do not freeze.

Once opened the vials, the reagents are stable for 30 days on-board the instrument.

For optimal stability remove reagents from the system and store them at 2-8°C in the original vial securely closed.

Samples

Use fresh serum or plasma (EDTA, heparin). Other anticoagulants should be evaluated before use. Samples can be stored at 2-8°C for 2 days. For longer periods, the serum could be frozen (-20°C). Avoid repeated freezing and thawing. Homogenize the samples before analysis.

Calibration

Use **quantex PROTEINS standard multipoint** [REF] 3000-2128. The concentrations in mg/dl and g/l are indicated on the standard insert data sheet. Recalibrate every 60 days, when a new lot of reagent is used, when control recovery falls out of the expected range or when adjustments are made to the instrument.

Quality control

It is recommended to use two levels of controls such as **quantex PROTEINS control I/II** [REF] 3000-2122. Analyze controls at least once each day. Expected ranges can be found on the control insert sheets. The control values should be within the established range. Otherwise, corrective measures should be taken by the user. For identification and resolution of out-of-control situations, references such as Westgard *et al.*⁵ are recommended.

If expected results are not obtained, do not use the kit.

Interferences

No significant interference from bilirubin up to concentrations of 50 mg/dl, hemoglobin up to concentrations of 500 mg/dl and rheumatoid factor up to concentrations of 500 IU/ml. For a comprehensive review of interfering substances, refer to the publication by Young *et al.*⁶

Reference Range

Concentrations of C3 (II) between 90 and 180 mg/dl (0.9 - 1.8 g/l) are considered normal.⁷

Precision

ILab 600	Samples/ Runs	Mean (mg/dl)	CV (%)	Samples/ Runs	Mean (mg/dl)	CV (%)
Within run	5/10	80.6	1.4	5/10	193.0	1.4
Total	5/10	80.6	2.3	5/10	193.0	1.7

Method Comparison

Test reagent (y)	quantex C3 (II)
Comparison reagent (x)	quantex C3
Instrument used	ILab 600
Slope	1.038
Y intercept	-1.2
Range (mg/dl)	82.0 - 463.9
Mean X (mg/dl)	182.8
Mean Y (mg/dl)	188.5
r	0.9989
n	50

Linearity

ILab 600/650: 5 to 500 mg/dl without the automatic rerun capability.
5 to 2500 mg/dl with the automatic rerun capability.

If after the automatic rerun the concentration of the sample exceeds the linearity range, dilute the sample 1:20 with saline solution, re-assay and multiply the result by the dilution factor.

quantex C3 (II)

3000-2340

LEER CAMBIOS SOMBREADOS

1 x 58 ml C3 (II) R1 (Tampón)

2 x 9,5 ml C3 (II) R2 (Reactivo)

Uso

Los reactivos **quantex C3 (II)** son para la determinación cuantitativa de complemento 3 (C3) en suero o plasma humano usando los sistemas de química clínica ILab™. Contacte con su distribuidor o con el Departamento Técnico de BLOKIT, S.A. para otras aplicaciones disponibles. Referirse al artículo "Effects of Disease on Clinical Laboratory Tests",¹ donde encontrará una recopilación de las causas que determinan un incremento o decremento en la concentración de complemento 3.

Sumario/Principio

El procedimiento está basado en la turbidimetría.²

Cuando una muestra que contiene complemento 3 se mezcla con el reactivo, se produce una agregación. El grado de agregación es directamente proporcional a la concentración de complemento 3 en la muestra y se determina midiendo el incremento de absorbancia a 600 nm. Los resultados se expresan en mg/dl o g/l de complemento 3 basados en la Preparación Internacional de Referencia para 14 Proteínas Séricas (CRM 470).³

Reactivos

- C3 (II) R1 (Tampón):
Tampón fosfato 30 mM pH 8,0.
- C3 (II) R2 (Reactivo):
Suero de cabra anti-complemento 3 humano en tampón fosfato 10 mM.

Todos los reactivos contienen azida sódica < 0,1%.

Precauciones

Los reactivos **quantex** son sólo para el diagnóstico IN VITRO.

Para uso exclusivo por profesionales.

La azida sódica puede reaccionar con tuberías y desagües de plomo o cobre dando lugar a azidas metálicas altamente explosivas. Al desechar los restos de reactivos, deje correr agua abundante.

Ya que ningún método puede ofrecer la total seguridad de la ausencia de agentes infecciosos, este producto debe manejarse con precaución.⁴

Depositar todos los materiales usados en recipientes adecuados para material biocontaminante.

Preparación de los Reactivos

- C3 (II) R1 (Tampón) : Listo para su uso. Colocar el contenedor en el plato de reactivos.
- C3 (II) R2 (Reactivo) : Listo para su uso. Colocar el contenedor en el plato de reactivos.

En caso necesario, transferir el material al contenedor adecuado.

Conservación y estabilidad de los reactivos

Los reactivos de viales que no hayan sido abiertos y se hayan conservado a 2-8°C son estables hasta la fecha de caducidad indicada en la etiqueta. No congelar.

Una vez abiertos los viales, los reactivos son estables durante 30 días en el instrumento.

Para una óptima estabilidad, sacar los reactivos de los instrumentos y conservarlos a 2-8°C en sus viales originales bien tapados.

Muestras

Usar suero fresco o plasma (EDTA, heparina). Otros anticoagulantes deben ser comprobados antes de utilizarse. Las muestras pueden ser conservadas durante 2 días entre 2-8°C. Si es por un período de tiempo más largo el suero puede congelarse (-20°C). Evitar congelar y descongelar las muestras repetidamente. Homogeneizar las muestras antes de analizarlas.

Calibración

Debe usarse el **quantex PROTEINS standard multipunto** REF 3000-2128. Las concentraciones en mg/dl y g/l se indican en la hoja de valores adjunta. Recalibrar cada 60 días, al cambiar el lote de reactivos, cuando el control reporte un valor fuera del rango de aceptación o cuando se hagan ajustes en el instrumento.

Control de calidad

Se recomienda usar dos niveles de control tales como **quantex PROTEINS control I/II** REF 3000-2122. Comprobar los controles por lo menos una vez por día. Ver rango de valores en la hoja adjunta al producto. Los valores de los controles deben encontrarse dentro del rango establecido. En caso contrario el usuario deberá adoptar medidas correctivas. Para la identificación y resolución de valores que reporten fuera del rango de aceptación, se recomienda consultar la publicación de Westgard, *et al.*⁵

Si no se obtienen los resultados esperados, no utilizar el kit.

Interferencias

No se observa interferencia por bilirrubina hasta concentraciones de 50 mg/dl, por hemoglobina hasta concentraciones de 500 mg/dl ni por factor reumatoide hasta concentraciones de 500 UI/ml. Para más información acerca de las interferencias referirse a la publicación de Young, *et al.*⁶

Valores de Referencia

Se consideran normales concentraciones de C3 (II) entre 90 y 180 mg/dl (0,9 - 1,8 g/l).⁷

Precisión

ILab 600	Muestras/ Ensayos	Media (mg/dl)	CV (%)	Muestras/ Ensayos	Media (mg/dl)	CV (%)
Dentro ensayo	5/10	80,6	1,4	5/10	193,0	1,4
Total	5/10	80,6	2,3	5/10	193,0	1,7

Comparación de Métodos

Reactivo de prueba (y)	quantex C3 (II)
Reactivo de comparación (x)	quantex C3
Instrumento usado	ILab 600
Pendiente	1,038
Intersección	-1,2
Rango (mg/dl)	82,0 - 463,9
Media X (mg/dl)	182,8
Media Y (mg/dl)	188,5
R	0,9989
n	50

Linealidad

ILab 600/650: 5 a 500 mg/dl sin activar la opción "rerun".
5 a 2500 mg/dl utilizando la opción "rerun".

