LAMPIRAN

Lampiran 1. Surat Keterangan Layak Etik

Kementerian Kesehatan
Poltekkes Yogyakarta
Komite Etik Penelitian Kesehatan
Jalan Tata Bumi No. 3, Banyuraden, Gamping, Sleman, D.I. Yogyakarta 55293
(0274) 617601
https://poltekkesjogja.ac.id

KETERANGAN LAYAK ETIK
DESCRIPTION OF ETHICAL EXEMPTION
"ETHICAL EXEMPTION"

No.DP.04.03/e-KEPK.1/437/2025

Protokol penelitian versi 1 yang diusulkan oleh :
The research protocol proposed by

Peneliti utama : Fadilah Yuliana Rahmawati
Principal In Investigator

Nama Institusi : Poltekkes Kemenkes Yogyakarta
Name of the Institution

Dengan judul:
Title
"Pengaruh Penyimpanan Serum Kontrol Liofilisat Komersial Setelah Rekonstitusi Yang Disimpan Pada Suhu -20°C Terhadap Hasil Pemeriksaan Kadar Ureum"

"Effect of Storage of Commercial Lyophilizate Control Serum After Reconstitution Stored at -20°C on the Results of Ureum Level Examination"

Dinyatakan layak etik sesuai 7 (tujuh) Standar WHO 2011, yaitu 1) Nilai Sosial, 2) Nilai Ilmiah, 3) Pemerataan Beban dan Manfaat, 4) Risiko, 5) Bujukan/Eksploitasi, 6) Kerahasiaan dan Privacy, dan 7) Persetujuan Setelah Penjelasan, yang merujuk pada Pedoman CIOMS 2016. Hal ini seperti yang ditunjukkan oleh terpenuhinya indikator setiap standar.

Declared to be ethically appropriate in accordance to 7 (seven) WHO 2011 Standards, 1) Social Values, 2) Scientific Values, 3) Equitable Assessment and Benefits, 4) Risks, 5) Persuasion/Exploitation, 6) Confidentiality and Privacy, and 7) Informed Concent, referring to the 2016 CIOMS Guidelines. This is as indicated by the fulfillment of the indicators of each standard.

Pernyataan Laik Etik ini berlaku selama kurun waktu tanggal 17 Maret 2025 sampai dengan tanggal 17 Maret 2026.

This declaration of ethics applies during the period March 17, 2025 until March 17, 2026.

March 17, 2025
Chairperson,

POLITEKNIK KESEHATAN YOGYAKARTA
KOMITE ETIK PENELITIAN KESEHATAN
KEMENTERIAN KESEHATAN

Dr. drg. Wiworo Haryani, M.Kes.

Lampiran 2. Surat Izin Peminjaman Tempat Penelitian

Kementerian Kesehatan
Poltekkes Yogyakarta
Jalan Tata Bumi No. 3, Banyuraden, Gamping, Sleman, D.I. Yogyakarta 55293
(0274) 617601
https://poltekkesjogja.ac.id

Kepada
Yth. **Ketua Jurusan Teknologi Laboratorium Medis**
Poltekkes Kemenkes Yogyakarta
Di tempat

Dengan Hormat,

Sehubungan dengan Penelitian Skripsi oleh Mahasiswa Sarjana Terapan Jurusan Teknologi Laboratorium Medis Poltekkes Kemenkes Yogyakarta, saya selaku peneliti:

Nama : Fadilah Yuliana Rahmawati
NIM : P71342324090
No. HP : 082196966907
Judul :Pengaruh Penyimpanan Serum Kontrol Liofilisat Komersial Setelah Rekonstitusi Yang Disimpan Pada Suhu -20°C Terhadap Hasil Pemeriksaan Kadar Ureum

Memohon izin untuk meminjam Ruang Laboratorium Kimia Klinik untuk melakukan Penelitian Skripsi. Adapun kegiatan yang akan dilaksanakan pada:

Hari, tanggal : Senin-Sabtu, (10 Maret – 22 April 2025)
Waktu : 08.00 – 17.00
Tempat : Laboratorium Kimia Klinik Jurusan Teknologi Laboratorium Medis Poltekkes Kemenkes Yogyakarta

Demikian surat permohonan peminjaman ini kami sampaikan. Adapun daftar alat dan bahan terlampir. Atas perhatian dan izin yang diberikan, kami ucapkan terimakasih.

Yogyakarta, 7 Maret 2025

Penanggungjawab Laboratorium Kimia Klinik	Pembimbing Tugas Akhir	Peneliti
Subrata Tri Widada, SKM, M.Sc.	**M.Atik Martsiningsih, S.Si., M.Sc**	**Fadilah Yuliana Rahmawati**
NIP. 19631128 198303 1 001	NIP. 19680323 198803 2 002	NIM P71342324090

Mengetahui,
PJ Laboratorium Jurusan
Teknologi Laboratorium Medis

Zulfikar Husni Faruq, M.Si.
NIP. 19890725 201902 1 001

Tembusan :

1. Mahasiswa
2. Koordinator Laboratorium Jurusan Teknologi Laboratorium Medis
3. Penanggung Jawab Ruang Laboratorium Jurusan Teknologi Laboratorium Medis
4. Petugas Laboratorium Jurusan Teknologi Laboratorium Medis
5. Satpam Jurusan Teknologi Laboratorium Medis

Lampiran 3. Surat Telah Menyelesaikan Penelitian

Kementerian Kesehatan
Poltekkes Yogyakarta
Jalan Tata Bumi No. 3, Banyuraden, Gamping, Sleman, D.I. Yogyakarta 55293
(0274) 617601
https://poltekkesjogja.ac.id

