LAMPIRAN

Lampiran 1. Ethical Exemption

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.1/372/2025

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

Peneliti utama : Titenia Meilaika Fatihah, A.Md,Kes
Principal In Investigator

Nama Institusi : Poltekkes Kemenkes Yogyakarta
Name of the Institution

Dengan judul:
Title
"Perbedaan Kadar SGPT Pada Serum Pasien Kanker Payudara Yang Segera Diperiksa dan Disimpan 7 Hari Pada Suhu 2-8°C"

"Differences in SGPT Levels in the Serum of Breast Cancer Patients Who Were Immediately Examined and Stored for 7 Days at a Temperature of 2-8°C"

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 05 Maret 2025 sampai dengan tanggal 05 Maret 2026.

This declaration of ethics applies during the period March 05, 2025 until March 05, 2026.

March 05, 2025
Chairperson,

POLITEKNIK KESEHATAN YOGYAKARTA
KOMITE ETIK PENELITIAN KESEHATAN
KEMENTERIAN KESEHATAN

Dr. drg. Wiworo Haryani, M.Kes.

Lampiran 2. Surat Izin Penelitian

Kementerian Kesehatan
RS Sardjito
Jalan Kesehatan Nomor 1, Sekip, Sinduadi, Sleman
D.I. Yogyakarta 55284
(0274) 631190, 587333
www.sardjitohospital.co.id

SURAT PERSETUJUAN PIMPINAN
NOMOR : AR.02.02/1.13/300/2025

Yang bertanda tangan dibawah ini

Nama	: dr. Indah Ajeng Ebtasari S., MSc., Sp.PK
NIP	: 198306082018012001
Jabatan	: Kepala Instalasi Laboratorium Terpadu
Institusi	: RSUP Dr. Sardjito

dengan ini memberikan izin kepada

Nama	: Titenia Meilaika Fatihah
NIM	: P71342324067
Jabatan	: Mahasiswa Prodi Sarjana Terapan Teknologi Laboratorium Medis
Institusi	: Poltekkes Kemenkes Yogyakarta
Judul Skripsi	: Perbedaan Kadar SGPT pada Serun Pasien Kanker Payudara Post Kemoterapi yang Segera Diperiksa dan Disimpan 7 Hari pada Suhu 2-8°C

untuk melakukan penelitian selama 1 bulan terhitung dari tanggal 7 Maret 2025 sampai dengan tanggal 31 Maret 2025 di Instalasi Laboratorium Terpadu RSUP Dr. Sardjito. Selama kegiatan dilaksanakan dimohon untuk menaati ketentuan yang berlaku di Instalasi Laboratorium Terpadu RSUP Dr. Sardjito.

Demikian surat persetujuan ini disampaikan, atas perhatiannya diucapkan terimakasih.

Yogyakarta, 3 Maret 2025
Kepala Instalasi Laboratorium Terpadu

dr. Indah Ajeng Ebtasari S., MSc., Sp.PK
NIP : 198306082018012001

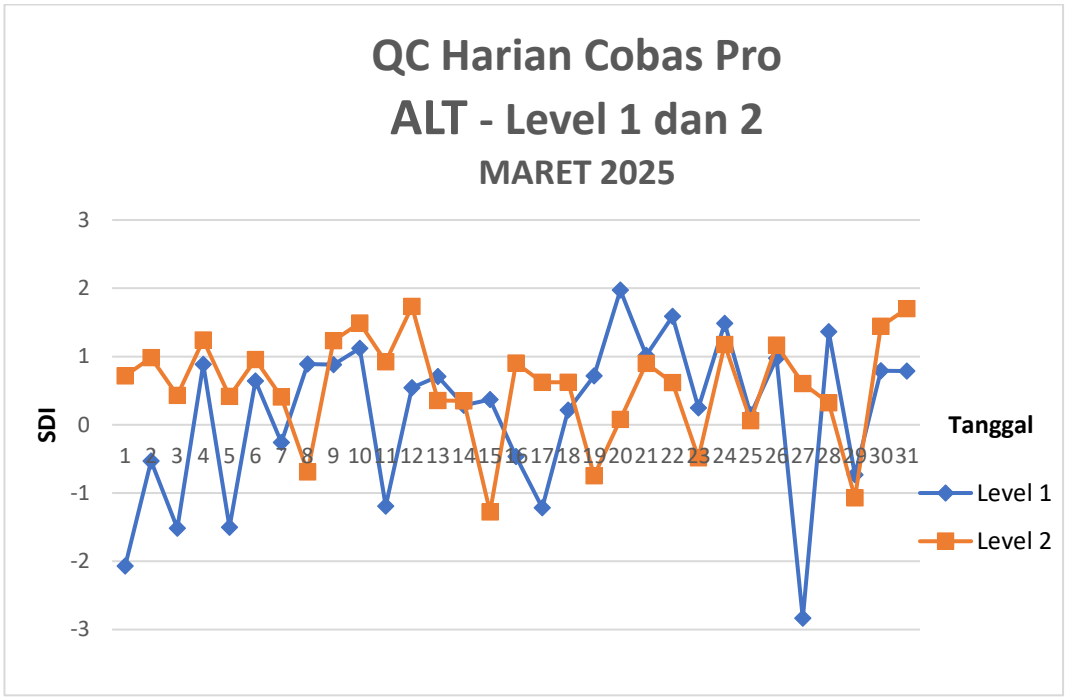
Lampiran 3. Data Hasil Laboratorium Pemeriksaan SGPT