Si la concentración de la muestra después de ser reanalizada automáticamente excede el rango de linealidad, diluir 1:20 con solución salina y volver a analizarla. Multiplicar el resultado por el factor de dilución.

quantex C3 (II)

3000-2340

LIRE LES CHANGEMENTS SURLIGNÉS

1 x 58 ml C3 (II) R1 (Tampon)

2 x 9,5 ml C3 (II) R2 (Réactif)

Utilisation

Les réactifs **quantex C3 (II)** sont pour la détermination quantitative du complément 3 (C3) dans le sérum ou le plasma humain, sur les analyseurs ILab™. Contacter votre distributeur ou le Département Technique de BLOKIT, S.A. pour autres applications disponibles. Se reporter à la publication "Effects of Disease on Clinical Laboratory Tests"¹ pour une revue des causes d'augmentation ou de diminution du complément 3.

Sommaire/Principe

La procédure est basée sur la méthode turbidimétrique.²

Quand un échantillon, qui contient complément 3, est mélangé avec ce réactif, une agrégation a lieu. Le degré d'agrégation est directement proportionnel à la concentration en complément 3 dans l'échantillon et est déterminé par l'augmentation d'absorbance à 600 nm. Les résultats sont exprimés en mg/dl ou en g/l de complément 3 par rapport à la Préparation Internationale de Référence pour 14 Protéines Sériques (CRM 470).³

Réactifs

- C3 (II) R1 (Tampon):
Tampon phosphate 30 mM pH 8,0.
- C3 (II) R2 (Réactif):
Sérum de chèvre anti-complément 3 humaine en tampon phosphate 10 mM.

Tous les réactifs contiennent < 0,1% d'azide de sodium.

Précautions

Les réactifs **quantex** sont destinés à un usage diagnostique IN VITRO.

Utilisation réservée aux professionnels.

L'azide sodique peut réagir au contact de tuyauteries et de bouches d'écoulement des eaux en plomb ou en cuivre. Cette réaction donne lieu à des azides métalliques hautement explosives. Lorsque vous jetez les restes de réactifs, veuillez laisser couler l'eau abondamment.

Compte tenu du fait qu'aucune méthode n'est capable d'offrir une garantie absolue de l'absence d'agents infectieux, ce produit doit être manipulé avec précaution.⁴

Déposer tout le matériel utilisé dans des récipients conçus pour le matériel bio-contaminant.

Préparation des Réactifs

- C3 (II) R1 (Tampon) : Prêt à l'emploi. Placer le réactif dans le compartiment réactifs.
- C3 (II) R2 (Réactif) : Prêt à l'emploi. Placer le réactif dans le compartiment réactifs.

En cas de besoin, transférer le matériau dans le récipient approprié.

Conservation et stabilité des réactifs

Conservés à 2-8°C, les réactifs contenus dans des flacons n'ayant pas été ouverts sont stables jusqu'à la date de péremption indiquée sur l'étiquette. Ne pas congeler.

Après l'ouverture des flacons, les réactifs restent stables pendant 30 jours dans l'instrument.

Pour une stabilité optimale, extraire les réactifs des instruments et les conserver à 2-8°C dans leurs flacons d'origine correctement bouchés.

Échantillons

Utiliser du sérum ou du plasma frais (EDTA, heparine). D'autres anticoagulants doivent être évalués avant leur utilisation. Les échantillons peuvent être conservés à 2-8°C pendant 2 jours. Pour des périodes plus longues, le sérum peut être congelé (-20°C). Éviter les cycles répétés de congélation/décongélation des échantillons. Bien mélanger les échantillons avant analyse.

Calibrage

Utiliser le **quantex PROTEINS standard multipoint** [REF] 3000-2128. Les concentrations en mg/dl et en g/l sont indiquées sur la feuille jointe. Recalibrer chaque 60 jours, quand un nouveau lot de réactif est utilisé, quand la valeur du contrôle est en dehors des limites fixées, ou quand des modifications sont apportées à l'analyseur.

Contrôle de qualité

Il est recommandé d'utiliser deux niveaux de contrôles tels que le **quantex PROTEINS contrôle I/II** [REF] 3000-2122. Utiliser au moins une fois tous les jours. Les limites et les valeurs cibles de ces contrôles sont indiquées sur les notices correspondantes. Les valeurs des contrôles doivent se situer dans l'intervalle établi. Dans le cas contraire, l'utilisateur devra adopter des mesures correctives. Pour l'identification et le traitement des contrôles hors limites, nous vous recommandons de vous référer à des règles telles que celles de Westgard *et col.*⁵

Si les résultats attendus ne sont pas obtenus, ne pas utiliser le coffret.

Interférences

Aucune interférence par bilirubine pour des concentrations jusqu'à 50 mg/dl, ni par l'hémoglobine pour des concentrations jusqu'à 500 mg/dl et ni par facteur rhumatoïde pour des concentrations jusqu'à 500 UI/ml. Pour plus de précisions sur les interférences, se reporter à la publication de Young *et col.*⁶

Valeurs de référence

Des concentrations en C3 (II) de 90 à 180 mg/dl (0,9 - 1,8 g/l) sont considérées comme normales.⁷

Précision

ILab 600	Échantillons/ Séries	Moyenne (mg/dl)	CV (%)	Échantillons/ Séries	Moyenne (mg/dl)	CV (%)
Dans la série	5/10	80,6	1,4	5/10	193,0	1,4
Total	5/10	80,6	2,3	5/10	193,0	1,7

Comparaison des Méthodes

Réactif testé (y)	quantex C3 (II)
Réactif de comparaison (x)	quantex C3
Analyseur utilisé	ILab 600
Pente	1,038
Ordonnée à l'origine	-1,2
Limites (mg/dl)	82,0 - 463,9
Moyenne X (mg/dl)	182,8
Moyenne Y (mg/dl)	188,5
r	0,9989
n	50

Linéarité

ILab 600/650: 5 à 500 mg/dl sans réanalyse automatique.
5 à 2500 mg/dl avec réanalyse automatique.

Si la concentration de l'échantillon, après réanalyse automatique, dépasse le rang de linéarité, diluer l'échantillon au 1:20 en solution saline, réanalyser et multiplier le résultat obtenu par le facteur de dilution.

quantex C3 (II)

3000-2340

HERVORGEHOBENE ÄNDERUNGEN LESEN1 x 58 ml C3 (II) R1 (Puffer)
2 x 9,5 ml C3 (II) R2 (Reagenz)**Verwendung**

Die **quantex C3 (II)** Reagenzien sind für die quantitative Bestimmung von Komplement 3 (C3) in Humanserum oder -plasma mit den ILab™ Analysensystemen. Bezüglich weiterer Applikationen wenden Sie sich bitte an die für Sie zuständige Vertriebsfirma oder die technische Abteilung der BIOKIT, S.A. Eine Übersicht der klinischen Bedeutung erhöhter und erniedrigter Komplement 3-Konzentrationen wurde von Friedman *et al.*¹ zusammengestellt.