SURAT KETERANGAN
Nomor : TL.02.01.470

Dengan ini menyatakan bahwa :

Nama	:	Fadilah Yuliana Rahmawati
NIM	:	P71342324090
Institusi	:	Prodi Sarjana Terapan Teknologi Laboratorium Medik Poltekkes Kemenkes Yogyakarta.
Judul penelitian	:	Pengaruh Penyimpanan Serum Kontrol Liofilisat Komersial Setelah Rekonstitusi Yang Disimpan Pada Suhu -20°c Terhadap Hasil Pemeriksaan Kadar Ureum

Bahwasanya mahasiswa tersebut di atas telah selesai melakukan penelitian di Laboratorium Kimia Klinik Jurusan Teknologi Laboratorium Medis Poltekkes Kemenkes Yogyakarta.

Demikian surat keterangan ini dibuat untuk dapat digunakan sebagaimana mestinya.

Yogyakarta, 30 April 2025
a.n. Ketua Jurusan

Muji Rahayu,S.Si,Apt, M.Sc.
NIP. 196606151985112001

Tembusan :

1. Mahasiswa
2. Koordinator Laboratorium Jurusan Teknologi Laboratorium Medis
3. Penanggung Jawab Ruang Laboratorium Jurusan Teknologi Laboratorium Medis
4. Petugas Laboratorium Jurusan Teknologi Laboratorium Medis
5. Satpam Jurusan Teknologi Laboratorium Medis

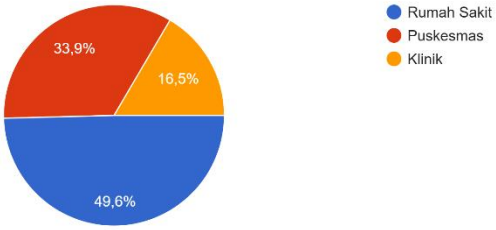
Lampiran 4. Instrumen Uji Pendahuluan

1. Dimana tempat anda bekerja atau pernah bekerja
   a. Rumah Sakit
   b. Puskesmas
   c. Klinik
2. Alat pemeriksaan kimia klinik apa yang anda gunakan*
   a. Kimia Analyze
   b. Spektrofotometer
3. Jenis serum kontrol apa yang digunakan
   a. Assayed (memiliki nilai rujukan)
   b. Unassayed (tidak memiliki nilai rujukan)
   c. Pooled sera / Kumpulan serum
4. Bentuk bahan kontrol apa yang anda gunakan
   a. Cair
   b. Serbuk
5. Bagaimana prosedur yang benar dalam mengelolah serum kontrol yang anda gunakan, apakah langsung digunakan di botol atau dipindahkan kedalam per cup
   a. Dipindahkan kedalam per cup
   b. Langsung digunakan
6. Dimana anda menyimpan serum kontrol yang anda gunakan
   a. Pada suhu - 20 C di bagian *Freezer* (Kulkas bagian atas)
   b. Pada suhu 2-8 C di bagian Chiller (Kulkas bagian bawah)
7. Bagaimana anda melakukan quality control di tempat anda bekerja
   a. Dilakukan setiap hari
   b. Dilakukan hanya saat ada permintaan pemeriksaan
8. Seberapa sering permintaan pemeriksaan Ureum di tempat anda bekerja*
   a. Rutin (Tiap hari selalu dilakukan)
   b. Sering (lebih dari 10-20 kali dalam sebulan)
   c. Jarang (dibawah 10 kali dalam sebulan)

Lampiran 5. Diagram Hasil Uji Pendahuluan

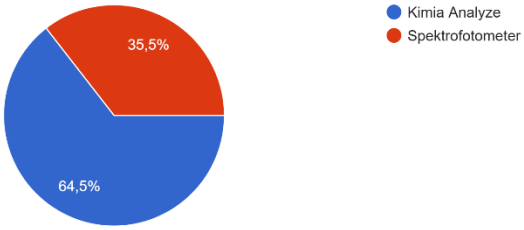
Dimana tempat anda bekerja atau pernah bekerja

121 jawaban



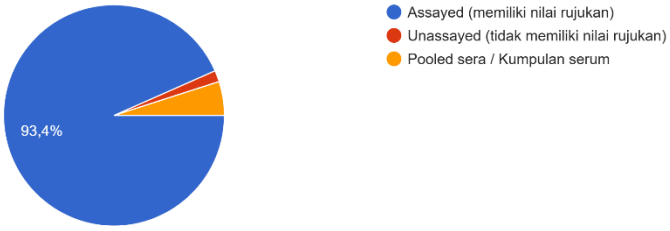
Alat pemeriksaan kimia klinik apa yang anda gunakan

121 jawaban



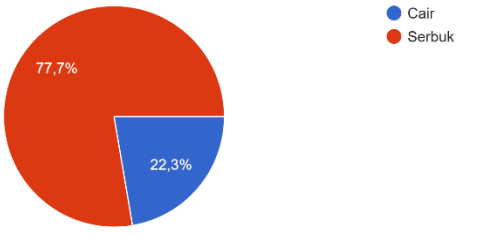
Jenis serum kontrol apa yang digunakan

121 jawaban



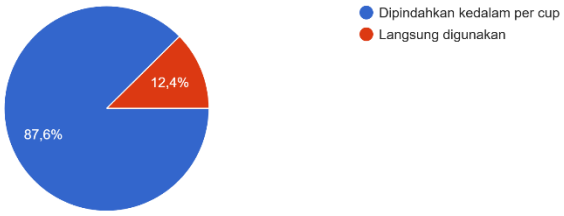
Bentuk bahan kontrol apa yang anda gunakan