No	Kode	Segera Diperiksa	Disimpan 7 Hari
1	PT 1	49	44
2	PT 2	26	23
3	PT 3	35	31
4	PT 4	47	44
5	PT 5	23	21
6	PT 6	35	33
7	PT 7	40	37
8	PT 8	37	34
9	PT 9	41	38
10	PT 10	27	25
11	PT 11	32	29
12	PT 12	35	33
13	PT 13	30	27
14	PT 14	47	45
15	PT 15	53	50
16	PT 16	45	42
17	PT 17	25	23
18	PT 18	27	25
19	PT 19	26	24
20	PT 20	37	34
21	PT 21	34	32
22	PT 22	55	50
23	PT 23	39	36
24	PT 24	65	63
25	PT 25	36	33
26	PT 26	44	42
27	PT 27	47	45
28	PT 28	63	60
29	PT 29	34	33
30	PT 30	45	43
31	PT 31	38	35
32	PT 32	56	53
33	PT 33	36	34
34	PT 34	40	38
35	PT 35	44	41

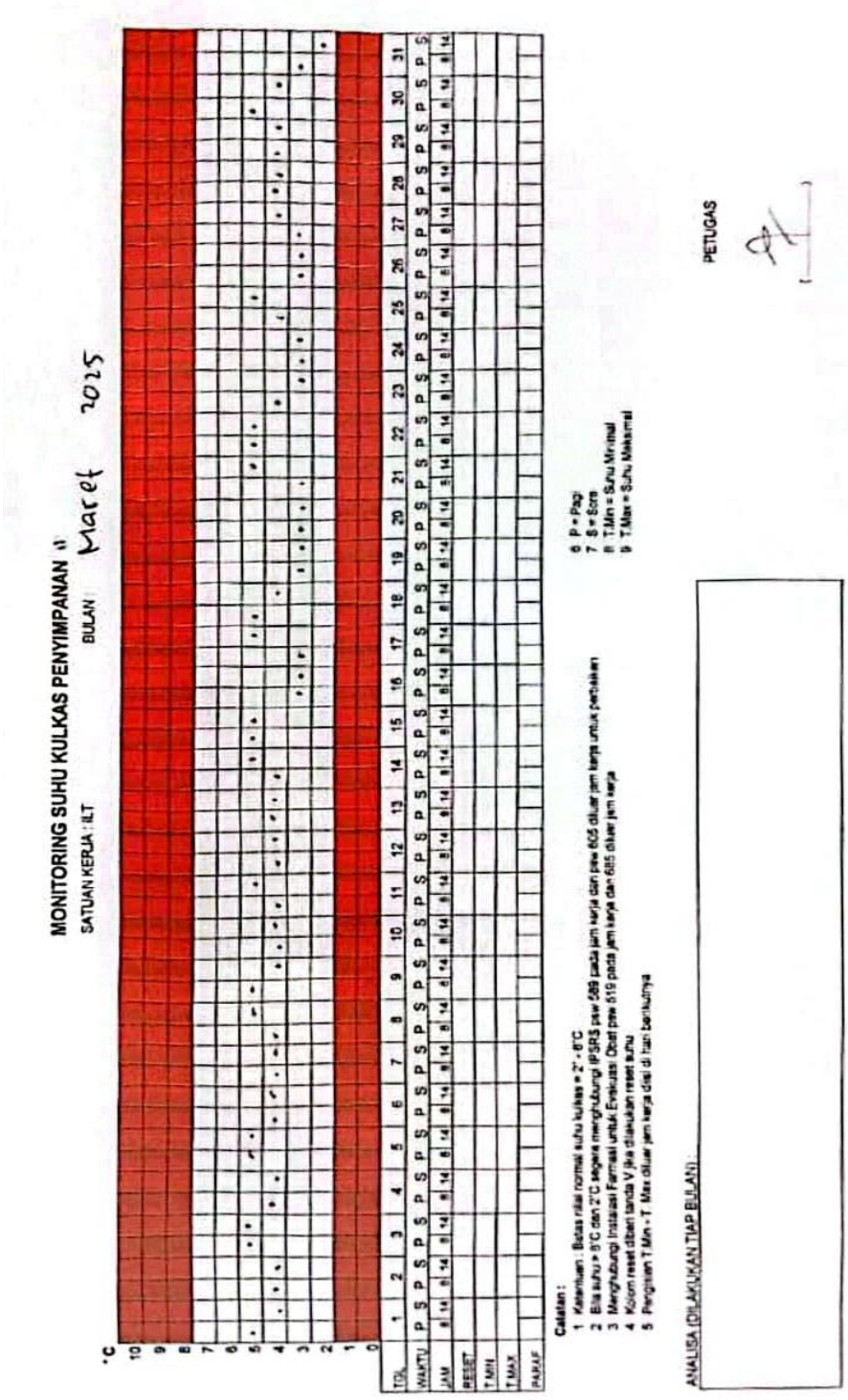
Lampiran 4. Grafik QC SGPT Maret 2025

LEVEL 1		
TGL	MEAN	SD
1	43,173	1,196
2	43,145	1,217
3	43,138	1,213
4	43,118	1,221
5	43,129	1,220
6	43,110	1,228
7	43,118	1,224
8	43,115	1,218
9	43,126	1,216
10	43,137	1,215
11	43,151	1,216
12	43,136	1,219
13	43,143	1,215
14	43,151	1,211
15	43,155	1,206
16	43,159	1,201
17	43,154	1,196
18	43,140	1,199
19	43,142	1,193
20	43,150	1,191
21	43,172	1,207
22	43,183	1,207
23	43,201	1,215
24	43,204	1,210
25	43,220	1,216
26	43,221	1,211
27	43,232	1,211
28	43,202	1,247
29	43,216	1,251
30	43,209	1,249
31	43,217	1,247

LEVEL 2		
TGL	MEAN	SD
1	113,337	3,708
2	113,364	3,699
3	113,400	3,698
4	113,416	3,683
5	113,461	3,693
6	113,476	3,678
7	113,510	3,676
8	113,524	3,661
9	113,500	3,652
10	113,542	3,661
11	113,593	3,681
12	113,624	3,679
13	113,682	3,712
14	113,694	3,697
15	113,705	3,683
16	113,664	3,693
17	113,693	3,690
18	113,713	3,680
19	113,733	3,670
