

Lampiran 1. Surat Layak Etik



Terakreditasi KEPPKN No. 005/KEPPKN/AKT/IV/2024

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.1/1314/2025

Protokol penelitian versi 1 yang diusulkan oleh :

The research protocol proposed by

Peneliti utama : Wanda Aprilia Putri
Principal In Investigator

Nama Institusi : Politeknik Kesehatan Kementerian
Kesehatan Yogyakarta

Name of the Institution

Dengan judul:

Title

"Kadar Glukosa pada Serum Lipemik dengan Penanganan Menggunakan Flokulan Kitosan dan High Speed Sentrifugasi"

"Glucose Levels in Lipemic Serum Treated with a Chitosan Flocculant and High Speed Centrifugation"

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 Consent, 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 22 Desember 2025 sampai dengan tanggal 22 Desember 2026.

This declaration of ethics applies during the period December 22, 2025 until December 22, 2026.



December 22, 2025

Chairperson,

Dr. drg. Wiworo Haryani, M.Kes.

Lampiran 2. Surat Izin Penelitian



Kementerian Kesehatan
Direktorat Jenderal
Sumber Daya Manusia Kesehatan
Politeknik Kesehatan Yogyakarta
Jalan Tata Bumi No. 3, Banyuraden, Gamping,
Sleman, D.I. Yogyakarta 55293
☎ (0274) 617601
🌐 <https://poltekkesjogja.ac.id>

Nomor : LB.02.01/F.XXVII.10/1225/2025 Yogyakarta, 04 Desember 2025
Lamp : -
Hal : Permohonan Izin Penelitian

Kepada Yth. :

Kepala Balai Besar Laboratorium Kesehatan Masyarakat Yogyakarta
di-
Yogyakarta

Dengan hormat,

Sehubungan dengan kegiatan penelitian yang akan dilakukan oleh mahasiswa Prodi Sarjana Terapan Teknologi Laboratorium Medis Jurusan Teknologi Laboratorium Medis Poltekkes Kemenkes Yogyakarta. Berkaitan dengan hal tersebut, dengan ini kami mohon izin dan bantuan Bapak/Ibu agar mahasiswa yang bersangkutan dapat melaksanakan kegiatan sesuai dengan perihal di atas. Adapun mahasiswa yang akan melakukan penelitian adalah :

Nama : Wanda Aprilia Putri
NIM : P07134222061
Judul : Kadar Glukosa pada Serum Lipemik dengan Penanganan Menggunakan Flokulan Kitosan dan High Speed Sentrifugasi

Demikian atas perhatian dan kerjasamanya diucapkan terima kasih.



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



Lampiran 3. Data Pemeriksaan Kadar Glukosa



FR/BBLabkesmasYk/7.8.m/Rev.1

LAPORAN HASIL UJI
RS.02.04/B.X.2/951/2026

Pengujian Instalasi Laboratorium Patologi Klinik & Imunologi

Jenis Sampel : Darah Vena (Serum Lipemik)
Parameter : Gula Darah Sewaktu
Metode Uji : *Glucose Oxidase/ Peroxidase*
Kegiatan : Penelitian
Asal Sampel : Wanda Aprilia Putri, Jalan Ngadinegaran MJ 3 No.62, Mantrijeron, Mantrijeron, Yogyakarta, Daerah Istimewa Yogyakarta,
Pengambil Sampel : Wanda Aprilia Putri
Tanggal dan Waktu : 19-12-2025 08:00:00
Pengambilan
Tanggal Penerimaan : 19-12-2025
Tanggal Pemeriksaan : 29-12-2025
Tanggal dan Waktu : 14-01-2026 11:17:53
Hasil Dilaporkan
Kondisi Sampel :