121 jawaban



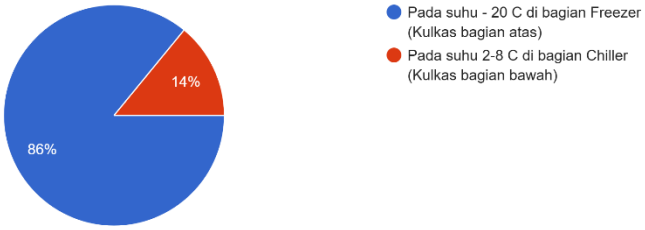
Bagaimana prosedur yang benar dalam mengelolah serum kontrol yang anda gunakan, apakah langsung digunakan di botol atau dipindahkan kedalam per cup

121 jawaban



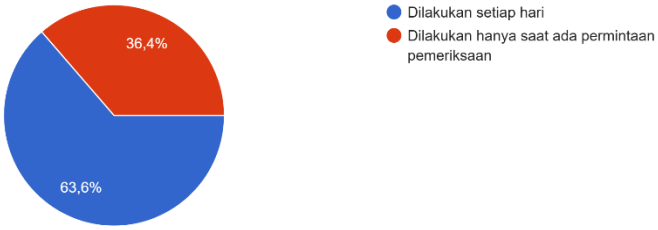
Dimana anda menyimpan serum kontrol yang anda gunakan

121 jawaban



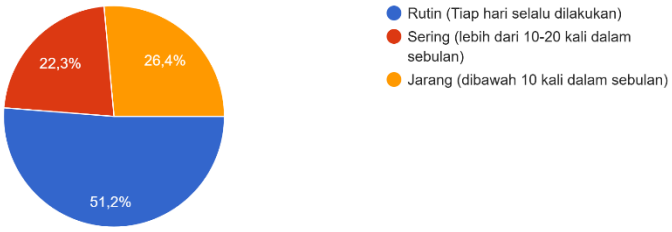
Bagaimana anda melakukan quality control di tempat anda bekerja