Zusammenfassung/Prinzip

Turbidimetrisches Messprinzip.²

Wenn die Probe, die Komplement 3 enthält, mit dem Reagenz gemischt wird, kommt es eine Aggregation vor. Der Grad der Aggregation ist proportional zur Komplement 3-Konzentration in der Probe und wird durch die Messung der Extinktionserhöhung bei 600 nm quantifiziert. Die Ergebnisse werden in mg/dl oder g/l Komplement 3 angegeben, basierend auf dem Internationalen Referenzmaterial für die Bestimmung von 14 Proteinen im Serum (CRM 470).³

Bestandteile

- C3 (II) R1 (Puffer):
Phosphat-Puffer, 30 mM pH 8,0.
 - C3 (II) R2 (Reagenz):
Anti-human Komplement 3 (Ziegen Serum) in Phosphat-Puffer 10 mM.
- Alle Reagenzien enthalten < 0,1% Natriumazid.

Vorsichtsmassnahmen

Die **quantex** Reagenzien sind ausschliesslich für die IN VITRO-Diagnostik bestimmt.

Für den ausschließlichen Gebrauch durch Fachpersonal.

Natriumazid kann auf Blei- oder Kupfer-Rohrleitungen und -Abflüsse reagieren und zu hochexplosiven Metallaziden führen. Beim Entfernen der Reagenzreste muss mit genügend Wasser nachgespült werden.

Da kein Nachweisverfahren die Abwesenheit von infektiösen Agenzien garantieren kann, ist dieses Produkt mit entsprechenden Vorsichtsmassnahmen zu handhaben.⁴

Alle benutzten Materialien sind separat in Behältern für biologische Abfälle zu entsorgen.

Herstellung der Arbeitslösung

- C3 (II) R1 (Puffer) : Gebrauchsfertig. Behälter in Reagenzienteller einsetzen.
- C3 (II) R2 (Reagenz) : Gebrauchsfertig. Behälter in Reagenzienteller einsetzen.

Bei Bedarf das Material dem geeigneten Behälter zuführen.

Lagerung und Haltbarkeit der Reagenzien

Die ungeöffneten Reagenzflaschen sind bei Lagerung zwischen 2-8°C bis zum auf dem Etikett angegebenen Verfallsdatum haltbar. Nicht einfrieren.

Nach Öffnung sind die Reagenzien im Gerät 30 Tage lang haltbar.

Für eine optimale Haltbarkeit sollten die Reagenzien nach dem Gebrauch aus dem Gerät entnommen und im Kühlschrank bei 2-8°C in der Originalflasche gut verschlossen aufbewahrt werden.

Proben

Frisches Serum oder Plasma (EDTA, Heparin) benutzen. Andere Antikoagulantien müssen zuvor evaluiert werden. Die Proben sind bei 2-8°C zu lagern. Bei Lagerung über 2 Tagen sollte das Serum bei (-20°C) eingefroren werden. Mehrmaliges Einfrieren und Auftauen vermeiden. Vor Testdurchführung Proben homogenisieren.

Kalibration

quantex PROTEINS Standard Mehrpunkt REF 3000-2128. Die Konzentrationen in mg/dl und g/l werden in der Packungsbeilage angegeben. Die Kalibration sollte jeweils nach 60 Tage, nach Chargenwechsel der Reagenzien, wenn die Kontrolle einen Wert ausserhalb des Akzeptanzbereichs liefert oder nach Justierarbeiten am Analysengerät durchgeführt werden.

Qualitätskontrolle

Es wird empfohlen, als Kontrollmaterial **quantex PROTEINS Kontrolle I/II** REF 3000-2122 zu verwenden. Mindestens einmal täglich sollte eine Präzisionskontrolle durchgeführt werden. Die Bereiche sind der jeweiligen Packungsbeilage zu entnehmen. Die Kontrollwerte müssen innerhalb des vorgeschriebenen Bereichs liegen. Andernfalls muss der Benutzer Massnahmen ergreifen, die für Abhilfe sorgen. Algorithmen zur Beurteilung der Qualitätskontrollergebnisse siehe z.B. Westgard *et al.*⁵

Sollten die erwarteten Werte nicht erreicht werden, ist die Packung nicht zu verwenden.

Störungen

Keine Störung durch Bilirubin bis zu einer Probenkonzentration von 50 mg/dl, durch Hämoglobin bis zu einer Probenkonzentration von 500 mg/dl und durch Rheumafaktor bis zu einer Probenkonzentration von 500 EI/ml. Eine umfassende Übersicht von möglichen Störfaktoren wurde von Young *et al.* zusammengestellt.⁶

Referenzbereich

Als normal gelten C3 (II)-Konzentrationen zwischen 90 und 180 mg/dl (0,9 - 1,8 g/l).⁷

Präzision

ILab 600	Proben/ Serien	Mittelwert (mg/dl)	CK (%)	Proben/ Serien	Mittelwert (mg/dl)	CK (%)
In der Serie	5/10	80,6	1,4	5/10	193,0	1,4
Total	5/10	80,6	2,3	5/10	193,0	1,7

Methodenvergleich

Test Reagenz (y)	quantex C3 (II)
Vergleichsreagenz (x)	quantex C3
Benutztes Gerät	ILab 600
Steigung	1,038
Ordinatenabschnitt	-1,2
Bereich (mg/dl)	82,0 - 463,9
Mittelwert X (mg/dl)	182,8
Mittelwert Y (mg/dl)	188,5
r	0,9989
n	50

Linearität

ILab 600/650: 5 bis 500 mg/dl bei ausgeschaltetem automatischen "rerun".
5 bis 2500 mg/dl bei eingeschaltetem automatischen "rerun".

Wenn die Konzentration der Probe nach einer automatischen Neuanalyse den Linearitätsbereich überschreitet, im Verhältnis 1:20 mit physiol. Kochsalzlösung verdünnen und die Bestimmung wiederholen. Ergebnis mit dem Verdünnungsfaktor multiplizieren.

quantex C3 (II)

3000-2340

VEDI CAMBI RISALTATI

1 x 58 ml C3 (II) R1 (Tampone)

2 x 9,5 ml C3 (II) R2 (Reagente)

Uso

I reagenti **quantex C3 (II)** sono per la determinazione quantitativa del complemento 3 (C3) nel siero e plasma umani sui sistemi per chimica clinica ILab™. Rivolgersi al distributore o alla Divisione Tecnica della BLOKIT, S.A. per altre applicazioni disponibili. Riferirsi alla pubblicazione "Effects of Disease on Clinical Laboratory Tests"¹ per un elenco delle cause d'innalzamento o diminuzione del complemento 3.

Sommario/PrincipioMetodo turbidimetrico.²

Quando un campione, che contiene complemento 3, è miscelato con il reagente da luogo ad una aggregazione. Il grado di aggregazione è direttamente proporzionale alla concentrazione de complemento 3 presente nel campione e viene determinato dall'incremento dell'assorbanza (600 nm). I risultati sono espressi in mg/dl o g/l di complemento 3 basati sullo Materiale di Riferimento Internazionale per la Determinazione di 14 Proteine Sieriche (CRM 470).³

Reagenti

- C3 (II) R1(Tampone):
Tampone fosfato 30 mM, pH 8,0.
- C3 (II) R2 (Reagente):
Siero di capra anti-complemento 3 umani in tampone fosfato 10 mM.

Tutti i reagenti contengono < 0,1% di sodio azide.

Precauzioni

I reagenti **quantex** sono per uso diagnostico IN VITRO.

Solo per uso professionale.