No	Nomor Sampel	Hasil Uji	Satuan
1	Sebelum-1	178,77	mg/dL
2	Sebelum-2	187,25	mg/dL
3	Sebelum-3	130,73	mg/dL
4	Sebelum-4	133,93	mg/dL
5	Sebelum-5	138,22	mg/dL
6	Sebelum-6	136,91	mg/dL
7	Sebelum-7	103,35	mg/dL
8	Sebelum-8	121,4	mg/dL
9	Sebelum-9	168,88	mg/dL
10	Sebelum-10	187,12	mg/dL
11	Sebelum-11	199,68	mg/dL
12	Sebelum-12	105,53	mg/dL
13	Sebelum-13	150,54	mg/dL

14	Sebelum-14	121,37	mg/dL
15	Sebelum-15	139,52	mg/dL
16	Sebelum-16	132,6	mg/dL
17	Sebelum-17	134,68	mg/dL
18	Sebelum-18	159,31	mg/dL
19	Sebelum-19	106,42	mg/dL
20	Sebelum-20	112,61	mg/dL
21	K-1	152,72	mg/dL
22	K-2	155,06	mg/dL
23	K-3	107,4	mg/dL
24	K-4	111,84	mg/dL
25	K-5	113,66	mg/dL
26	K-6	131,71	mg/dL
27	K-7	85,43	mg/dL
28	K-8	106,65	mg/dL
29	K-9	148,13	mg/dL
30	K-10	176,69	mg/dL
31	K-11	195,46	mg/dL
32	K-12	98,6	mg/dL
33	K-13	139,37	mg/dL
34	K-14	105,2	mg/dL
35	K-15	119,13	mg/dL
36	K-16	121,05	mg/dL
37	K-17	125,3	mg/dL
38	K-18	138,19	mg/dL
39	K-19	101,91	mg/dL
40	K-20	94,59	mg/dL

41	H-1	168,79	mg/dL
42	H-2	172,69	mg/dL
43	H-3	116,95	mg/dL
44	H-4	119,18	mg/dL
45	H-5	117,01	mg/dL
46	H-6	124,43	mg/dL
47	H-7	88,45	mg/dL
48	H-8	109,22	mg/dL
49	H-9	151,27	mg/dL
50	H-10	153,73	mg/dL
51	H-11	197,37	mg/dL
52	H-12	101,38	mg/dL
53	H-13	140,71	mg/dL
54	H-14	111,54	mg/dL
55	H-15	124,34	mg/dL
56	H-16	122,27	mg/dL
57	H-17	125,06	mg/dL
58	H-18	143,69	mg/dL
59	H-19	99,04	mg/dL
60	H-20	98,71	mg/dL

Keterangan:

* : Parameter Terakreditasi

Bantul, 14-01-2026

Penanggungjawab Laboratorium Patologi Klinik dan Imunologi



(dr. Siti Maryam, Sp.PK)
NIP 3402126312740003

Lampiran 4. Hasil Analisis Deskriptif

No. Sampel	Kadar Glukosa (mg/dL)			B-A	C-A	B-C
	Sebelum Penanganan	Penanganan Menggunakan Flokulan Kitosan	Penanganan Menggunakan <i>High Speed</i> Sentrifugasi			
	(A)	(B)	(C)			
1	178,77	152,72	168,79	-26,05	-9,98	-16,07
2	187,25	155,06	172,69	-32,19	-14,56	-17,63
3	130,73	107,4	116,95	-23,33	-13,78	-9,55
4	133,93	111,84	119,18	-22,09	-14,75	-7,34
5	138,22	113,66	117,01	-24,56	-21,21	-3,35
6	136,91	131,71	124,43	-5,2	-12,48	7,28
7	103,35	85,43	88,45	-17,92	-14,9	-3,02
8	121,4	106,65	109,22	-14,75	-12,18	-2,57
9	168,88	148,13	151,27	-20,75	-17,61	-3,14
10	187,12	176,69	153,73	-10,43	-33,39	22,9
11	199,68	195,46	197,37	-4,22	-2,31	-1,91
12	105,53	98,6	101,38	-6,93	-4,15	-2,78
13	150,54	139,37	140,71	-11,17	-9,83	-1,34
14	121,37	105,2	111,54	-16,17	-9,83	-6,34
15	139,52	119,13	124,34	-20,39	-15,18	-5,21
16	132,6	121,05	122,27	-11,55	-10,33	-1,22
17	134,68	125,3	125,06	-9,38	-9,62	0,24
18	159,31	138,19	143,69	-21,12	-15,62	-5,5
19	106,42	101,91	99,04	-4,51	-7,38	2,87
20	112,61	94,59	98,71	-18,02	-13,9	-4,12
Rerata	142,44	126,4	129,29	-16,04	-13,15	-2,89