20	113,709	3,663
21	113,712	3,647
22	113,739	3,644
23	113,758	3,635
24	113,744	3,623
25	113,779	3,628
26	113,780	3,614
27	113,815	3,619
28	113,832	3,609
29	113,841	3,596
30	113,811	3,598
31	113,852	3,613


QC Harian Cobas Pro
ALT - Level 1 dan 2
MARET 2025
SDI
3
2
1
0
-1
-2
-3
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31
Tanggal
Level 1
Level 2

Lampiran 5. Form Pemantauan Suhu Kulkas



MONITORING SUHU KULKAS PENYIMPANAN
SATUAN KERJA : ILT
BULAN : Maret 2015

°C

Catatan :
1. Keterangan : Batas nilai normal suhu kulkas = 2° - 8°C
2. Bila suhu > 8°C dan 2°C segera menghubungi IPSRS pew 589 pada jam kerja dan pew 605 diluar jam kerja untuk perbaikan
3. Menghubungi Instalasi Farmasi untuk Evakuasi Obat pew 519 pada jam kerja dan 685 diluar jam kerja
4. Kolom reset diberi tanda V jika dilakukan reset suhu
5. Pengisian T.Min - T.Max diluar jam kerja diisi di hari berikutnya
6. P = Pagi
7. S = Sore
8. T.Min = Suhu Minimal
9. T.Max = Suhu Maksimal

ANALISA (DILAKUKAN TIAP BULAN) :

PETUGAS

Lampiran 6. Sertifikat Kalibrasi Alat Cobas Pro c503

No. 733/CERT/FP/I/2024

S E R T I F I K A T

PT. Roche Indonesia, Diagnostics Division
Menerangkan bahwa alat tersebut dibawah ini

Cobas Pro c503

Seri No. : 21A1-09

RSUP Dr. Sardjito

Jl. Kesehatan No.01 SEKIP

Yogyakarta

Sesuai dengan hasil service dan kalibrasi

Dinyatakan layak pakai

Berlaku sampai dengan : 26 Mei 2025

Surabaya, 26 Mei 2024

Febby Ekadiarta
Associate Technical Service Manager
(East-Central Java)