La sodio azide può reagire a contatto con tubature e scarichi in piombo o in rame, formando azidi metalliche altamente esplosive. Far scorrere acqua in abbondanza quando si gettano i residui dei reagenti.

Poiché nessun metodo può offrire la totale sicurezza dell'assenza di agenti infettivi, questo prodotto deve essere manipolato con precauzione.⁴

Depositare tutti i materiali utilizzati in recipienti idonei per materiale biocontaminante.

Preparazioni dei Reagenti

- C3 (II) R1 (Tampone) : Pronto all'uso. Porre il contenitore sul piatto portareagenti.
- C3 (II) R2 (Reagente) : Pronto all'uso. Porre il contenitore sul piatto portareagenti.

Se necessario, trasferire il materiale nel contenitore adeguato.

Conservazione e stabilità dei reagenti

I reagenti contenuti in flaconi sigillati sono stabili a 2-8°C fino alla data di scadenza stampata sull'etichetta. Non congelare.

Dopo l'apertura dei flaconi, i reagenti rimangono stabili per 30 giorni nello strumento.

Per una migliore stabilità del prodotto, si consiglia di rimuovere i reagenti dallo strumento e di conservarli a 2-8°C nel flacone originale ben chiuso.

Campioni

Usare siero fresco o plasma (EDTA, eparina). Altri anticoagulanti dovranno essere valutati prima dell'uso. I campioni possono essere conservati a 2-8°C per non più di 2 giorni. Per tempi più lunghi il siero può essere congelato (-20°C). Non procedere a ripetuti congelamenti e scongelamenti. Miscelare i campioni prima dell'analisi.

Calibrazione

Utilizzare il **quantex PROTEINS standard multipunto** [REF] 3000-2128. Le concentrazioni in mg/dl e g/l sono indicate nel foglio allegato. Ricalibrare ogni 60 giorni, quando viene introdotto un nuovo lotto di reagente, quando il valore di controllo è fuori range o quando vengono eseguiti degli interventi di manutenzione sullo strumento

Controllo di qualità

Si raccomanda di utilizzare due livelli di controllo come il le **quantex PROTEINS controllo I/II** [REF] 3000-2122. Analizzare i controlli almeno una volta al giorno. I valori attesi sono reperibili sui relativi fogli illustrativi. I valori dei controlli devono trovarsi nell'intervallo corrispondente. In caso contrario, l'utente dovrà adottare le opportune misure correttive. Per l'identificazione di situazioni anomale, si raccomanda di fare riferimento a studi come quello di Westgard *et al.*⁵
Se non si ottengono i risultati sperati, scartare il kit.

Interferenze

Nessuna interferenza da bilirubina fino a concentrazioni di 50 mg/dl, da emoglobina fino a concentrazioni di 500 mg/dl e neanche da fattore reumatoide fino a concentrazioni di 500 UI/ml. Per un esame completo delle sostanze che provocano interferenza, fare riferimento alla pubblicazione di Young *et al.*⁶

Valori di Riferimento

Sono attesi valori di C3 (II) tra 90 e 180 mg/dl (0,9 - 1,8 g/l).⁷

Precisione

ILab 600	Campioni/ Runs	Media (mg/dl)	CV (%)	Campioni/ Runs	Media (mg/dl)	CV (%)
Nel-run	5/10	80,6	1,4	5/10	193,0	1,4
Totale	5/10	80,6	2,3	5/10	193,0	1,7

Comparazione di Metodi

Reagente de prova (y)	quantex C3 (II)
Reagente de comparazione (x)	quantex C3
Strumento utilizzato	ILab 600
Slope	1,038
Intercetta	-1,2
Intervallo (mg/dl)	82,0 - 463,9
Media X (mg/dl)	182,8
Media Y (mg/dl)	188,5
r	0,9989
n	50

Linearità

ILab 600/650: 5 a 500 mg/dl senza la funzione di "re-run".
5 a 2500 mg/dl con la funzione di "re-run" attivata.

Se anche dopo il "re-run" automatico la concentrazione del campioni risulta superiore al range di linearità diluire il campione 1:20 con soluzione salina, rianalizzare e moltiplicare il risultato ottenuto per il fattore di diluizione.

quantex C3 (II)

3000-2340

LER ALTERAÇÕES DESTACADAS

1 x 58 ml C3 (II) R1 (Tampão)

2 x 9,5 ml C3 (II) R2 (Reativo)

Utilização

Os reativos **quantex C3 (II)** são utilizados para a determinação quantitativa do complemento 3 (C3) em soro ou plasma humano, utilizando os sistemas de química clínica ILab™. Contactar seu distribuidor ou o Departamento Técnico de BIOKIT, S.A. para outras aplicações disponíveis. Consultar o artigo "Effects of Disease on Clinical Laboratory Tests",¹ onde existe uma recompilação das diversas causas que determinam o aumento ou diminuição na concentração de complemento 3.

Sumário/Princípio

O processo está baseado na turbidimetria.²

Quando uma amostra que contém complemento 3 é misturada com o reativo, ocorre uma agregação. O grau de agregação é diretamente proporcional à concentração de complemento 3 na amostra e determina-se medindo o aumento de absorvância a 600 nm. Os resultados são expressados em mg/dl ou g/l de complemento 3 com base na Preparação Internacional de Referência para 14 Proteínas Séricas (CRM 470).³

Reativos

- C3 (II) R1 (Tampão):
Tampão fosfato 30 mM pH 8,0.
- C3 (II) R2 (Reagente):
Soro de cabra anti-complemento 3 humano em tampão fosfato 10 mM.

Todos os reativos contêm azida sódica < 0,1%.

Precauções

Os reativos **quantex** são para o diagnóstico IN VITRO.

Para uso exclusivamente por profissionais.

A azida sódica pode reagir com os encanamentos e ralos de chumbo ou cobre, originando azidas metálicas altamente explosivas. Ao descartar os restos de reativos, fazê-lo em abundante volume de água.

Dado que nenhum método pode oferecer a total segurança da ausência de agentes infecciosos, este produto deve ser manipulado com precaução.⁴

Descartar todos os materiais usados em recipientes adequados para material bio-contaminante.

Preparação dos Reativos

- C3 (II) R1 (Tampão) : Pronto para usar. Colocar o recipiente no prato de reagentes.
- C3 (II) R2 (Reagente) : Pronto para usar. Colocar o recipiente no prato de reagentes.

Se necessário, passe o material ao recipiente adequado.

Conservação e Estabilidade dos Reativos

Os reativos em recipientes que não tenham sido abertos e tenham sido conservados entre 2-8°C são estáveis até a data de validade indicada no rótulo. Não congelar.

Depois de abertos os frascos, os reativos são estáveis durante 30 dias no equipamento.

Para otimizar a estabilidade, se devem retirar os reativos dos equipamentos e se devem conservar a 2-8°C nos recipientes originais bem tapados.

Amostras

Usar soro fresco ou plasma (EDTA, heparina). Outros anticoagulantes devem ser avaliados antes de serem utilizados. As amostras podem ser conservadas por 2 dias entre 2-8°C. Para guardar por um período de tempo mais longo o soro deve ser congelado (-20°C). Evitar congelar e descongelar as amostras repetidamente. Homogeneizar as amostras antes de serem analisadas.

Calibração

Deve utilizar-se o **quantex PROTEINS standard multiponto** [REF] 3000-2128. As concentrações em mg/dl e g/l vêm indicadas na folha em anexo. Recalibrar cada 60 dias, cada vez que se mude o lote de reagentes, quando o controle apresentar um valor fora do limite de aceitação ou quando são feitos ajustes ao equipamento.