121 jawaban

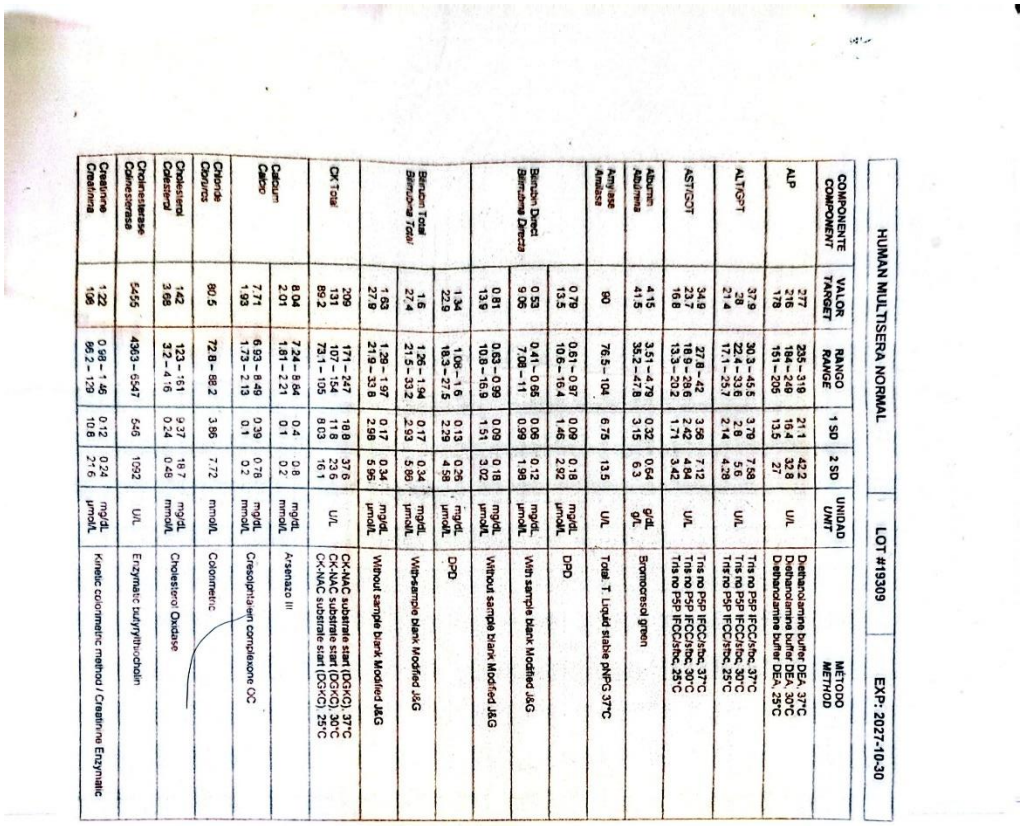


Seberapa sering permintaan pemeriksaan Ureum di tempat anda bekerja

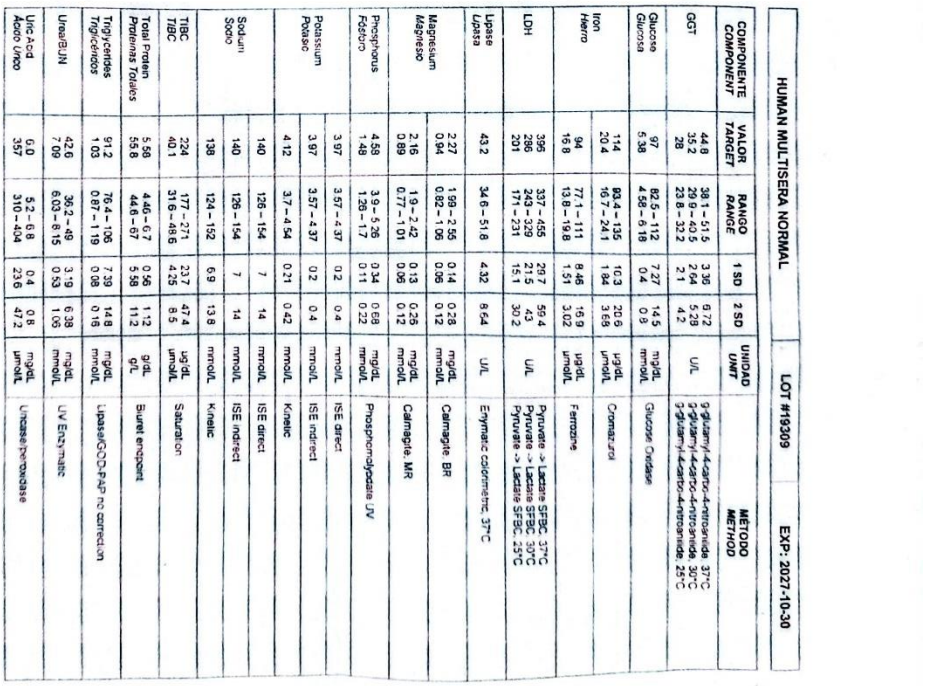
121 jawaban



Lampiran 6. Insert Kit Serum Control



HUMAN MULTISERA NORMAL					LOT #19309	EXP: 2027-10-30
COMPONENTE COMPONENT	VALOR TARGET	RANGO RANGE	1 SD	2 SD	UNIDAD UNIT	METODO METHOD
ALP	277 216 178	235 – 319 184 – 249 151 – 205	21.1 16.4 13.5	42.2 32.8 27	U/L	Diethanolamine buffer DEA 37°C Diethanolamine buffer DEA 30°C Diethanolamine buffer DEA 25°C
ALT/GPT	37.9 28 21.4	30.3 – 45.5 22.4 – 33.6 17.1 – 25.7	3.79 2.8 2.14	7.58 5.6 4.28	U/L	Tris no P5P IFCC/AbC 37°C Tris no P5P IFCC/AbC 30°C Tris no P5P IFCC/AbC 25°C
AST/GOT	34.9 23.7 16.8	27.8 – 42 18.9 – 28.6 13.3 – 20.2	3.56 2.42 1.71	7.12 4.84 3.42	U/L	Tris no P5P IFCC/AbC 37°C Tris no P5P IFCC/AbC 30°C Tris no P5P IFCC/AbC 25°C
Albumin Albúmina	4.15 41.5	3.51 – 4.79 35.2 – 47.8	0.32 3.15	0.64 6.3	g/dL g/L	Bromocresol green
Amylase Amilasa	60	76.5 – 104	6.75	13.5	U/L	Total T. Liquid stable pNPG 37°C
Bilirubin Direct Bilirrubina Directa	0.79 13.5	0.61 – 0.97 10.6 – 16.4	0.09 1.46	0.18 2.92	mg/dL µmol/L	DPD
	0.53 9.06	0.41 – 0.65 7.08 – 11	0.06 0.99	0.12 1.98	mg/dL µmol/L	With sample blank Modified J&G
Bilirubin Total Bilirrubina Total	0.81 13.9	0.63 – 0.99 10.8 – 16.9	0.09 1.51	0.18 3.02	mg/dL µmol/L	Without sample blank Modified J&G
	1.34 22.9	1.06 – 1.6 18.3 – 27.5	0.13 2.29	0.25 4.58	mg/dL µmol/L	DPD
	1.6 27.4	1.26 – 1.94 21.5 – 33.2	0.17 2.93	0.34 5.86	mg/dL µmol/L	Without sample blank Modified J&G
	1.63 27.9	1.29 – 1.97 21.9 – 33.6	0.17 2.98	0.34 5.96	mg/dL µmol/L	Without sample blank Modified J&G
CK Total	209 131 89.2	171 – 247 107 – 154 73.1 – 105	19.8 11.8 8.03	37.6 23.6 16.1	U/L	CK-NAC substrate start (DGKG) 37°C CK-NAC substrate start (DGKG) 30°C CK-NAC substrate start (DGKG) 25°C
Calcium Calcio	8.04 2.01	7.24 – 8.84 1.81 – 2.21	0.4 0.1	0.8 0.2	mg/dL mmol/L	Arsenazo III
	7.71 1.93	6.93 – 8.49 1.73 – 2.13	0.39 0.1	0.78 0.2	mg/dL mmol/L	Cresolphtalein complexone CC
Chloride Cloruros	80.5	72.8 – 88.2	3.86	7.72	mmol/L	Colorimetric
Cholesterol Colesterol	142 3.68	123 – 161 3.2 – 4.16	9.37 0.24	18.7 0.48	mg/dL mmol/L	Cholesterol Oxidase
Cholinesterase Colinesterasa	5455	4393 – 6547	548	1092	U/L	Enzymatic butyrylthiocholin
Creatinine Creatinina	1.22 108	0.98 – 1.46 86.2 – 129	0.12 10.8	0.24 21.6	mg/dL µmol/L	Kinetic colorimetric method / Creatinine Enzymatic



