LAMPIRAN

LAMPIRAN 1. Surat pernyataan persetujuan untuk ikut serta dalam penelitian atau *informed consent*

Saya yang bernama Nanang Kusmana, S.Si dengan jabatan selaku Nasional manager mutu dan pengembangan produk laboratorium klinik Pramita Jalan RE Martadinata Kota Bandung dengan sukarela memberikan izin untuk mengambil data hasil pemeriksaan Aktivitas enzim AST dan ALT yang dibutuhkan dalam penelitian ini tanpa tekanan atau paksaan siapapun.

Bandung, Juli 2020

Nasional Manager Mutu dan
Pengembangan Produk,

Nanang Kusmana, S.Si

LAMPIRAN 2. Waktu Penelitian

Kegiatan	2020							
	Des	Jan	Feb	Mar	Apr	Mei	Juni	Juli
Penyusunan proposal								
Sidang proposal								
Perbaikan proposal								
Bimbingan Skripsi								
Waktu Penelitian								
Penyusunan Skripsi								
Sidang Skripsi								
Perbaikan Skripsi								
Pengumpulan Skripsi								

LAMPIRAN 3. DATA PEMERIKSAAN AST dan ALT

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
1	L	30	18	41	20.0	1.05	83	198	117	Negatif	Negatif	Gastritis (maag), Kacamata Minus, Kacamata Silender, Sinusitis	120	80	Dalam batas normal
2	L	24	12	15	19.3	0.65	83	195	72	Negatif	Negatif	Operasi saluran pencernaan, Kacamata Minus, Kacamata (+)	(110/70) Normal		Sinus bradycardia.
3	L	25	26	33	21.1	0.84	90	186	80	Negatif	Negatif	Amandel/tonsilitis, Lain-lain (Allergi), Typoid, Lain-lain (Penyakit daerah tropis)	120	80	SR, HR 60 x/m, Normo ECG
4	L	25	26	30	19.0	0.80	95	140	65	Negatif	Negatif	Tidak Ada	120	80	Normal ECG
5	L	25	22	34	16.3	1.09	75	129	55	Negatif	Negatif	Haemorrhoid (wasir/ambeien), Kacamata Minus, Allergi Hirupan, Lain-lain (Allergi)	(120/80) Normal		Normal sinus rhythm.
6	L	25	25	38	15.1	0.87	74	153	64	Negatif	Negatif	gangguan penglihatan, alergi debu	(110/70) Normal		Normal sinus rythm.
7	L	26	18	35	17.1	0.80	95	183	74	Negatif	Negatif	-	110	70	Normal Sinus Rhythm
8	L	26	35	42	19.9	0.82	92	184	85	Negatif	Negatif	Pernah diopname (DBD dan tifoid 3 tahun yang lalu) dan Operasi (Umur 1 tahun), Alergi udara, Maag/gastritis	120	70	Sinus Ritme, HR 70x/menit, Normoaxis
9	L	27	23	23	12.8	0.90	104	198	76	Negatif	Negatif	-	110	80	Normal Sinus Rhythm
10	L	27	15	17	18.3	0.78	100	180	53	Negatif	Negatif	Typoid	120	80	Sinus arrhythmia (normal variant) Normal ECG
11	L	27	22	13	21.0	1.06	89	168	62	Negatif	Negatif	Pernah dirawat dirumah sakit Memakai kacamata	120	80	Irama sinus 80 x/m, axis frontal Normal - EKG Normal
12	L	27	16	21	20.2	1.04	92	183	77	Negatif	Negatif	Pernah diopname dan Operasi (Usus buntu tahun 2017).	120	80	Sinus ritme, HR 63x/menit, Normoaxis,
13	L	27	18	29	21.6	0.97	96	194	98	Negatif	Negatif	Pernah Opname (Maag 1 tahun yang lalu), Pernah Operasi (Angkat kencing kodok, Sinusitis tahun 2016),	120	80	Sinus Ritme, HR 62x/menit, Reguler
14	L	27	23	48	16.7	1.00	94	177	108	Negatif	Negatif	Pernah operasi karena kecelakaan dan direposisi. Alergi debu, alergi obat (asam mefenamat), ambeiien.	(100/70) Normal		Sinus bradycardia 53 Bpm
15	L	27	17	16	26.6	1.05	75	180	63	Negatif	Negatif	-	(110/80) Normal		Normo sinus rhytm HR : 64 bpm
16	L	27	18	22	14.3	0.90	82	177	106	Negatif	Negatif	-	(113/66) Normal		Within Normal Limit Findings Within Normal Limit ECG
17	L	28	26	28	17.0	0.90	98	197	107	Negatif	Negatif	Kacamata Minus	120	80	Dalam batas normal
18	L	28	18	46	23.0	0.89	109	139	144	Negatif	Negatif	Asma, Kacamata Minus	120	80	Normal ECG
19	L	28	29	36	25.7	0.90	91	154	77	Negatif	Negatif	-	100	80	Normal Sinus Rhythm
20	L	28	14	13	19.3	0.80	92	181	114	Negatif	Negatif	Gastritis (maag), Kacamata Minus, Kacamata Silender	120	70	Normal Sinus Rhythm