Lampiran 7. Perhitungan Data Statistik

Descriptives				
			Statistic	Std. Error
Segera	Mean		39.80	1.769
	95% Confidence Interval for Mean	Lower Bound	36.21	
		Upper Bound	43.39	
	5% Trimmed Mean		39.33	
	Median		38.00	
	Variance		109.518	
	Std. Deviation		10.465	
	Minimum		23	
	Maximum		65	
	Range		42	
	Interquartile Range		13	
	Skewness		.576	.398
	Kurtosis		.034	.778
Ditunda	Mean		37.14	1.728
	95% Confidence Interval for Mean	Lower Bound	33.63	
		Upper Bound	40.66	
	5% Trimmed Mean		36.63	
	Median		35.00	
	Variance		104.538	
	Std. Deviation		10.224	
	Minimum		21	
	Maximum		63	
	Range		42	
	Interquartile Range		13	
	Skewness		.628	.398
	Kurtosis		.223	.778

1. Uji *Shapiro-Wilk*

Tests of Normality

Kolmogorov-Smirnov[a]			Shapiro-Wilk
Statistic	df	Sig.	Statistic
.092	35	.200*	.961
.106	35	.200*	.958

a. Lilliefors Significance Correction

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

2. Uji *Paired Samples Test*

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Segera - Ditunda	2.657	.838	.142	2.369	2.945	18.755	34	.000

Lampiran 8. Kit Insert Reagen SGPT

08104697500V8.0

ALTP2

cobas®

Alanine Aminotransferase acc. to IFCC II

Order information

REF		CONTENT		Analyzer(s) on which **cobas c** pack(s) can be used
08104697190*	08104697500	Alanine Aminotransferase acc. to IFCC II (800 tests)	System-ID 2014 001	**cobas c** 303, **cobas c** 503, **cobas c** 703
08104697214*	08104697500	Alanine Aminotransferase acc. to IFCC II (800 tests)	System-ID 2014 001	**cobas c** 303, **cobas c** 503, **cobas c** 703

Materials required (but not provided):

10759350190	Calibrator f.a.s. (12 x 3 mL)	Code 20401	
05117003190	PreciControl ClinChem Multi 1 (20 x 5 mL)	Code 20391	
05947626190	PreciControl ClinChem Multi 1 (4 x 5 mL)	Code 20391	
05117216190	PreciControl ClinChem Multi 2 (20 x 5 mL)	Code 20392	
05947774190	PreciControl ClinChem Multi 2 (4 x 5 mL)	Code 20392	
08063494190	Diluent NaCl 9 % (123 mL)	System-ID 2906 001	

* Some kits shown may not be available in all countries.

English

System information

ALTP2: ACN 20140

Intended use

In vitro test for the quantitative determination of alanine aminotransferase (ALT) with pyridoxal phosphate activation in human serum and plasma on **cobas c** systems.

Summary

Alanine aminotransferase (ALT) measurements, performed with this device, in human serum and plasma are used as an aid in diagnosis of hepatocellular injury and in monitoring chronic liver injury.

The enzyme alanine aminotransferase (ALT) is present in highest concentrations in the liver, in the cytosol of the hepatocytes, although it is also found in the kidney, and, in much smaller quantities, in heart and skeletal muscle cells.[1] ALT catalyzes the transfer of amino groups from L-alanine to α-ketoglutarate, resulting in L-glutamate and pyruvate. This is a critical process of the tricarboxylic acid cycle, in which the coenzyme pyridoxal phosphate (also known as pyridoxal-5-phosphate or active vitamin B6) is required. When liver injury occurs, ALT is released from injured liver cells and causes a significant serum elevation.[1]

Measurement of ALT activity is therefore used for the diagnosis of hepatic diseases such as acute and chronic viral hepatitis, nonalcoholic fatty liver disease (NAFLD), alcohol-related liver disease, ischemic hepatopathy, autoimmune hepatitis, biliary injury, suspected malignant infiltration, cholestasis.[1] Serum elevations of ALT activity are rarely observed in conditions other than parenchymal liver disease.[2] In addition, ALT testing is recommended for monitoring chronic hepatitis status and progression.[3]

Although both serum aspartate aminotransferase (AST) and ALT become elevated whenever disease processes affect liver cell integrity, evidence suggests that ALT is a more specific marker of hepatic injury than AST. Moreover, elevations of ALT activity persist longer than elevations of AST activity.[1,4]

In patients with vitamin B6 deficiency (insufficient endogenous pyridoxal phosphate), serum aminotransferase activity may be decreased. The addition of pyridoxal phosphate to this assay causes an increase in aminotransferase activity (activation higher for AST than for ALT) and prevents falsely low aminotransferase test results in these samples.[2]

Test principle

This assay follows the recommendations of the IFCC, but was optimized for performance and stability.[5]

ALT catalyzes the transfer of an amino group between L-alanine and 2-oxoglutarate to form pyruvate and L-glutamate. The pyruvate then reacts with NADH in the presence of lactate dehydrogenase (LDH) to form L-lactate and NAD^+. Pyridoxal phosphate serves as a coenzyme in the amino transfer reaction. It ensures full enzyme activation.

$$\text{L-Alanine} + \text{2-oxoglutarate} \xrightarrow{\text{ALT}} \text{pyruvate} + \text{L-glutamate}$$

$$\text{Pyruvate} + \text{NADH} + \text{H}^+ \xrightarrow{\text{LDH}} \text{L-lactate} + \text{NAD}^+$$

The rate of the NADH oxidation is directly proportional to the catalytic ALT activity. It is determined by measuring the decrease in absorbance.