HUMAN MULTISERA NORMAL					LOT #19309	EXP: 2027-10-30
COMPONENTE COMPONENT	VALOR TARGET	RANGO RANGE	1 SD	2 SD	UNIDAD UNIT	METODO METHOD
GGT	44.9 35.2 28	38.1 – 51.5 29.9 – 40.5 23.8 – 32.2	3.38 2.64 2.1	6.72 5.29 4.2	U/L	g-glutamyl-4-carbo-4-nitroanilide 37°C g-glutamyl-4-carbo-4-nitroanilide 30°C g-glutamyl-4-carbo-4-nitroanilide 25°C
Glucose Glucosa	97 5.38	82.5 – 112 4.58 – 6.18	7.27 0.4	14.5 0.9	mg/dL mmol/L	Glucose Oxidase
Iron Hierro	114 20.4	89.4 – 135 16.7 – 24.1	10.3 1.84	20.6 3.68	µg/dL µmol/L	Cromazurol
	94 16.8	77.1 – 111 13.8 – 19.8	8.45 1.51	16.9 3.02	µg/dL µmol/L	Ferrozine
LDH	396 286 201	337 – 455 243 – 329 171 – 231	29.7 21.4 15.1	59.4 42.9 30.2	U/L	Pyruvate -> Lactate SFBC 37°C Pyruvate -> Lactate SFBC 30°C Pyruvate -> Lactate SFBC 25°C
Lipase Lipasa	43.2	34.6 – 51.8	4.32	8.64	U/L	Enzymatic colorimetric 37°C
Magnesium Magnesio	2.27 0.94	1.99 – 2.55 0.82 – 1.06	0.14 0.06	0.28 0.12	mg/dL mmol/L	Calmagite BR
	2.16 0.89	1.9 – 2.42 0.77 – 1.01	0.13 0.06	0.26 0.12	mg/dL mmol/L	Calmagite, MR
Phosphorus Fósforo	4.59 1.48	3.9 – 5.26 1.26 – 1.7	0.34 0.11	0.69 0.22	mg/dL mmol/L	Phosphomolybdate UV
Potassium Potasio	3.97	3.57 – 4.37	0.2	0.4	mmol/L	ISE direct
	3.97	3.57 – 4.37	0.2	0.4	mmol/L	ISE indirect
Sodium Sodio	4.12	3.7 – 4.54	0.21	0.42	mmol/L	Kinetic
	140	126 – 154	7	14	mmol/L	ISE direct
	140	126 – 154	7	14	mmol/L	ISE indirect
TIBC TIBC	138	124 – 152	6.9	13.8	mmol/L	Kinetic
	224 40.1	177 – 271 31.6 – 48.6	23.7 4.25	47.4 8.5	ug/dL µmol/L	Saturation
Total Protein Proteínas Totales	5.58 55.8	4.46 – 6.7 44.6 – 67	0.56 5.58	1.12 11.2	g/dL g/L	Biuret endpoint
Triglycerides Triglicéridos	91.2 1.03	78.4 – 105 0.87 – 1.19	7.39 0.08	14.8 0.16	mg/dL mmol/L	Lipase/GDO-PAP no correction
Urea/BUN	42.6 7.09	36.2 – 49 6.03 – 8.15	3.19 0.53	6.38 1.06	mg/dL mmol/L	UV Enzymatic
Uric Acid Ácido Úrico	6.0 357	5.2 – 6.8 310 – 404	0.4 23.6	0.8 47.2	mg/dL µmol/L	Uricase peroxidase

Lampiran 7. Insert Kit Reagen Glory Ureum

Glory® Diagnostics

UREA Berthelot CE

GD-URB100	GD-URB400
2 x 50 mL	4 x 100 mL
CONTENTS	**CONTENTS**
R1. Reagent 1 x 2 mL	R1. Reagent 2 x 4 mL
R2. Reagent 1 x 48 mL	R2. Reagent 2 x 96 mL
R3. Reagent 1 x 50 mL	R3. Reagent 2 x 100 mL
CAL.Standard 1 x 3 mL	CAL.Standard 1 x 3 mL
For *in vitro* diagnostic use only	

UREA

Urease/Salycilate

Enzymatic colorimetric method

ENDPOINT

PRINCIPLE

Urea is hydrolyzed by urease[1,2] into ammonia and carbon dioxide. The ammonia generated reacts with alkaline hypochlorite and sodium salicylate in presence of sodium nitroprusside as coupling agent to yield a green cromophore. The intensity of the color formed is proportional to the concentration of urea in the sample.

$$\text{Urea} + H_2O \xrightarrow{\text{UREASE}} 2\,NH_3 + CO_2$$

$$NH_4^+ + \text{Salycilate} + \text{NaClO} \xrightarrow[OH^-]{\text{NITROPRUSSIDE}} \text{Indophenol} + \text{NaCl}$$

REAGENT COMPOSITION

R1 **Enzyme reagent.** Urease > 500 U/mL. Stabilizers.

R2 **Buffered chromogen.** Phosphate buffer 20 mmol/L pH 6.9, EDTA 2 mmol/L, sodium salycilate 60 mmol/L, sodium nitroprusside 3.4 mmol/L.

R3 **Alkaline hypochlorite.** Sodium hypochlorite 10 mmol/L, NaOH 150 mmol/L.

CAL **Urea standard.** Urea 50 mg/dL (8.3 mmol/L)
Organic matrix based primary standard. Concentration value is traceable to Standard Reference Material 909b.