Lampiran 5. Hasil Analisis Statistik

Hasil Uji Statistik Kadar Glukosa pada Serum Lipemik sebelum dan setelah Penanganan Menggunakan Flokulan Kitosan serta *High Speed* Sentrifugasi

A. Uji Normalitas/ Distribusi Data

Tests of Normality

	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Standardized Residual for Sebelum	.194	20	.048	.932	20	.167
Standardized Residual for Kitosan	.125	20	.200*	.942	20	.258
Standardized Residual for High_Speed	.210	20	.021	.938	20	.216

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

a. Lilliefors Significance Correction

B. Uji Homogenitas Data

Mauchly's Test of Sphericity^a

Measure: Glukosa

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon ^b		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Penanganan	.523	11.678	2	.003	.677	.711	.500

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: Penanganan

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.

C. Uji Beda *Tests of Within-Subjects Effects*

Tests of Within-Subjects Effects

Measure: Glukosa

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Penanganan	Sphericity Assumed	4692.676	2	2346.338	21.303	.000
	Greenhouse-Geisser	4692.676	1.354	3466.304	21.303	.000
	Huynh-Feldt	4692.676	1.421	3302.282	21.303	.000
	Lower-bound	4692.676	1.000	4692.676	21.303	.000
Error(Penanganan)	Sphericity Assumed	4185.412	38	110.142		
	Greenhouse-Geisser	4185.412	25.722	162.716		
	Huynh-Feldt	4185.412	27.000	155.017		
	Lower-bound	4185.412	19.000	220.285		

D. Uji Besar Pengaruh *Pairwise Comparisons*

Pairwise Comparisons

Measure: Glukosa

(I) Penanganan	(J) Penanganan	Mean Difference (I-J)	Std. Error	Sig. ^b	95% Confidence Interval for Difference ^b	
					Lower Bound	Upper Bound
1	2	20.036*	3.912	.000	9.767	30.306
	3	17.149*	3.783	.001	7.218	27.081
2	1	-20.036*	3.912	.000	-30.306	-9.767
	3	-2.887	1.851	.406	-7.746	1.972
3	1	-17.149*	3.783	.001	-27.081	-7.218
	2	2.887	1.851	.406	-1.972	7.746

Based on estimated marginal means

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

b. Adjustment for multiple comparisons: Bonferroni.

Lampiran 6. Perhitungan Evaluasi Bias

Data:

Ki = Kitosan, Hi = *High Speed* (kontrol)

n = 20

- 1) Percent difference tiap sampel (dibanding kontrol):

$$di(\%) = ((Ki - Hi) / Hi) * 100$$

- 2) Hasil hitung di(%) untuk 20 sampel (dibulatkan 2 desimal):

$$d1 = -9,52$$

$$d2 = -10,21$$

$$d3 = -8,17$$

$$d4 = -6,16$$

$$d5 = -2,86$$

$$d6 = 5,85$$

$$d7 = -3,41$$

$$d8 = -2,35$$

$$d9 = -2,08$$

$$d10 = 14,94$$

$$d11 = -0,97$$

$$d12 = -2,74$$

$$d13 = -0,95$$

$$d14 = -5,68$$

$$d15 = -4,19$$

$$d16 = -1,00$$

$$d17 = 0,19$$

$$d18 = -3,83$$

$$d19 = 2,90$$

$$d20 = -4,17$$

- 3) Bias persen (rata-rata percent difference):