Controle de Qualidade

Recomenda-se utilizar dois níveis de controles, tais como **quantex PROTEINS controle I/II** [REF] 3000-2122. Os controles devem ser analisados pelo menos uma vez por dia. Ver limite de valores na folha anexa ao produto. Os valores dos controles devem encontrar-se dentro da margem estabelecida. Caso contrário o usuário deverá tomar medidas corretivas. Consultar a publicação Westgard *et al.*⁵ para proceder à identificação e resolução de valores que estejam fora do limite de aceitação.

Se os resultados esperados não são obtidos, não utilizar o kit.

Interferências

Não se observa interferência por bilirrubina até concentrações de 50 mg/dl, por hemoglobina até concentrações de 500 mg/dl nem por fator reumatóide até concentrações de 500 UI/ml. Consultar a publicação Young *et al.*⁶ para mais informações acerca das interferências.

Valores de Referência

São consideradas concentrações normais de C3 (II) entre 90 e 180 mg/dl (0,9 - 1,8 g/l).⁷

Precisão

ILab 600	Amostras/ Ensaio	Média (mg/dl)	CV (%)	Amostras/ Ensaio	Média (mg/dl)	CV (%)
Dentro ensaio	5/10	80,6	1,4	5/10	193,0	1,4
Total	5/10	80,6	2,3	5/10	193,0	1,7

Comparação de Métodos

Reativo de prova (y)	quantex C3 (II)
Reativo de comparação (x)	quantex C3
Equipamento utilizado	ILab 600
Desvio	1,038
Intersecção	-1,2
Limite (mg/dl)	82,0 - 463,9
Média X (mg/dl)	182,8
Média Y (mg/dl)	188,5
R	0,9989
N	50

Linearidade

ILab 600/650: 5 a 500 mg/dl sem ativar a opção "rerun".
5 a 2500 mg/dl utilizando a opção "rerun".

Caso a concentração da amostra exceda o limite de linearidade depois de ser reanalisada automaticamente, diluir 1:20 com uma solução salina e voltar a analisar a amostra. Multiplicar o resultado pelo fator de diluição.

quantex C3 (II)

3000-2340

ΔΙΑΒΑΣΤΕ ΤΙΣ ΦΩΤΙΣΜΕΝΕΣ ΑΛΛΑΓΕΣ

1 x 58 ml C3 (II) R1 (Ρυθμιστικό Διάλυμα)

2 x 9,5 ml C3 (II) R2 (Αντιδραστήριο)

Χρήση για την οποία προορίζεται

Τα αντιδραστήρια **quantex C3 (II)** χρησιμοποιούνται για τον ποσοτικό προσδιορισμό του συμπληρώματος 3 (C3) στον ανθρώπινο ορό ή το πλάσμα χρησιμοποιώντας τους Χημικούς Αναλυτές ILab™. Για άλλες διαθέσιμες εφαρμογές συμβουλευτείτε τον προμηθευτή σας ή το Τεχνικό Τμήμα της BIOKIT, S.A. Για τη συνοπτική αναφορά των αιτίων που οδηγούν σε αύξηση ή μείωση της συγκέντρωσης του συμπληρώματος 3, ανατρέξτε στη δημοσίευση Κλινικής Χημείας "Effects of Disease on Clinical Laboratory Tests".¹

Περίληψη/ ΑρχήΑνοσοθολωσιμετρική δοκιμασία.²

Ύστερα από την ανάμειξη του δείγματος που περιέχει συμπλήρωμα 3 με το αντιδραστήριο, αναπτύσσεται συσσωμάτωση. Ο βαθμός της συσσωμάτωσης είναι ανάλογος προς τη συγκέντρωση του συμπληρώματος 3 στο δείγμα και μπορεί να προσδιοριστεί ποσοτικά μετρώντας την αύξηση της απορρόφησης στα 600 nm. Με βάση το Διεθνές Υλικό Αναφοράς για τη Μέτρηση 14 Πρωτεϊνών του Ορού (CRM 470), τα αποτελέσματα εκφράζονται σε mg/dl ή g/l συμπληρώματος 3.³

Αντιδραστήρια

- C3 (II) R1 (Ρυθμιστικό Διάλυμα): Ρυθμιστικό διάλυμα φωσφορικού 30 mM pH 8,0.
 - C3 (II) R2 (Αντιδραστήριο): Ορός αίγας έναντι του ανθρώπινου συμπληρώματος 3 εντός ρυθμιστικού διαλύματος φωσφορικού 10 mM.
- Όλα τα αντιδραστήρια περιέχουν < 0,1% αζίδιο του νατρίου.

Προφυλάξεις

Τα αντιδραστήρια **quantex** προορίζονται για IN VITRO διαγνωστική χρήση.

Για επαγγελματική μόνον χρήση.

Το αζίδιο του νατρίου ενδέχεται να αντιδράσει με το μόλυβδο ή το χαλκό των σωληνώσεων και των υδραυλικών εγκαταστάσεων και να σχηματιστούν υψηλά εκρηκτικά αζίδια. Μετά την απόρριψη των υπολειμμάτων των αντιδραστηρίων, ξεπλύνετε τις αποχετεύσεις με άφθονο νερό.

Καθώς καμία μέθοδος δεν μπορεί να εγγυηθεί με απόλυτη βεβαιότητα την απουσία μολυσματικών παραγόντων, ο χειρισμός αυτού του προϊόντος θα πρέπει να γίνεται με προσοχή.⁴

Η απόρριψη των χρησιμοποιημένων υλικών θα πρέπει να γίνεται σε περιέκτη κατάλληλο για επικίνδυνα βιολογικά απόβλητα.

Παρασκευή αντιδραστηρίων

- C3 (II) R1 (Ρυθμιστικό Διάλυμα): Έτοιμο για χρήση. Τοποθετήστε τον περιέκτη στο δίσκο αντιδραστηρίων.
 - C3 (II) R2 (Αντιδραστήριο) : Έτοιμο για χρήση. Τοποθετήστε τον περιέκτη στο δίσκο αντιδραστηρίων.
- Σε περίπτωση ανάγκης, το υλικό να μεταφερθεί στο κατάλληλο δοχείο.

Αποθήκευση και σταθερότητα αντιδραστηρίων

Τα αντιδραστήρια που δεν έχουν ανοιχτεί, εφόσον φυλάσσονται σε θερμοκρασία 2-8°C, παραμένουν σταθερά έως την ημερομηνία λήξης που αναγράφεται στην ετικέτα του φιαλιδίου.

Μην καταψύχετε.

Μετά το άνοιγμα των φιαλιδίων, τα αντιδραστήρια παραμένουν σταθερά επί 30 ημέρες εντός του αναλυτή.

Για την επίτευξη ιδανικής σταθερότητας, τα αντιδραστήρια θα πρέπει να αφαιρούνται από τον αναλυτή, να μεταφέρονται στο αρχικό φιαλίδιο το οποίο θα πρέπει να είναι ερμητικά κλειστό και να φυλάσσονται σε θερμοκρασία 2-8°C.

Δείγματα

Χρησιμοποιείτε πρόσφατα συλλεγμένο ορό ή πλάσμα (EDTA, ηπαρίνη). Η χρήση άλλων αντιπηκτικών θα πρέπει να αξιολογείται πριν από τη διαδικασία. Τα δείγματα μπορούν να αποθηκευτούν επί 2 ημέρες σε θερμοκρασία 2-8°C. Για μακρύτερες περιόδους αποθήκευσης, τα δείγματα ορού μπορούν να καταψυχθούν (-20°C). Αποφύγετε τις επανειλημμένες καταψύξεις και τήξεις. Πριν από την ανάλυση ομογενοποιήστε τα δείγματα.