Reagents - working solutions

R1 TRIS buffer: 230 mmol/L, pH 7.15 (37 °C); L-alanine: 1140 mmol/L; LDH (microorganisms): ≥ 94 µkat/L; pyridoxamine phosphate: 0.23 mmol/L; albumin (bovine): 0.25 %; stabilizers; preservative

R3 NADH: ≥ 0.71 mmol/L; 2-oxoglutarate: 96 mmol/L; preservative

R1 is in position B and R3 is in position C.

Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C:	See expiration date on **cobas c** pack label.
On-board in use and refrigerated on the analyzer:	12 weeks

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.
Serum
Plasma: Li-heparin and K_2- and K_3-EDTA plasma

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

See the limitations and interferences section for details about possible sample interferences.

ALTP2

Alanine Aminotransferase acc. to IFCC II

cobas®

Stability: 4 days at 15-25 °C
7 days at 2-8 °C

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum and plasma

Test definition

Reporting time	10 min		
Wavelength (sub/main)	700/340 nm		
Reagent pipetting		Diluent (H_2O)	
R1	52 µL	48 µL	
R3	15 µL	–	
Sample volumes	*Sample*	*Sample dilution*	
		Sample	*Diluent (NaCl)*
Normal	4.5 µL	–	–
Decreased	4.5 µL	10 µL	90 µL
Increased	4.5 µL	–	–

For further information about the assay test definitions refer to the application parameters setting screen of the corresponding analyzer and assay.

Calibration

Calibrators	S1: H_2O S2: C.f.a.s.
Calibration mode	Linear
Calibration frequency	Automatic full calibration - after reagent lot change Full calibration - as required following quality control procedures

Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Traceability: This method has been standardized against the original IFCC formulation using calibrated pipettes together with a manual photometer providing absolute values and the substrate-specific absorptivity, ε.[5]

Quality control

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 12 weeks. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

cobas c systems automatically calculate the analyte activity of each sample in the unit U/L (µkat/L).

Conversion factor: U/L x 0.0167 = µkat/L

Limitations - interference

Criterion: Recovery within ± 4.0 U/L of initial values of samples ≤ 40 U/L and ± 10 % for samples > 40 U/L.

Icterus:[6] No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:[6] No significant interference up to an H index of 100 (approximate hemoglobin concentration: 62.2 µmol/L or 100 mg/dL). Contamination with erythrocytes will elevate results, because the analyte level in erythrocytes is higher than in normal sera. The level of interference may be variable depending on the content of analyte in the lysed erythrocytes.

Lipemia (Intralipid):[6] No significant interference up to an L index of 500. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.
Lipemic samples may cause > Abs flagging.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[7,8]

Drug interferences are measured based on recommendations given in CLSI guidelines EP07 and EP37 and other published literature. Effects of concentrations exceeding these recommendations have not been characterized.

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.[9]

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on **cobas c** systems. All special wash programming necessary for avoiding carry-over is available via the **cobas** link. The latest version of the carry-over evasion list can be found with the NaOHD/SMS/SCCS Method Sheet. For further instructions, refer to the operator's manual.

Limits and ranges

Measuring range

5-700 U/L (0.08-11.7 µkat/L)

Determine samples having higher activities via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank	= 5 U/L (0.08 µkat/L)
Limit of Detection	= 5 U/L (0.08 µkat/L)
Limit of Quantitation	= 5 U/L (0.08 µkat/L)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the activity below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low activity samples.

The Limit of Detection corresponds to the lowest analyte activity which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte activity that can be reproducibly measured with a total error of 20 %. It has been determined using low activity alanine aminotransferase samples.

ALTP2

Alanine Aminotransferase acc. to IFCC II

cobas®

Stability: 4 days at 15-25 °C
7 days at 2-8 °C

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

See "Order information" section

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		Sample	*Diluent (NaCl)*
Normal	4.5 µL	–	–
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Calibration mode	Linear
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Traceability: This method has been standardized against the original IFCC formulation using calibrated pipettes together with a manual photometer providing absolute values and the substrate-specific absorptivity, ε.[5]

Quality control

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. It is recommended to perform quality control always after lot calibration and subsequently at least every 12 weeks. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

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Limits and ranges

Measuring range

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Limit of Quantitation	= 5 U/L (0.08 µkat/L)

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the activity below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low activity samples.