$$Bias(\%) = (d1 + d2 + \dots + d20) / 20$$

$$Jumlah \Sigma di(\%) = -44,4205718868$$

$$Bias(\%) = -44,4205718868 / 20$$

$$Bias(\%) = -2,2210285943 \approx -2,22\%$$

- 4) SD persen (SD sampel): → **STDEV.S di excel**

$$SD(\%) = \sqrt{(\Sigma(di - Bias)^2) / (n - 1)}$$

$$\Sigma(di - Bias)^2 = 588,5445122528$$

$$SD(\%) = \sqrt{588,5445122528 / 19}$$

$$SD(\%) = 5,565611104 \approx 5,57\%$$

5) Limits of Agreement (LoA) 95%:

$$\text{Lower LoA}(\%) = \text{Bias}(\%) - 1,96 * \text{SD}(\%)$$

$$\text{Upper LoA}(\%) = \text{Bias}(\%) + 1,96 * \text{SD}(\%)$$

$$1,96 * \text{SD}(\%) = 1,96 * 5,565611104 = 10,908597764$$

$$\text{Lower LoA}(\%) = -2,2210285943 - 10,908597764$$

$$\text{Lower LoA}(\%) = -13,129626358 \approx -13,13\%$$

$$\text{Upper LoA}(\%) = -2,2210285943 + 10,908597764$$

$$\text{Upper LoA}(\%) = 8,6875691697 \approx +8,69\%$$

6) Bandingkan dengan TEa CLIA glukosa $\pm 8\%$:

Syarat memenuhi TEa:

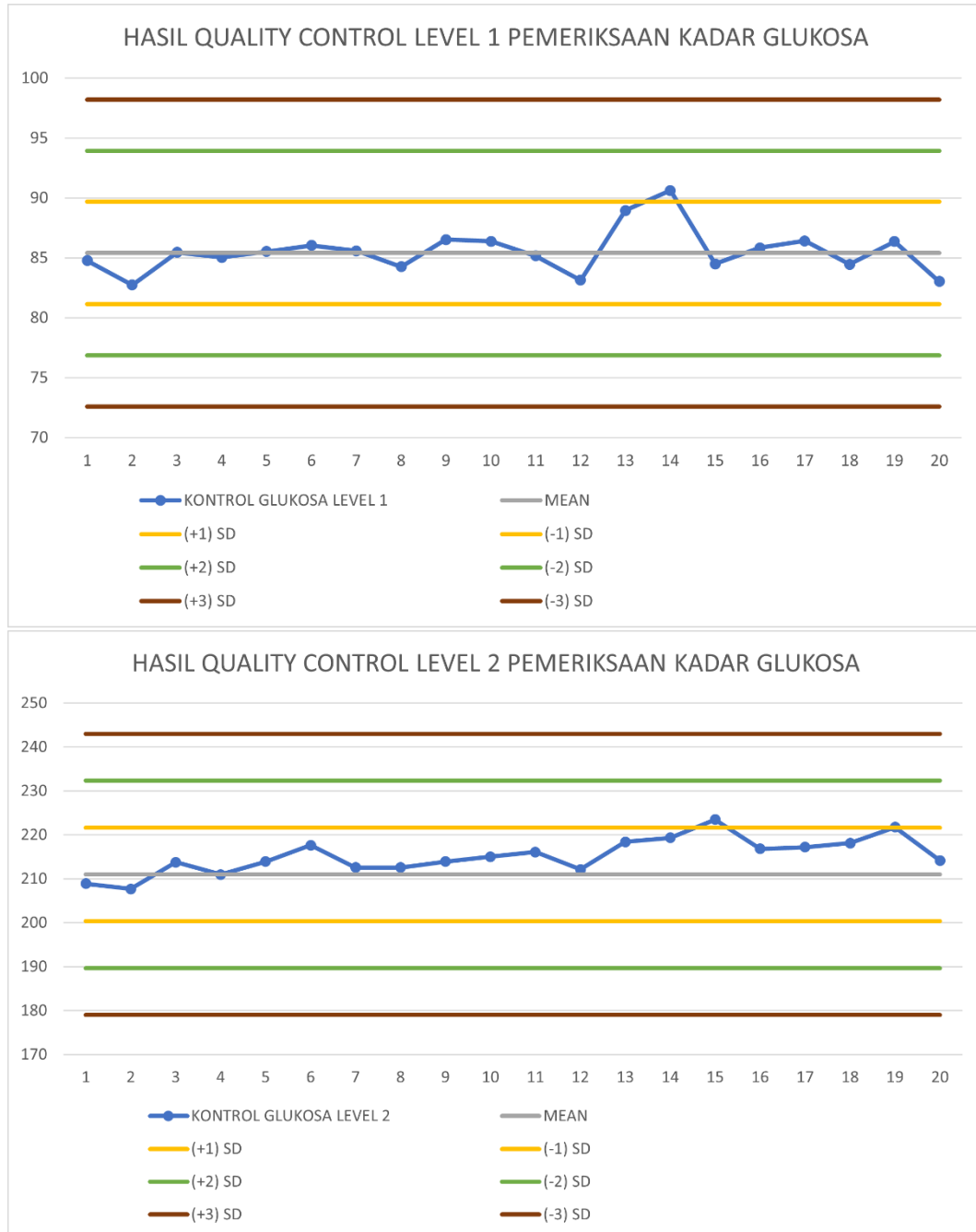
$$\text{Lower LoA}(\%) \geq -8 \text{ dan } \text{Upper LoA}(\%) \leq +8$$