Βαθμονόμηση

Χρησιμοποιήστε το **quantex PROTEINS standard multipoint** REF 3000-2128. Οι συγκεντρώσεις αναγράφονται στο φύλλο δεδομένων του προτύπου σε mg/dl και g/l. Επαναλαμβάνετε τη βαθμονόμηση κάθε 60 ημέρες ή όταν χρησιμοποιείτε αντιδραστήρια από καινούργια παρτίδα, όταν οι τιμές των controls βρίσκονται εκτός του αναμενόμενου εύρους ή όταν πραγματοποιείτε ρυθμίσεις στον αναλυτή.

Ποιοτικός έλεγχος

Συνιστάται η χρήση controls δύο επιπέδων όπως τα **quantex PROTEINS control I/II** [REF] 3000-2122. Η ανάλυση των controls θα πρέπει να πραγματοποιείται τουλάχιστον μία φορά την ημέρα. Το αναμενόμενο εύρος αναγράφεται στο ένθετο φύλλο των controls. Οι τιμές των controls θα πρέπει να βρίσκονται εντός του προκαθορισμένου εύρους. Στην αντίθετη περίπτωση θα πρέπει να ληφθούν διορθωτικά μέτρα από το χειριστή. Για τον εντοπισμό και τη διευθέτηση των περιπτώσεων κατά τις οποίες οι τιμές των controls βρίσκονται εκτός του προκαθορισμένου εύρους, ανατρέξτε σε βιβλιογραφικές αναφορές όπως αυτή του Westgard *et al.*⁵ Εάν δεν ληφθούν τα αναμενόμενα αποτελέσματα, μη χρησιμοποιήσετε τη συσκευασία.

Παρεμβολές

Δεν παρατηρούνται σημαντικές παρεμβολές από τη χολερυθρίνη έως τα 50 mg/dl, την αιμοσφαιρίνη έως τα 500 mg/dl και ρευματοειδή παράγοντα έως τα 500 IU/ml. Για πιο αναλυτικές πληροφορίες σχετικά με τις ουσίες που προκαλούν παρεμβολή, ανατρέξτε στη δημοσίευση του Young *et al.*⁶

Εύρος αναφοράς

Φυσιολογικές θεωρούνται οι συγκεντρώσεις C3 (II) που κυμαίνονται από 90 έως 180 mg/dl (0,9 - 1,8 g/l).⁷

Επαναληψιμότητα

ILab 600	Δείγματα / Κύκλοι	Μέση τιμή (mg/dl)	CV (%)	Δείγματα / Κύκλοι	Μέση τιμή (mg/dl)	CV (%)
Εντός κύκλου	5/10	80,6	1,4	5/10	193,0	1,4
Ολική	5/10	80,6	2,3	5/10	193,0	1,7

Σύγκριση της Μεθόδου

Αντιδραστήριο (y)	quantex C3 (II)
Αναλυτής σύγκρισης (x)	quantex C3
Αναλυτής	ILab 600
Κλίση	1,038
Σημείο τομής στον άξονα y	-1,2
Εύρος (mg/dl)	82,0 - 463,9
Μέση τιμή X (mg/dl)	182,8
Μέση τιμή Y (mg/dl)	188,5
r	0,9989
n	50

Γραμμικότητα

ILab 600/650: 5 έως 500 mg/dl χωρίς τη δυνατότητα αυτόματης επανάληψης κύκλου.
5 έως 2500 mg/dl με τη δυνατότητα αυτόματης επανάληψης κύκλου.

Εάν μετά την αυτόματη επανάληψη του κύκλου η συγκέντρωση του δείγματος υπερβαίνει το όριο γραμμικότητας, αραιώστε το δείγμα 1:20 με ισότονο διάλυμα NaCl, επαναλάβετε τη δοκιμασία και πολλαπλασιάστε το αποτέλεσμα επί το συντελεστή αραιώσης.

quantex C3 (II)

3000-2340

READ HIGHLIGHTED CHANGES

1 x 58 ml C3 (II) R1 (Buffer)
2 x 9.5 ml C3 (II) R2 (Reagent)

ILab 600/650 Test Parameters

Photometric Test Parameters	
Test nº	77
Test Name, Test Code	C3 (II), C3 (II)
Sample Type	Serum
Reporting Unit, Decimal Points	mg/dl, 1
Reaction Cycle	Standard
Twin Analysis	OFF
Methodology Type, Measuring Point	End point, 17/33
Photometric Methodology	1 Wavelength
Primary/Secondary Wavelength	600
Sampling Conditions	
Sampling 1 Sample vol.	3
Sample/Diluent vol.	0/0
Sampling 2 Sample vol.	3
Sample/Diluent vol.	30/120
Sampling 3 Sample vol.	9
Sample/Diluent vol.	0/0
Sampling 4	***
Diluent Code	Saline
Diluent Warning Limit	**
First Run	Sampling 1
Below/Above Normal Range	***
Panic L	***
Panic H	Sampling 2
Non Linear	**
Prozone	N/A
HIGH!, ABS	Sampling 2
Reagent volumes	
R1 Code	02771
Rgt/Dil. Vol., Stirring	190/0, ON Buffer
Low Vol. Warning Limit	***
Stability (days)	**
R2 Code	02772
Rgt/Dil. Vol., Stirring	75/10, ON Reagent
Low Vol. Warning Limit	***
Stability (days)	**
Ranges and Evaluation Criteria	
Normal Range-Male	*
Normal Range-Female	*
Normal Range-Other	*
Valid Range	0 – 500*
Hemolysis/Icterus/Lipemia Limit	***
Reaction Slope	Positive
Absorbance Limit	Above, 3200
Prozone Limit	N/A
Non Linear Limit	N/A
Slope/Intercept correction	1/0
Qualitative Report	OFF
Calibration Conditions	
Calibration	5 Points, point to point, 2 Reps
Stability (days)	60
Calibrator, Concentration	PROTEINS Std.****
R-Blank Limit (mAbs)	150
Cal. Reps Range (%)	***
Min. Cal. Response (mAbs)	***
Cal. Factor Change (%)	***
M-Point Curve Fit (%)	N/A
Auto R-Blank by Bottle	ON

* Operator definable, see the insert.

** Operator definable.

*** Optional.

**** Lot dependent, see concentration on standard value data sheet.

N/A Not applicable to this test.

ILab is a trademark of Instrumentation Laboratory.

quantex C3 (II)

3000-2340

1 x 58 mL C3 (II) R1 (Buffer)
2 x 9.5 mL C3 (II) R2 (Reagent)

ILab 900/1800 Test Parameters

Photometric Test Parameters	
Test Name	[C3 II]
Bar Code	[]
Measuring method	[Endpoint]
Calibration method	[1 Point]
Unit	[mg/dl]
Measuring points	[14] [43] [] []
Photometric method	[Single]
Wavelength 1, 2, 3	[600] []
Sample Vol. N, D, I	[4] [2] [9]
R1V. - Stir Mode [Nor.]	[250] [Yes] [0] Buffer
R2V. - Stir Mode [Nor.]	[100] [Yes] [0] Reagent
No. Decimal points	[1]
Samples type	[Serum]
Normal range MALE L - H	[*] [*]
FEMALE L - H	[*] [*]
Valid range LL - HH	[0] [500]
Correction const. 1, 2	[1.000] [0]
W1-Abs Inc/Dec, Limit	[Inc] [2500]
Hemolysis limit	[*]
Icteric limit	[*]
Lipemic limit	[*]
Calib. Replicates	[2]
Replicates, Sens. Limit	[2500] [0]
Slope - Offset limits	[999] [2500]
Partner Test, Const.	[++] [0.000]
Prozone, Limit	[++] [++]
Calibration Parameters	
Multipoint Calibration	[Multilinear]
Calibrator N° 1 Conc.	[*]
Calibrator N° 2 Conc.	[*]
Calibrator N° 3 Conc.	[*]
Calibrator N° 4 Conc.	[*]
Calibrator N° 5 Conc.	[*]

* Operator definable.