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
21	L	28	19	12	25.7	0.70	73	185	51	Negatif	Negatif	Gasritis (maag), Kacamata minus, Operasi caesar	100	70	Normal sinus ritmis
22	L	28	17	15	17.7	1.08	83	184	96	Negatif	Negatif	Hemorrhoid (+)	100	60	Normal
23	L	28	19	20	21.3	0.78	97	197	92	Negatif	Negatif	Pernah diopname dan dioperasi (Cesar, Bulan 2 Tahun 2019)	100	60	Sinus Ritme, HR 67x/menit, Normoaxis
24	L	28	12	17	17.1	0.82	81	178	115	Negatif	Negatif	Tidak ada	110	70	Normal Sinus Rhythm Normal ECG
25	L	28	24	34	21.1	0.95	88	182	109	Negatif	Negatif	Memakai kacamata, Tipus	120	64	Normo Sinus Rhtm, 59-60x/ menit, Normoaxis
26	L	28	24	33	18.3	0.90	94	183	103	Negatif	Negatif	Tidak Ada	110	60	Normal ECG
27	L	28	19	15	26.2	1.13	100	174	89	Negatif	Negatif	Pernah opname karena asam lambung. Riwayat alergi ding	(120/80) Normal		Normal
28	L	29	18	23	33.1	1.10	93	171	123	Negatif	Negatif	Gastritis (maag), Haemorrhoid (wasir/ambeien), Kacamata Minus, Kacamata Silender, Infeksi saluran	110	80	Dalam batas normal
29	L	29	18	27	17.8	1.00	92	157	67	Negatif	Negatif	Asma, DHF/Demam berdarah, Typoid	120	80	Dalam batas normal
30	L	29	17	11	21.4	0.92	83	171	52	Negatif	Negatif	gangguan penglihatan	120	80	Normal Sinus Rhythm Normal ECG
31	L	29	19	25	25.7	0.84	80	165	141	Negatif	Negatif	-	(110/70) Normal		Normal sinus rhythm.
32	L	29	23	51	27.8	0.63	85	176	131	Negatif	Negatif	Gastritis (maag), Tuberculosa (TBC)	(100/70) Normal		Normal sinus rhythm.
33	L	29	24	27	28.0	1.00	99	179	110	Negatif	Negatif	kacamata minus	(110/70) Normal		Dalam batas normal
34	L	30	17	25	16.2	0.90	97	184	89	Negatif	Negatif	Haemorrhoid (wasir/ambeien), Kacamata Minus	120	80	Dalam batas normal
35	L	30	16	23	25.7	1.10	75	171	51	Negatif	Negatif	-	110	70	Normal sinus ritmis.
36	L	30	27	36	18.8	1.01	94	176	82	Negatif	Negatif	Typoid, Infeksi usus	130	70	Sinus aritmia (varian normal) HR : 77 bpm
37	L	30	17	19	17.1	0.93	98	177	121	Negatif	Negatif	Allergi Hirupan, DHF/Demam berdarah, Typoid	(100/60) Normal		Normal sinus rhythm.
38	L	30	21	22	17.0	0.97	96	155	72	Negatif	Negatif	Asma, Lain-lain (Allergi)	(96/70) Normal		Normal sinus rhythm
39	L	30	14	27	16.6	0.95	89	193	95	Negatif	Negatif		(110/80) Normal		- NSR 61 bpm, axis N - Normal resting ECG
40	L	30	21	17	25.3	0.91	87	189	99	Negatif	Negatif	Kacamata Minus	(110/80) Normal		Normal