Hasil:

$$\text{Lower LoA}(\%) = -13,13 \text{ (lebih kecil dari } -8) \rightarrow \text{tidak memenuhi}$$

$$\text{Upper LoA}(\%) = +8,69 \text{ (lebih besar dari } +8) \rightarrow \text{tidak memenuhi}$$

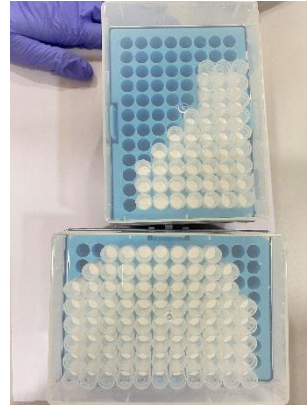
Lampiran 7. Grafik Levey Jennings



Lampiran 8. Dokumentasi Penelitian



a. Yellow Tip



b. White Tip



c. Mikropipet



d. Mikropipet



e. *Centrifuge*



f. *High Speed Centrifuge*



g. Mikrotube



h. Alat Chemistry Analyzer Biosystem A15



i. Sampel Serum Lipemik



j. Flokulan Kitosan



k. Neraca Analitik



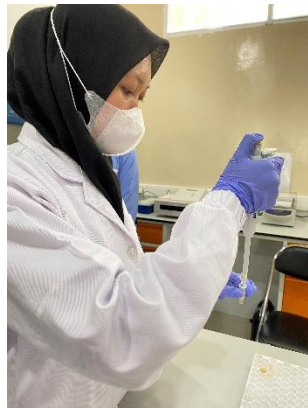
l. Reagen Glukosa



m. Kegiatan Penimbangan
Flokulan Kitosan



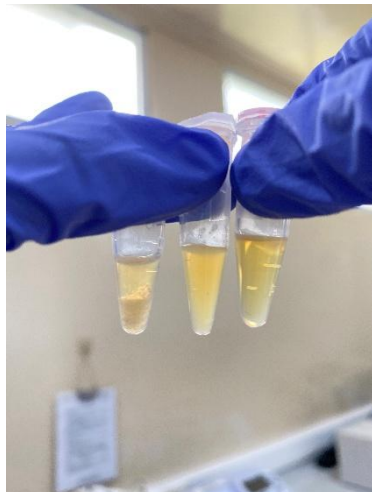
n. Kegiatan Sentrifugasi



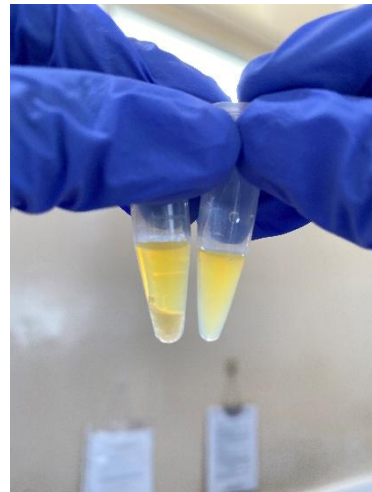
o. Kegiatan Pemipetan Sampel



p. Kegiatan *Running* Spesimen



q. Perbandingan Sampel
Flokulan Kitosan – Sampel Lipemik –
High Speed Sentrifugasi



r. Perbandingan Sampel
Flokulan Kitosan – Sampel Lipemik

Lampiran 9. Certificate of Analysis Chitosan

Sigma-Aldrich.

3050 Spruce Street, Saint Louis, MO 63103, USA

Website: www.sigmaaldrich.com

Email USA: techserv@sial.com

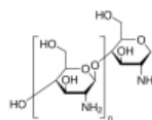
Outside USA: eurtechserv@sial.com

Certificate of Analysis

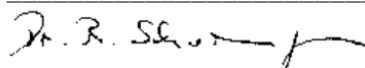
Product Name:

Chitosan - medium molecular weight

Product Number: 448877
Batch Number: BCCM5232
Brand: ALDRICH
CAS Number: 9012-76-4
Formula: C₁₂H₂₄N₂O₉
Quality Release Date: 19 NOV 2024



Test	Specification	Result
Appearance (Color)	Off White to Beige and Faint Brown to Light Brown	Faint Beige
Appearance (Form)	Conforms to Requirements	Powder
Assay	$\geq 75\%$	91 %
Deacetylation		
Viscosity (C = 1%, 1% Acetic Acid)	200 - 800 cps	381 cps



Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland CH