++ Not applicable to this test.

ILab is a trademark of Instrumentation Laboratory.

Preliminary

Chemistry Definition



Description: C3(II)
Unit: mg/dL
Decimals: 1
LIS Code: C3
Unit Factor: 1,0
Slope: 1,00
Intercept: 0,00

Reference Range

	LOW VALUES			HIGH VALUES				
Male:	0	0	0	90	180	500	500	500
Female:	0	0	0	90	180	500	500	500
Children:	0	0	0	90	180	500	500	500
Low Alert	Low Alert	Very Low	Low	Normal Values		High	Very High	High Alert
Rerun:	No	No				No	No	



Reaction Type: End Point
Direction: None
E.P. Limit (abs): 1,0000
Depl Limit (abs): 0
First Limit (abs): 0
Linear Factor: 0
Fit: 0

Parameter

	Predilut.->	S.+R. 1->	Reag. 2 ->	Reag. 3 ->	Incubation ->	Read
Times (sec):		0	90	0		296
Dil./Rgt. Code:		C3	C3Itx			*) = kinetic
Lot Number:					Filter 1 (nm): 620 Filter 2 (nm): (none) Bicr. Factor: 1,00	
Ratio/Vol. (ul):		320	125	0		
Rinse (ul):		0	0	0		
Sample (ul):		5				

Lin Limit. Low: 0
High: 500
Rerun when Over: No

RBL Min (abs): -0,500
Max (abs): 2,5000



Calculation Model: Point to Point
Factor: 0
Sample Blank: Yes



RBL Stability (days): 15
Calibration Stab. (days): 15
Dinamic Controls (min): None

C3(II)

** Operator definable
N/A Not applicable to this test

REAGENT PREPARATION

R1 Preparation : Ready to use
R2 Preparation : Ready to use

C3 (II)

Rev.: 12/10

Kits:

Reagents : quantex C3 (II) reagent+buffer COD. 3000-2340

Std/s : quantex PROTEINS standard multipoint COD. 3000-2128

Ctrl/s : quantex PROTEINS control I/II COD. 3000-2122



For more extensive information, please refer to the package insert

Assay Settings

Kit Components	Reagent form	Reagent Reconstitution
Reagents:		
Buffer	1 x 58 mL	Ready to use
Reagent	2 x 9,5 mL	Ready to use
Std/s:	5 x 1 mL	Ready to use
Ctrl/s:	3 x 1 mL (lyoph) 3 x 1 mL (lyoph)	Reconstitution: 1 mL of distilled water

Reagents not included in the kit

Distilled water
Saline Solution on board for sample dilution (rerun)

Sample

Serum
Plasma

Bar code 1,2,3,4,6

R 1	02771
R 2	02772

Reagent code

C3 Buffer	0277
C3 Reagent	0277

Calibration

Standard multipoint 5 levels. Ready to use.
Use saline solution as Std. for concentration 0.

Performance Characteristics

Precision

Sample ng/mL	Within Series		Total	
	CV%	n	CV%	N

Measuring Range normal run

5- 500 mg/dL

Measuring Range with automatic rerun

5 - 2500 mg/dL

Detection Limit

Prozone

Quantification limit

Reference Range

90-180 mg/dL. Refer to the Package Insert for more information

Calibration Stability

Calculation

Patient values are calculated automatically by comparison with the calibration curve

Interferences

Stability 2-8°C in original vials

Reagent :	up to expiration data
Buffer :	up to expiration data
Calibrator/s :	up to expiration data
Control/s:	up to expiration data 15 days after reconstitution

Method Comparison

Slope	Intercept	r	Ref. Method
mean x	mean y	n	

Notes

C3 (II)

Kits:

Reagents : quantex C3 (II) reagent+buffer COD. 3000-2340

Std/s : quantex PROTEINS standard multipoint COD. 3000-2128

Ctrl/s : quantex PROTEINS control I/II COD. 3000-2122



For more extensive information, please refer to the package insert

Instrument Settings

Chemistry Parameters		R1	
Method	<input type="text"/>	Reagent Name	<input type="text" value="C3"/> Volume <input type="text" value="190"/> μ L
Name	<input type="text" value="C3 (II)"/>	R2	<input type="text" value="enable"/>
Unit	<input type="text" value="mg/dL"/>	Reagent Name	<input type="text" value="C3"/> Volume <input type="text" value="75"/> μ L
Assay Type	<input type="text" value="End"/>	Wast	<input type="text" value="disable"/> Reagent Name <input type="text"/>
		Diluent	<input type="text" value="enable"/> Reagent Type <input type="text" value="Saline"/>
Measuring Points	1 <input type="text" value="enable"/> start <input type="text" value="12"/> end <input type="text" value="13"/>	Decimal Points	<input type="text" value="0"/>
	2 start <input type="text" value="25"/> end <input type="text" value="26"/>	Normal Range	<input type="text" value="90"/> <input type="text" value="180"/>
Wave Length		Technical Range (Conc)	<input type="text" value="0"/> <input type="text" value="500"/> mAbs/10
Prim	<input type="text" value="600"/> <input type="text" value="Sec"/>		<input type="text" value="-30000"/> <input type="text" value="30000"/>
Sampling Volume	<input type="text" value="3"/> μ L	RPT Wash (R1)	<input type="text" value="Sys Water"/>
Dilution	<input type="text" value="disable"/>	(R2)	<input type="text" value="Sys Water"/>
Rerun (High)	<input type="text" value="3"/> μ L	Instrument Factor a	<input type="text" value="1"/> <input type="text" value="b"/> <input type="text" value="0"/>
Dilution	<input type="text" value="enable"/>	Stirring Speed	R1 <input type="text" value="high"/> R2 <input type="text" value="high"/>
Rerun (Low)	<input type="text" value="30"/> μ L <input type="text" value="120"/> μ L		
	<input type="text" value="9"/> μ L		

Calibration Checks

Limit Checks		Sampling Method for Standards	
Duplicate Limit	<input type="text" value="50"/> mAbs/10	<input checked="" type="checkbox"/> Duplicate	
Sensitivity Limit	<input type="text" value="350"/> mAbs/10	<input type="checkbox"/> Triplicate	
Linearity Limit	<input type="text" value="30"/> %	Blank measurement	
Prozone Limit	<input type="text" value="0,00"/> <input type="text" value="upper"/>	<input checked="" type="checkbox"/> Enable Reagent blank	
SL1-S	<input type="text" value="1"/> <input type="text" value="SL1-F"/> <input type="text" value="3"/>	None ▼	
SL2-S	<input type="text" value="23"/> <input type="text" value="SL2-F"/> <input type="text" value="26"/>	Reagent blank measurement at calibration	
Sens	<input type="text" value="250"/> mAbs/10	<input checked="" type="checkbox"/> Reagent blank (system water)	
Absorbance Limit		<input type="text"/> Multiplex measurement is the same as stds.	
Reaction	<input type="text" value="Increase"/>	Reagent Blank Limit Checks	
Limit	<input type="text" value="25000"/> mAbs/10	<input type="text"/> Duplicate limit <input type="text" value="50"/> mAbs/10	

Calibration

Calculation	Point to point			
	Conc	WORK	MASTER	Lot
S1				
S2				
S3				
S4				
S5				
S6				
S7				

*This calibration is only an example

**DECLARACIÓN CE DE CONFORMIDAD
CE DECLARATION OF CONFORMITY**

CE

Don Pau Planas Almazán, en calidad de Director de Biokit S.A.
Mr. Pau Planas Almazán, as Director of Biokit S.A.