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
41	L	30	13	10	16.9	0.84	74	148	81	Negatif	Negatif	-	(110/70) Normal		Normal sinus rhythm
42	L	30	27	53	20.5	0.70	89	186	94	Negatif	Negatif	Pernah operasi tangan kiri dipasang pen	(100/70) Normal		Dalam batas normal
43	L	31	29	49	22.1	0.96	98	193	96	Negatif	Negatif	Pernah operasi, Alergi	130	90	Normo sinus rhytm HR : 80 bpm
44	L	31	15	19	20.1	0.83	96	147	90	Negatif	Negatif	Pernah diopname (Infeksi saluran pencernaan, Diare tahun 2018), Demam berdarah dan Tifus (Tahun 2015)	110	80	Ekg Normal
45	L	31	15	19	17.4	0.96	99	186	70	Negatif	Negatif	Tidak ada	120	80	Sinus ritme, HR 71x/menit, Normoaxis,
46	L	31	20	33	16.3	0.80	89	196	129	Negatif	Negatif	Buta warna	(111/70) Normal		Normal
47	L	31	17	27	20.1	0.90	94	175	49	Negatif	Negatif	Pernah opname karena tifus, Maag	(110/80) Normal		Normal
48	L	31	17	32	19.7	1.00	92	171	136	Negatif	Negatif	-	(100/70) Normal		Normal
49	L	31	24	40	19.4	1.00	90	190	134	Negatif	Negatif	Kacamata Minus, Kacamata Silender, Nyeri punggung/back pain., Lain-lain (Allergi)	(100/80) Normal		Irama sinus 75 x/menit. EKG normal
50	L	31	13	11	15.9	1.01	94	149	123	Negatif	Negatif	-	(110/70) Normal		Normal
51	L	31	18	18	21.0	0.90	85	159	93	Negatif	Negatif	Allergi Hirupan	(120/80) Normal		- Normal sinus ritme - Normal ECG
52	L	31	28	25	32.1	0.61	93	159	87	Negatif	Negatif	Kacamata Silender	(120/70) Normal		Normal sinus rhythm.
53	L	31	18	36	15.0	0.83	89	135	115	Negatif	Negatif	Batuk lebih dari 1 bulan, Kacamata Minus, Kacamata Silender	(110/70) Normal		Normal sinus rhythm.
54	L	32	14	23	21.5	0.90	89	157	58	Negatif	Negatif	Gastritis (maag)	130	80	Dalam batas normal
55	L	32	19	30	26.5	0.91	87	169	123	Negatif	Negatif	Olahraga : 1x/minggu	120	70	Normal
56	L	32	24	34	30.8	1.09	103	192	54	Negatif	Negatif	Alergi debu, Maag	120	70	Normo sinus rhythm Normal ECG
57	L	32	19	18	20.9	1.08	96	193	87	Negatif	Negatif	-	(120/80) Normal		Normal
58	L	32	33	32	20.7	1.05	82	145	65	Negatif	Negatif	Lain-lain (Sistem Pendengaran/THT), Lain-lain (Ginjal & Saluran Kemih), Lain-lain (Tulang, Sendi & Otot)	(120/80) Normal		- Normal sinus ritme - Normal ECG
59	L	32	16	11	13.7	0.98	89	128	73	Negatif	Negatif	Gastritis (maag)	(110/80) Normal		- Normal sinus ritme - Normal ECG
60	L	32	23	22	27.8	1.14	79	190	140	Negatif	Negatif	Kacamata Minus	(120/70) Normal		Normal sinus rhythm.