STORAGE AND STABILITY

Store at 2-8ºC.
All the kit compounds are stable until the expiry date stated on the label. Do not use reagents over the expiration date.
Store the vials tightly closed, protected from light and prevented contaminations during the use.

Discard if appear signs of deterioration:
- Presence of particles and turbidity.
- Blank absorbance (A) at 600 nm > 0.110 in 1cm cuvette.

REAGENT PREPARATION

Working reagent. Mix 1 volume of **R1** + 24 volumes of **R2**. Stable for 4 weeks at 2-8ºC and for 7 days at 15-25ºC.

SAMPLES

Serum or heparinized plasma free of hemolysis and urine (see Notes). Other anticoagulants (ammonium heparinate or double oxalate of potassium and ammonium) must not be used.
Urea in serum, plasma or urine is stable 7 days at 2-8ºC. Freeze for longer storage.

INTERFERENCES

- Lipemia (intralipid 20 g/L) does not interfere.
- Bilirubin (40 mg/dL) does not interfere
- Hemoglobin (>2 g/L) may affect the results.
- Other drugs and substances may interfere[3].

MATERIALS REQUIRED

- Photometer or colorimeter capable of measuring absorbances at 600 ± 10 nm.
- Constant temperature incubator set at 37ºC.
- Cuvettes with 1-cm pathlength.
- Pipettes to measure reagent and samples.

PROCEDURE

1. Bring reagents and samples to room temperature.
2. Pipette into a cuvette:

TUBES	Blank	Sample	CAL.Standard
Working reagent	1.0 mL	1.0 mL	1.0 mL
Sample	–	10 µL	–
CAL.Standard	–	–	10 µL

3. Mix and incubate for 5 minutes at 37ºC or for 10 minutes at room temperature (16-25ºC).
4. Pipette:

R3	1.0 mL	1.0 mL	1.0 mL

5. Mix thoroughly and incubate the tubes for 5 minutes at 37ºC or for 10 minutes at room temperature (16-25ºC).
5. Read the absorbance (A) of the samples and the standard at 600 nm against the reagent blank.

The color is stable for at least 2 hours protected from light.

CALCULATIONS

Serum, plasma

$$\frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times C_{\text{Standard}} = \text{mg/dL urea}$$

Samples with concentrations higher than 300 mg/dL (50 mmol/L) should be diluted 1:5 with saline and assayed again. Multiply the results by 5.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

Glory Diagnostics
Manufactured in the Spain

Urine

Dilute the sample 1:50 with distilled water and multiply the result by 50.

If results are to be expressed as SI units apply:
mg/dL x 0.1665 = mmol/L

To convert urea mass units to those of urea nitrogen apply:
mg/dL x 0.467 = mg/dL BUN

REFERENCE VALUES [5]

Serum, plasma

Newborns (< 10 days)	6.4 - 53.5 mg/dL (1.1 - 9.0 mmol/L)
Adults (12-60 years)	15 - 40 mg/dL (2.5 - 6.6 mmol/L)

In adults over 60 years of age, the reference interval is 17-50 mg/dL (2.8-8.3 mmol/L) and the concentrations tend to be slightly higher in males than in females.

Urine

Adults (normal diet)	26 - 43 g/24-h (428 - 714 mmol/24-h)

A high-protein diet causes significant increases in plasma urea concentrations and urinary excretion.
It is recommended that each laboratory establishes its own reference range.

QUALITY CONTROL

The use of a standard to calculate results allows to obtain an accuracy independent of the system or instrument used.
To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

REF **BC600** HUMAN MULTISERA NORMAL
Borderline level of urea. Assayed.

REF **BC650** HUMAN MULTISERA ABNORMAL
Elevated level of urea. Assayed.

If the values are found outside of the defined range, check the instrument, reagents and procedure.
Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

CLINICAL SIGNIFICANCE

Urea is the chief end product of protein metabolism in the body. The importance of the urea concentration in blood lies in its value as an indicator of kidney function.

Azotemia (an abnormal increase in plasma urea level) is seen mainly in renal disorders, dehydration, increase protein catabolism, high-protein diets, or gastrointestinal hemorrhage. There are two types of azotemia. The first, *prerenal azotemia*, is caused by impaired perfusion of the Kidneys due to decreased cardiac output or for any of the former causes. The second, *postrenal azotemia*, is caused by an obstruction in the urine outflow such as nephrolithiasis, prostatism, and tumors of the genitourinary tract.
The clinical significance of the urea level in plasma is usually determined in conjugation with the plasma creatinine level. In prerenal azotemia, an increase in the plasma urea level is usually associated with a normal plasma creatinine level, where as in postrenal azotemia, there is an increase in both the urea and the plasma creatinine levels. A decrease in the urea plasma level may be associated with acute dehydration, malnutrition, and pregnancy.

NOTES

- Collect a 24-hour urine specimen into a plastic bottle free of preservatives. Keep the sample refrigerated to minimize urea hydrolysis by microorganisms or other agents.
- This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meets the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact to the distributor for any question on the application method.
- Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

ANALYTICAL PERFORMANCE

- ***Detection Limit :*** 4.79 mg/dL
- ***Linearity :*** Up to 300 mg/dL
- ***Precision:***

mg/dL	Within-run		Between-run	
Mean	62.3	141.06	62.3	141.06
SD	2.18	5.76	2.91	5.86
CV%	3.33	4.28	4.68	4.16
N	10	10	10	10

- ***Sensitivity :*** 8.900 mA/min / mg/dL Urea.
- ***Correlation.*** This assay (y) was compared with a similar commercial method (x). The results were:
  N = 50 r = 0.99 y = 0.923x + 0.4987

The analytical performances have been generated using on automatic instrument. Results may vary depending on the instrument.