The Limit of Detection corresponds to the lowest analyte activity which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte activity that can be reproducibly measured with a total error of 20 %. It has been determined using low activity alanine aminotransferase samples.

ALTP2

Alanine Aminotransferase acc. to IFCC II

cobas®

Expected values

U/L

Acc. to IFCC/Standard Method 94 with pyridoxal phosphate activation measured at 37 °C:[10]

Males:	10-50 U/L
Females:	10-35 U/L

Consensus values with pyridoxal phosphate activation:[11]

Males:	up to 50 U/L
Females:	up to 35 U/L

µkat/L*

Acc. to IFCC/Standard Method 94 with pyridoxal phosphate activation measured at 37 °C:[10]

Males:	0.17-0.84 µkat/L
Females:	0.17-0.58 µkat/L

Consensus values with pyridoxal phosphate activation:[11]

Males:	up to 0.84 µkat/L
Females:	up to 0.58 µkat/L

*calculated by unit conversion factor

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data on the analyzers are given below. These data represent the performance of the analytical procedure itself.

Results obtained in individual laboratories may differ due to heterogenous sample materials, aging of analyzer components and mixture of reagents running on the analyzer.

Precision

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP05-A3 requirements with repeatability (n = 84) and intermediate precision (2 aliquots per run, 2 runs per day, 21 days). Results for repeatability and intermediate precision were obtained on the **cobas c** 503 analyzer.

Repeatability	*Mean* *U/L*	*SD* *U/L*	*CV* *%*
PCCC1[a)]	49.4	0.534	1.1
PCCC2[b)]	127	3.04	2.4
Human serum 1	12.8	0.474	3.7
Human serum 2	30.8	0.601	2.0
Human serum 3	54.7	0.965	1.8
Human serum 4	359	2.45	0.7
Human serum 5	630	2.81	0.4

Intermediate precision	*Mean* *U/L*	*SD* *U/L*	*CV* *%*
PCCC1[a)]	49.2	1.80	3.7
PCCC2[b)]	127	4.96	3.9
Human serum 1	12.8	0.611	4.8
Human serum 2	30.8	0.818	2.7
Human serum 3	54.7	1.58	2.9
Human serum 4	359	3.28	0.9
Human serum 5	638	5.07	0.8

a) PreciControl ClinChem Multi 1

b) PreciControl ClinChem Multi 2

The data obtained on **cobas c** 503 analyzer(s) are representative for **cobas c** 303 analyzer(s) and **cobas c** 703 analyzer(s).

Method comparison

ALT values for human serum and plasma samples obtained on a **cobas c** 503 analyzer (y) were compared with those determined using the test ALTLP on a **cobas c** 501 analyzer (x).

Sample size (n) = 100

Passing/Bablok[12]	Linear regression
y = 0.993x + 1.52 U/L	y = 0.988x + 1.71 U/L
τ = 0.988	r = 1.000

The sample activities were between 8.9 and 683 U/L.

ALT values for human serum and plasma samples obtained on a **cobas c** 303 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 503 analyzer (x).

Sample size (n) = 50

Passing/Bablok[12]	Linear regression
y = 1.036x - 0.787 U/L	y = 1.039x - 1.61 U/L
τ = 0.997	r = 1.000

The sample activities were between 27.0 and 635 U/L.

ALT values for human serum and plasma samples obtained on a **cobas c** 703 analyzer (y) were compared with those determined using the corresponding reagent on a **cobas c** 503 analyzer (x).

Sample size (n) = 65

Passing/Bablok[12]	Linear regression
y = 1.004x - 0.634 U/L	y = 1.003x - 0.635 U/L
τ = 0.974	r = 1.000

The sample concentrations were between 6.07 and 647 U/L.

References

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume for reconstitution
GTIN	Global Trade Item Number
Rx only	For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0123

Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com
+800 5505 6606

Roche

Lampiran 9. Logbook Penelitian

LOGBOOK KEGIATAN PENELITIAN

DI RSUP DR SARDJITO YOGYAKARTA TAHUN 2025

Nama : Titenia Meilaika Fatihah
NIM : P71342324067
Universitas : Politeknik Kesehatan Kemenkes Yogyakarta