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
61	L	32	15	16	19.3	0.84	89	179	55	Negatif	Negatif	Kacamata Minus	(120/70) Normal		Sinus bradycardia.
62	L	32	26	29	21.0	0.83	95	162	99	Negatif	Negatif	Lain-lain (Allergi)	(120/80) Normal		Normal sinus rhythm
63	L	33	13	20	30.0	1.00	76	149	40	Negatif	Negatif	Kacamata Minus, Lain-lain (Penyakit lainnya)	120	80	Normal Sinus Rhythm
64	L	33	25	25	19.3	0.80	75	167	125	Negatif	Negatif	Gastritis (Maag)	110	80	Normal sinus ritmis
65	L	33	17	18	11.8	0.87	98	170	54	Negatif	Negatif	Pernah operasi, Demam berdarah, Typoid, Hernia, Hemoroid	120	70	Normo sinus rhythm Normal ECG
66	L	33	19	11	21.2	0.91	83	123	65	Negatif	Negatif	Tidak Ada	120	80	Dalam batas normal
67	L	33	16	16	18.4	0.84	87	116	53	Negatif	Negatif	Kacamata Minus, Kacamata Silender	110	70	Normal
68	L	33	20	16	34.1	1.10	93	193	75	Negatif	Negatif	Tidak Ada	100	70	Normal ECG
69	L	33	21	29	15.9	0.99	95	128	124	Negatif	Negatif	Pernah opname dan operasi karena patah tulang fibula sinis	(110/70) Normal		Normal
70	L	33	17	19	17.8	0.90	97	160	65	Negatif	Negatif	-	(90/60) Normal		Normo sinus ritme HR : 63 bpm
71	L	33	26	31	20.1	1.20	96	172	99	Negatif	Negatif	-	(120/80) Normal		normal sinus rhytm, hr 70x/menit, normoaxis(normal ecg)
72	L	33	19	29	14.4	0.93	95	177	107	Negatif	Negatif	Tuberculosa (TBC)	(110/80) Normal		SB. HR 48X/MENIT
73	L	33	20	12	22.3	1.11	82	198	63	Negatif	Negatif	Kacamata Minus, Allergi Hirupan	(120/80) Normal		- Normal sinus ritme - Normal ECG
74	L	33	14	15	23.3	1.02	84	148	57	Negatif	Negatif	-	(100/70) Normal		Dalam batas normal
75	L	33	17	26	38.5	0.78	91	176	82	Negatif	Negatif	Asma, Kacamata Minus, Kacamata Silender, Allergi Hirupan, Lain-lain (Allergi), Pernah operasi	(120/80) Normal		Sinus bradycardia.
76	L	33	23	14	22.0	1.00	94	148	85	Negatif	Negatif	Gastritis (maag), Asma, Allergi Makanan, Lain-lain (Allergi)	(100/70) Normal		Sinus bradikardia 58 x/menit
77	L	34	17	23	19.8	1.00	96	169	127	Negatif	Negatif	Pernah sakit sinus/ polip	110	80	Normo sinus rhythm Normal ECG
78	L	34	27	49	23.1	0.94	99	178	74	Negatif	Negatif	Gastritis (maag), Hipertensi, Pernah operasi, Insomnia	110	80	Normo sinus rhythm Normal ECG
79	L	34	13	13	22.2	1.04	92	159	54	Negatif	Negatif	Tidak Ada	120	80	- Normal sinus ritme - Normal ECG
80	L	34	14	11	14.0	1.05	94	154	95	Negatif	Negatif	Lain-lain (Penyakit lainnya)	(110/70) Normal		Normal ECG

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
81	L	34	17	16	20.6	1.14	79	139	98	Negatif	Negatif	-	(120/80) Normal		- Normal sinus ritme - Normal ECG
82	L	34	25	33	19.4	0.87	99	166	84	Negatif	Negatif	-	(120/70) Normal		Dalam batas normal
83	L	34	22	24	24.9	1.16	88	150	132	Negatif	Negatif	Nyeri punggung/back pain.	(110/80) Normal		Dalam batas normal
84	L	35	16	14	22.7	1.04	95	189	86	Negatif	Negatif	Tidak ada	120	80	Normo sinus ritme HR : 66 bpm
85	L	35	16	26	26.7	0.92	90	162	93	Negatif	Negatif	Pernah diopname (Maag 1 Tahun yang lalu), Alergi (Debu), Tifus (4 Tahun yang lalu), Abeien/wasir/hemoroid.	110	70	Sinus Ritme, HR 71x/menit, Normoaxis
86	L	35	12	13	12.8	0.80	89	187	53	Negatif	Negatif	demam thypoid 2019	110	80	Normo Sinus Rhythm
87	L	35	25	25	24.2	0.80	96	155	52	Negatif	Negatif	Tidak Ada	110	70	Normal ECG
88	L	35	22	28	15.2	1.00	98	163	119	Negatif	Negatif	-	110	70	NORMAL SINUS RHYTM
89	L	35	14	11	19.7	1.06	96	191	143	Negatif	Negatif	**Pernah operasi bisul (abses di pipi kiri & tangan) 2019, ganglion pergelangan tangan kiri 2 tahun yang**	(110/70) Normal		Normal
90	L	35	17	22	21.8	1.06	93	180	127	Negatif	Negatif	Lain-lain (Allergi)	(120/80) Normal		Sinus bradikardi
91	L	35	29	31	17.0	0.99	83	188	69	Negatif	Negatif	Alergi debu, Demam berdarah th 2002	(114/71) Normal		Sinus Rhythm, 60x/mnt
92	L	35	17	11	28.7	1.05	85	140	29	Negatif	Negatif	Lain-lain (Sistem Penglihatan)	(110/70) Normal		- Normal sinus ritme - Normal ECG
93	L	35	18	29	17.1	1.10	82	177	118	Negatif	Negatif	Kacamata Minus	(110/70) Normal		Normal sinus rhythm.
94	L	35	19	16	25.0	0.83	95	159	102	Negatif	Negatif	Gastritis (maag), Tuberculosa (TBC), Vertigo (pusing memutar), Kacamata Minus, Kacamata Silender, Lain-lain	(110/70) Normal		Normal sinus rhythm
95	L	35	19	10	26.9	1.00	96	174	65	Negatif	Negatif	-	(120/80) Normal		Dalam batas normal
96	L	36	15	12	21.4	1.00	96	182	116	Negatif	Negatif	Kacamata Minus	110	70	Normal Sinus Rhythm
97	L	36	16	16	19.9	0.87	99	174	102	Negatif	Negatif	Olahraga : Jogging 1x/minggu	120	80	Normal ECG
98	L	36	12	14	14.7	0.93	82	170	83	Negatif	Negatif	Typoid : Waktu SD	110	70	Normal
99	L	36	13	12	25.0	0.84	82	129	72	Negatif	Negatif	Pernah opname karena DBD.	(130/80) Normal		Normal
100	L	36	18	30	21.7	0.93	97	201	130	Negatif	Negatif	Lain-lain (Allergi)	(120/80) Normal		Normal