DECLARA / *DECLARES:*

Que el producto / *That the product:* **quantex C3 (II)**

Código / *Code:* **3000-2340**

cumple con las exigencias mencionadas en el Anexo I y los Requisitos Esenciales de la Directiva 98/79/CE.

meets the provisions referred to in Annex I and Essential Requirements of the Directive 98/79/CE.



Pau Planas

Lliçà d'Amunt, a **31** de **enero** de **2011**

Biokit S.A.

Can Malé, s/n. 08186 Lliçà d'Amunt
Barcelona, Spain
Tel. +34 93 860 90 00
Fax +34 93 860 90 09
www.biokit.com

BIOKIT S.A. 08186 Lliçà d'Amunt (Barcelona) Spain Phone: (34) 93 860 9000 Fax: (34) 93 860 9029 e-mail: biokit@biokit.com	SAFETY DATA SHEET	Date: 29-11-10	Rev.: 00
	Code: 3000-2340		Pag.: 1 of 3

1. Identification of preparation

Product name: Quantex C3 (II)

2. Composition/information on ingredients

Kit components:

C3 (II) R1: Contains potassium phosphate buffer / PEG, sodium chloride, surfactant and 0,09 % w/w of sodium azide.

C3 (II) R2: Contains sodium phosphate buffer / Anti-human C3 polyclonal antibody (goat), sodium chloride and 0,09 % of sodium azide.

3. Hazards identification

The reagents contain less than 0.1% wt of Sodium Azide (NaN_3) as preservative.

CAS-Nº: 26628-22-8

EINECS-Nº: 247-852-1

4. First aid measures

Inhalation: Remove from exposure and move to fresh air immediately. If breathing is difficult, give oxygen. SPEED IS ESSENTIAL, OBTAIN MEDICAL AID IMMEDIATELY. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Eye contact: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid immediately.

Skin contact: Get medical aid immediately. Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. SPEEDY ACTION IS CRITICAL!

Ingestion: POISON material. If swallowed, get medical aid immediately. Only induce vomiting if directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

5. Fire-fighting measures

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Containers may explode in the heat of a fire. Forms explosion sensitive compounds with some metals such as lead and copper. Form hydrazoic acid vapor in contact with acid or water. Hydrazoic acid vapor is highly toxic and a dangerous explosive. Hydrazoic acid is shock sensitive. Extinguishing Media: Do NOT use water directly on fire. Use dry chemical.

Flash Point: Not applicable.

Autoignition Temperature: Not available.

Explosion Limits, Lower: Not available.

Upper: Not available.

6. Accidental release measures

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks: Vacuum or sweep up material and place into a suitable disposal container. Wear a self contained breathing apparatus and appropriate personal protection. (See Exposure Controls, Personal Protection section). Avoid generating dusty conditions. Provide ventilation. Evacuate unnecessary personnel. Do not flush down the drain. Over a period of time, sodium azide may react with copper, lead, brass, or solder in plumbing systems to form an accumulation of the highly explosive compounds of lead azide and copper azide.

Do not let this chemical enter the environment.

BIOKIT S.A. 08186 Lliçà d'Amunt (Barcelona) Spain Phone: (34) 93 860 9000 Fax: (34) 93 860 9029 e-mail: biokit@biokit.com	SAFETY DATA SHEET	Date: 29-11-10	Rev.: 00
	Code: 3000-2340	Pag.: 2 of 3	

7. Handling and storage

Handling: Minimize dust generation and accumulation. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale. Use only in a chemical fume hood. Acids should not be used around this material unless absolutely necessary and then only after careful planning.

Contact with acids liberates toxic gas.

Storage: Store in a cool, dry place. Store in a tightly closed container. Keep away from acids. Do not store in metal containers. Store at 2 to 8 °C.

8. Exposure controls/personal protection

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.

Skin: Wear appropriate protective gloves to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

9. Physical and chemical properties

Appearance:

C3 (II) R1: Transparent solution.

C3 (II) R2: Transparent solution.

Odour: Odorless

Boiling point: N/A

Melting point: N/A

Flash point: N/A

Ignition temperature: N/A

Explosion limits: N/A

Vapour pressure: N/A

Density: N/A

Viscosity: N/A

Solubility in water: soluble

10. Stability and reactivity

Conditions to Avoid: Incompatible materials, dust generation, moisture, metals, strong acids, temperatures above 250°C.

Incompatibilities with Other Materials: Acids, metals, halogenated hydrocarbons, acid chlorides.

Hazardous Decomposition Products: Nitrogen oxides, sodium oxide, hydrazoic acid.

Hazardous Polymerization: Will not occur.

11. Toxicological information

LD50/LC50:

CAS: 26628-22-8:

Inhalation, mouse: LC50 = 32400 ug/m3;

Inhalation, rat: LC50 = 37 mg/m3;

Oral, mouse: LD50 = 27 mg/kg;

Oral, rat: LD50 = 27 mg/kg;

Skin, rabbit: LD50 = 20 mg/kg;

Skin, rat: LD50 = 50 mg/kg;

BIOKIT S.A. 08186 Lliçà d'Amunt (Barcelona) Spain Phone: (34) 93 860 9000 Fax: (34) 93 860 9029 e-mail: biokit@biokit.com	SAFETY DATA SHEET	Date: 29-11-10 Rev.: 00 Pag.: 3 of 3
	Code: 3000-2340	

12. Ecological information

Ecotoxicity: Fish: Rainbow trout: LC50 = 0.8-1.6 mg/L; 96 Hr.; 13 degrees C Fish:

Bluegill/Sunfish: LC50 = 0.7-0.8 mg/L; 96 Hr.; 18 degrees C No data available.

Environmental: Aquatic Fate: Photolysis of sodium azide may result in metal nitrides initially, with the eventual formation of the free metal and nitrogen gas.

Physical: No information available.

Other: Harmful to aquatic life in very low concentrations.

13. Disposal considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

Disposal should be made in accordance with existing disposal practices employed for patient serum samples or infectious waste.

14. Transport information

Fragile containers, handle with care. Protect from high temperatures.

15. Regulatory information

According to 1999/45/EC Directive and 91/155/EEC Directive and following modifications.

16. Other information

Intended use: The reagents **quantex C3 (II)** are intended for the quantitative determination of complement 3 (C3) in human serum or plasma using the ILab™ Chemistry Systems.

For IN VITRO diagnostic use.

The Controls contain sodium azide as a preservative. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion. Use proper disposal procedures.

The above information is believed to be correct, but does not purpose to be all inclusive and should be used only as a guide. BIOKIT S.A. shall not be held for any damage resulting from handling or use of the product.