Sigma-Aldrich warrants, that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current Specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchaser must determine the suitability of the product for its particular use. See reverse side of invoice or packing slip for additional terms and conditions of sale.



Lampiran 10. Package Insert Reagen Glukosa (Genuine Biosystem)

N BIO - GLUCOSE (GOD / POD method)

KIT NAME	KIT SIZE	CAT. NO
N BIO - Glucose	5 x 100 ml	MGLU05100M
N BIO - Glucose	1000 ml	MGLU01000M

INTRODUCTION

Glucose is a simple six-carbon sugar. Oxidative metabolism of glucose provides the energy for most cellular processes. Glucose level in the blood is tightly controlled by several hormones. Elevated glucose level is the classic sign of diabetes mellitus. Glucose level abnormalities (hyper- or hypoglycemia) might be caused also by pancreas tumors and diseases of liver, thyroid gland or adrenal Glands.

METHOD PRINCIPLE

Colorimetric, enzymatic method with glucose oxidase.

glucose + H₂O + O₂ $\xrightarrow{\text{GOD}}$ gluconic acid + H₂O₂

2 H₂O₂ + phenol + 4-aminoantipyrine $\xrightarrow{\text{POD}}$

4-(p-benzochinonononimino)-phenazone + 4 H₂O
(red colour)

The colour intensity is proportional to the glucose concentration.

KIT CONTENTS

Reagent Name	MGLU05100M	MGLU01000M
R1 - Glucose Reagent	5 x 100 ml	1000 ml
R2 - Glucose Standard	1 vial	1 vial

Refer standard value mentioned in the vial.

WORKING REAGENT PREPARATION AND STABILITY

The reagent is ready to use.

The reagent when stored at 2-8°C is stable up to expiry date printed on the package. The reagents are stable for 8 weeks on board the analyser at 2-10°C. Protect from contamination.

CONCENTRATIONS IN THE TEST

glucose oxidase (GOD)	≥20000 U/L
peroxidase (POD)	≥2000 U/L
4 - Hydroxybenzoic acid	10 mmol/L
Phosphate buffer	50 mmol/L
Mutarotase	≥1500 U/L

WARNINGS AND NOTES

Product for in vitro diagnostic use only.