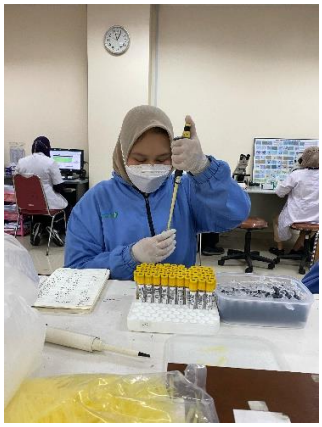
No	Tanggal	Kegiatan	Paraf TTLM
1.	10 Maret 2025	Melakukan pengumpulan spesimen serum yang sesuai kriteria, kemudian serum yang telah diperiksa kadar albuminnya dengan segera oleh tenaga ATLM RSUP Dr. Sardjito dicatat. Setelah itu sisa serum dipindahkan ke cup serum untuk disimpan selama 7 hari pada suhu 2-8°C.	
2.	11 Maret 2025	Melakukan pengumpulan spesimen serum yang sesuai kriteria, kemudian serum yang telah diperiksa kadar albuminnya dengan segera oleh tenaga ATLM RSUP Dr. Sardjito dicatat. Setelah itu sisa serum dipindahkan ke cup serum untuk disimpan selama 7 hari pada suhu 2-8°C.	
3.	12 Maret 2025	Melakukan pengumpulan spesimen serum yang sesuai kriteria, kemudian serum yang telah diperiksa kadar albuminnya dengan segera oleh tenaga ATLM RSUP Dr. Sardjito dicatat. Setelah itu sisa serum dipindahkan ke cup serum untuk disimpan selama 7 hari pada suhu 2-8°C.	
4.	13 Maret 2025	Melakukan pengumpulan spesimen serum yang sesuai kriteria, kemudian serum yang telah diperiksa kadar albuminnya dengan segera oleh tenaga ATLM RSUP Dr. Sardjito dicatat. Setelah itu sisa serum dipindahkan ke cup serum untuk disimpan selama 7 hari pada suhu 2-8°C.	
5.	14 Maret 2025	Melakukan pengumpulan spesimen serum yang sesuai kriteria, kemudian serum yang telah diperiksa kadar albuminnya dengan segera oleh tenaga ATLM RSUP Dr. Sardjito dicatat. Setelah itu sisa serum dipindahkan ke cup serum untuk disimpan selama 7 hari pada suhu 2-8°C.	
6.	16 Maret 2025	Melakukan pengumpulan spesimen serum yang sesuai kriteria, kemudian serum yang telah diperiksa kadar albuminnya dengan segera oleh tenaga ATLM RSUP Dr. Sardjito dicatat. Setelah itu sisa serum dipindahkan ke cup serum untuk disimpan selama 7 hari pada suhu 2-8°C.	

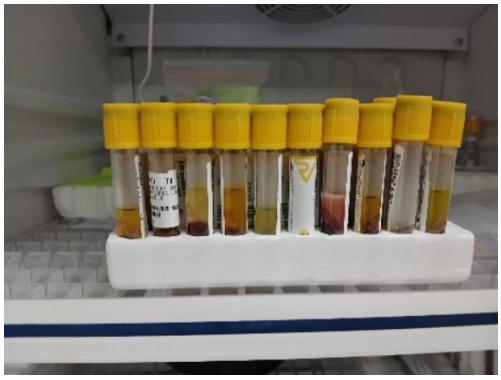
		Melakukan pemeriksaan kadar albumin setelah inkubasi selama 7 hari suhu 2-8°C pada serum yang diperiksa segera menggunakan alat Roche Cobas Pro pada tanggal 10 Maret 2025	
7.	17 Maret 2025	Melakukan pengumpulan spesimen serum yang sesuai kriteria, kemudian serum yang telah diperiksa kadar albuminnya dengan segera oleh tenaga ATLM RSUP Dr. Sardjito dicatat. Setelah itu sisa serum dipindahkan ke cup serum untuk disimpan selama 7 hari pada suhu 2-8°C. Melakukan pemeriksaan kadar albumin setelah inkubasi selama 7 hari suhu 2-8°C pada serum yang diperiksa segera menggunakan alat Roche Cobas Pro pada tanggal 11 Maret 2025	
8.	18 Maret 2025	Melakukan pemeriksaan kadar albumin setelah inkubasi selama 7 hari suhu 2-8°C pada serum yang diperiksa segera menggunakan alat Roche Cobas Pro pada tanggal 12 Maret 2025	
9.	19 Maret 2025	Melakukan pemeriksaan kadar albumin setelah inkubasi selama 7 hari suhu 2-8°C pada serum yang diperiksa segera menggunakan alat Roche Cobas Pro pada tanggal 13 Maret 2025	
10.	20 Maret 2025	Melakukan pemeriksaan kadar albumin setelah inkubasi selama 7 hari suhu 2-8°C pada serum yang diperiksa segera menggunakan alat Roche Cobas Pro pada tanggal 14 Maret 2025	
11.	23 Maret 2025	Melakukan pemeriksaan kadar albumin setelah inkubasi selama 7 hari suhu 2-8°C pada serum yang diperiksa segera menggunakan alat Roche Cobas Pro pada tanggal 17 Maret 2025	
12.	24 Maret 2025	Melakukan pemeriksaan kadar albumin setelah inkubasi selama 7 hari suhu 2-8°C pada serum yang diperiksa segera menggunakan alat Roche Cobas Pro pada tanggal 18 Maret 2025	