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QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

Glory Diagnostics
Manufactured in the Spain

Lampiran 8. Kontrol Suhu Penyimpanan

No	Suhu (°C)
1	20,3
2	20,7
3	20,2
4	20,0
5	20,0
6	21,1
7	20,0
8	19,8
9	20,2
10	20,1
11	20,0
12	20,0
13	20,2
14	20,0
15	20,3
16	20,0
17	19,8
18	20,6
19	20,1
20	20,2
21	20,0
22	19,2
23	20.3
24	20,1
25	20,0
26	19,8
27	20.3
28	20,0
29	20.2
30	20,0
31	19,6
32	19,3
33	20,1
34	21,2
35	19,7
36	20,0
37	19,5
38	20,3
39	20,5
40	21,2

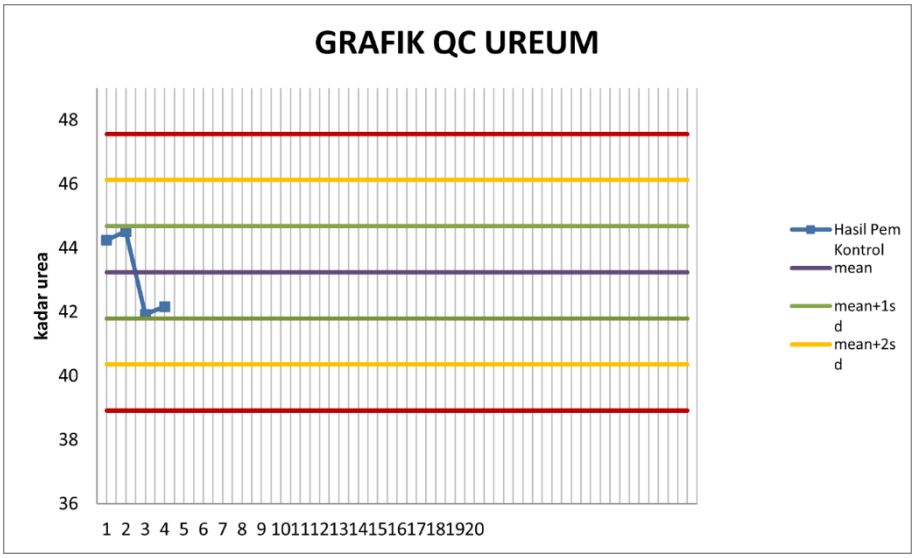
Lampiran 9. Quality Control

A. Periode Pendahuluan

PERIODE PENDAHULUAN UREUM		RANGE KONTROL
Nomor	**Hasil Pemeriksaan Serum Kontrol Periode Pendahuluan**	
1	43,38	
2	43,79	
3	43,55	
4	44,24	
5	43,19	
6	44,92	
7	44,89	
8	45,17	
9	41,33	
10	40,25	
11	40,98	**36,2 - 49**
12	41,05	
13	41,92	
14	43,25	
15	42,50	
16	43,75	
17	43,53	
18	44,16	
19	44,51	
20	44,33	
Mean	**43,23**	Rerata
SD	1,44	
Mean + 1SD	44,68	
Mean + 2SD	46,12	Batas Peringatan Atas
Mean + 3SD	47,56	Batas Kontrol Atas
Mean - 1SD	41,79	
Mean - 2SD	40,35	Batas Peringatan Bawah
Mean - 3SD	38,91	Batas Kontrol Bawah

B. Periode Kontrol

Periode Kontrol	
Hari Perlakuan	Hasil Pemeriksaan Serum kontrol periode kontrol
Hari 0	44,24
Hari 20	44,51
Hari 30	41,92
Hari 40	42,16



Lampiran 10. Hasil Analisis Deskriptif

PERLAKUKAN	Hari 0	Hari 20	Hari 30	Hari 40
kadar Ureum	43,38	43,17	42,33	41,48
	43,79	43,23	41,73	42,05
	43,55	43,75	42,90	41,08
	44,24	43,53	42,37	41,33
	43,19	44,16	42,27	40,25
	44,92	44,51	43,22	40,98
	44,89	43,21	41,92	41,05
	45,17	42,71	43,25	42,16
RATA-RATA	**44,14**	**43,53**	**42,50**	**41,30**
Minimum	43,19	42,71	41,73	40,25
Maksimum	45,17	44,16	43,22	42,16
Standar diviasi	0,77	0,58	0,56	0,61
Coefisien Variarant	1,74	1,33	1,32	1,48
Nilai Bahan Kontrol		42,6		
Bias	3,62	2,19	0,24	3,06
PERLAKUKAN	0 hari dan 20 hari	0 hari dan 30 hari	0 hari dan 40 hari	
Selisihh				
Pesentasi Selisihh	1,38%	3,72%	6,44%	

Lampiran 11. Hasil Uji Statistika

1. Uji Distribusi data Kadar Ureum terhadap serum kontrol *liofilisat* komersial setelah rekonstitusi yang disimpan pada suhu -20ºC selama 0 hari, 20 hari, 30 hari dan 40 hari.