The reagents are usable when the absorbance of the working reagent is less than 0.300 (read against distilled water, wavelength λ=500 nm, cuvette l=1 cm, at temp. 25°C).

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 500 nm (Hg 546 nm)
- Thermostat at 37°C
- General laboratory equipment

SPECIMEN

Use fresh unhaemolysed serum. The stability of glucose in specimen is reduced by bacterial contamination and by glycolysis. Serum or plasma should be separated from the cells, as soon as possible, to prevent glycolysis.



PROCEDURE

These reagents may be used both for manual assay and in several automatic analysers. Applications for them are available on request.

MANUAL PROCEDURE - END POINT METHOD

Wavelength	500 nm
Temperature	20-25°C / 37°C
Cuvette	1 cm

Pipette into the cuvettes:

Reagent	Blank (B)	Standard (S)	Test (T)
R1 Glucose Reagent	1000 µl	1000 µl	1000 µl
Bring up the temperature of determination. Then add,			
Distilled Water	10 µl		
R2 - Glucose Standard		10 µl	
Sample			10 µl

Mix well, incubate for 10 min. at 37°C or 15 min at 20-25°C. Read the absorbance of the test A(T) and standard A(S) against reagent blank (RB).

CALCULATION

Glucose concentration = A(T) / A(S) x standard concentration

MANUAL PROCEDURE - FIXED TIME KINETIC METHOD

Wavelength	500 nm
Temperature	20-25°C / 37°C
Cuvette	1 cm

Pipette into the cuvettes:

Reagent	Standard (S)	Test (T)
R1 Glucose Reagent	1000 µl	1000 µl
Bring up the temperature of determination. Then add,		
R2 - Glucose Standard	10 µl	
Sample		10 µl

Mix well and after exactly 60 sec read absorbance A1 of the test (T) and standard (S) against Reagent blank. After next 60 sec repeat absorbance reading (A2) and calculate ΔA (A2 - A1) for the test and standard.

Calculation

Glucose concentration = ΔA(T)/ΔA(S) x standard concentration

REFERENCE VALUES

Serum/Plasma	65 to 110 mg/dl
CSF	40 to 70 mg/dl

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To Ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

For Fully Automated analyzers by using multi calibrator or glucose standard the calibration curve can plot and the same should be prepared every 8 weeks or with change of reagent lot number.

PERFORMANCE CHARACTERISTICS

- **Sensitivity / Limit of Quantitation:** 0.5 mg/dl (0.03 mmol/l)
- **Linearity:** up to 500 mg/dl (27.5 mmol/l) using automatic analysers; up to 400 mg/dl (22 mmol/l) for manual procedure. If glucose concentration exceeds the range of linearity, dilute sample with 0.9% NaCl and repeat the assay. Multiply the result by the dilution factor.
- **Specificity / Interferences**
Haemoglobin up to 2.5 g/dl, ascorbate up to 62 mg/l, bilirubin Up to 20 mg/dl and triglycerides up to 500 mg/dl do not interfere with the test.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

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2. Kaplan L.A., Pesce A.J.: Clinical Chemistry. Theory, analysis and correlation, The C. V. Mosby Company, St. Louis (1989).
3. Kaplan L.A., Pesce A.J., ed. Chemistry Theory, Analysis, and Correlation, 3rd ed. St Louis, MO: Mosby, 635 (1996).
4. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: WB Saunders, 268-272 (1995).
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7. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, PA: WB Saunders, 776-777, 1815, (1999).

SYSTEM PARAMETERS

Method	End Point
Wavelength	505 nm
Zero Setting	Reagent Blank
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	10 mins
Delay Time	-----
Read Time	-----
No. of Reading	-----
Interval Time	-----
Sample Volume	0.01 ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Standard vial
Units	mg/dl
Factor	-----
Reaction Slope	Increasing
Linearity	500 mg/dl



Genuine Biosystem Private Limited

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