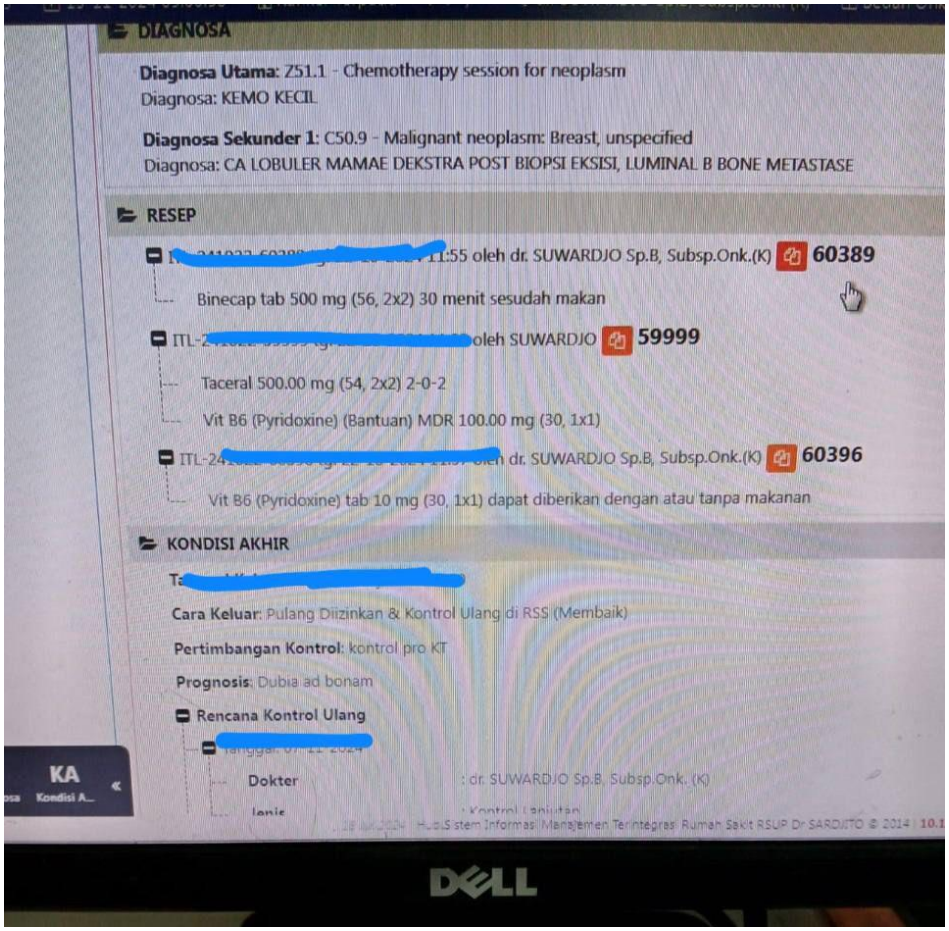
Yogyakarta, 24 Maret 2025
Pendamping Laboratorium

(Ika Oktavia)

Lampiran 10. Dokumentasi






DIAGNOSA
Diagnosa Utama: Z51.1 - Chemotherapy session for neoplasm
Diagnosa: KEMO KECIL
Diagnosa Sekunder 1: C50.9 - Malignant neoplasm: Breast, unspecified
Diagnosa: CA LOBULER MAMAE DEKSTRA POST BIOPSI EKSISI, LUMINAL B BONE METASTASE
RESEP
11:55 oleh dr. SUWARDJO Sp.B, Subsp.Onk.(K) 60389
Binecap tab 500 mg (56, 2x2) 30 menit sesudah makan
oleh SUWARDJO 59999
Taceral 500.00 mg (54, 2x2) 2-0-2
Vit B6 (Pyridoxine) (Bantuan) MDR 100.00 mg (30, 1x1)
dr. SUWARDJO Sp.B, Subsp.Onk.(K) 60396
Vit B6 (Pyridoxine) tab 10 mg (30, 1x1) dapat diberikan dengan atau tanpa makanan
KONDISI AKHIR
Cara Keluar: Pulang Diizinkan & Kontrol Ulang di RSS (Membaik)
Pertimbangan Kontrol: kontrol pro KT
Prognosis: Dubia ad bonam
Rencana Kontrol Ulang
Dokter : dr. SUWARDJO Sp.B, Subsp.Onk. (K)
KA
Kondisi A...
Sistem Informasi Manajemen Terintegrasi Rumah Sakit RSUP Dr SARDJITO © 2014
DELL