   Hipotesis

   H_0 : Data Berdistribusi Normal

   H_a : Data tidak berdistribusi normal

   Ketentuan

   H_0 diterima jika *Sig* (*Shapiro-Wilk*) ≥ 0,05

   H_0 ditolak jika *Sig* (*Shapiro-Wilk*) < 0,05

   Hasil

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Standardized Residual for Hari0	,208	8	,200*	,903	8	**,304**
Standardized Residual for Hari20	,198	8	,200*	,955	8	**,759**
Standardized Residual for Hari30	,214	8	,200*	,918	8	**,416**
Standardized Residual for Hari40	,178	8	,200*	,946	8	**,669**

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

   Keputusan

   Data Hasil Kadar Ureum terhadap serum kontrol *liofilisat* komersial setelah rekonstitusi yang disimpan pada suhu -20ºC selama 0 hari, 20 hari, 30 hari dan 40 hari karena pada *Sig* pada *Shapiro-Wilk* ≥ 0,05.

   Kesimpulan

   Data Hasil Kadar Ureum terhadap serum kontrol *liofilisat* komersial setelah rekonstitusi yang disimpan pada suhu -20ºC selama 0 hari, 20 hari, 30 hari dan 40 hari berdistribusi normal

2. Uji Homogenitas Data (Kesamaan Varians)

   Hipotesis

   H_0 : Data homogen (varian sama)

   H_a : Data tidak homogen (varian tidak sama)

Ketentuan

H_0 diterima jika *Sig* (*Mauchly's Test of Sphericity*) ≥ 0,05

H_0 ditolak jika *Sig* (*Mauchly's Test of Sphericity*) < 0,05

Hasil

Mauchly's Test of Sphericity[a]

Measure: MEASURE_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Hari	,585	3,070	5	,693	,745	1,000	,333

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. Design: Intercept

Within Subjects Design: Hari

b. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Keputusan

H_0 diterima karena *Sig* (*0,693*) ≥ 0,05

Kesimpulan

Data homogen, maka untuk membuat keputusan uji *Repeated Measures Anova* sig yang dibaca pada *Spherecity Assumed*.

3. Uji Beda Lebih Dua Sampel Berpasangan (*Repeated Measures Anova*)

Hipotesis

H_0 : Tidak ada pengaruh penyimpanan serum kontrol komersial setelah rekonstitus pada suhu -20ºC terhadap hasil kadar Ureum yang disimpan pada 0 hari, 20 hari, 30 hari dan 40 hari

H_a : Ada pengaruh penyimpanan serum kontrol komersial setelah rekonstitusi pada suhu -20ºC terhadap hasil kadar Ureum yang disimpan pada 0 hari, 20 hari, 30 hari dan 40 hari

Ketentuan

H_0 diterima jika *Sig* ≥ 0,05

H_0 ditolak jika *Sig* < 0,05

Hasil

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Hari	Sphericity Assumed	37,338	3	12,446	31,082	,000
	Greenhouse-Geisser	37,338	2,235	16,709	31,082	,000
	Huynh-Feldt	37,338	3,000	12,446	31,082	,000
	Lower-bound	37,338	1,000	37,338	31,082	,001
Error(Hari)	Sphericity Assumed	8,409	21	,400		
	Greenhouse-Geisser	8,409	15,642	,538		
	Huynh-Feldt	8,409	21,000	,400		
	Lower-bound	8,409	7,000	1,201		

Keputusan

H_0 Ditolak karena pada *Sphericity Assumed* (0,000) < 0,05

Kesimpulan

ada pengaruh penyimpanan serum kontrol komersial setelah rekonstitusi pada suhu -20ºC terhadap hasil kadar Ureum yang disimpan pada 0 hari, 20 hari, 30 hari dan 40 hari.

4. Besar Pengaruh Variabel Bebas Terhadap Variabel Terikat

Pairwise Comparisons

Measure: Ureum

(I) Hari	(J) Hari	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
1	2	,608	,376	,903	-,761	1,976
	3	1,642*	,265	,003	,680	2,605

	4	2,844*	,283	,000	1,815	3,873
2	1	-,608	,376	,903	-1,976	,761
	3	1,035*	,255	,029	,107	1,963
	4	2,236*	,399	,005	,785	3,688
3	1	-1,642*	,265	,003	-2,605	-,680
	2	-1,035*	,255	,029	-1,963	-,107
	4	1,201*	,290	,026	,146	2,257
4	1	-2,844*	,283	,000	-3,873	-1,815
	2	-2,236*	,399	,005	-3,688	-,785
	3	-1,201*	,290	,026	-2,257	-,146

Based on estimated marginal means

***. The mean difference is significant at the ,05 level.**

b. Adjustment for multiple comparisons: Bonferroni.

Jika sig lebih >0,005 maka tidak ada penurunan

Maka kadar ureum pada serum kontrol *liofilisat* komersial setelah rekonstitusi dan disimpan selama 20 hari pada suhu -20ºC adalah tidak mengalami penurunan

Rata-rata penurunan kadar ureum pada serum kontrol *liofilisat* komersial setelah rekonstitusi dan disimpan selama 30 hari pada suhu -20ºC adalah 1,64 mg/dL (CI 95% = 0,680 - 2,605)

Rata-rata penurunan kadar ureum pada serum kontrol *liofilisat* komersial setelah rekonstitusi dan disimpan selama 40 hari pada suhu -20ºC adalah 2,84 mg/dL (CI 95% = 1,815 - 2,605)

Lampiran 12. Dokumentasi Penelitian

Rekonstitusi Serum Kontrol

Pemisahan Serum Kontrol Ke Cup Serum

Reagen Ureum

Pemantauan Serum Control

Pembuatan Reagen Kerja

Pemeriksaan Kadar Ureum