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
101	L	36	20	32	12.8	0.83	90	198	128	Negatif	Negatif	DHF/Demam berdarah	(110/80) Normal		NORMAL
102	L	36	19	9	17.2	0.91	83	185	88	Negatif	Negatif	-	(130/80) Normal		- Normal sinus ritme - Normal ECG
103	L	36	15	14	17.0	0.93	87	171	56	Negatif	Negatif	Haemorrhoid (wasir/ambeien), Kacamata Minus, Kacamata Silender, Lain-lain (Allergi), Lain-lain (	(130/80) Normal		Normal sinus rhythm
104	L	36	18	23	25.7	1.00	87	178	101	Negatif	Negatif	Gastritis (maag) ; Ya, jarang kambuh, Kacamata Minus, Allergi Makanan Seafood, DHF/Demam Berdarah	(120/70) Normal		Normal Sinus Rhythm
105	L	37	23	32	12.8	1.00	88	168	87	Negatif	Negatif	-	120	80	Normal Sinus Rhythm
106	L	37	27	25	19.3	0.77	90	198	95	Negatif	Negatif	Riwayat alergi obat yg mengandung zulfa	(120/80) Normal		Normo Sinus Rhythm Normal ECG
107	L	37	19	19	15.0	0.87	91	176	134	Negatif	Negatif	Gastritis (maag), Tuberculosa (TBC), Lain-lain (Allergi), Pernah operasi	(110/70) Normal		Normal sinus rhythm.
108	L	37	25	60	17.4	0.90	93	170	75	Negatif	Negatif	Kacamata minus dan (+) serta gangguan tiroid (gondok, hipo/hipertiroid) tahun 2016	(100/60) Normal		Normal sinus rhythm.
109	L	37	16	24	22.2	1.10	89	182	108	Negatif	Negatif	Asma saat kecil	(110/70) Normal		Dalam batas normal
110	L	37	16	22	22.3	0.89	89	178	86	Negatif	Negatif	Post op gigi	(100/70) Normal		- Normal resting ECG - Normal sinus rhytm - Normal axis - No ST-T Changes
111	L	37	26	52	16.0	0.95	78	127	118	Negatif	Negatif	Allergi Makanan	(120/80) Normal		Normal resting ECG
112	L	38	21	40	23.8	1.00	85	150	94	Negatif	Negatif	DHF/Demam berdarah, Lain-lain (Sistem Penglihatan)	110	70	Normal ECG
113	L	38	25	30	19.3	0.82	91	179	86	Negatif	Negatif	-	(100/70) Normal		Normal sinus rhythm.
114	L	38	20	26	24.9	1.14	93	182	71	Negatif	Negatif	Kacamata Minus, Typoid	(120/70) Normal		Sinus bradycardia.
115	L	38	17	18	17.4	1.00	85	182	114	Negatif	Negatif	-	(96/60) Normal		Normal
116	L	38	18	20	25.6	1.07	82	154	98	Negatif	Negatif	-	(120/80) Normal		Normal ECG
117	L	39	14	17	19.0	0.87	96	182	116	Negatif	Negatif	Kacamata Minus	120	80	Normal ECG
118	L	39	15	19	19.5	1.01	92	192	76	Negatif	Negatif	(-)	110	80	NORMAL ECG
119	L	39	15	24	18.4	0.89	82	189	91	Negatif	Negatif	Mengalami cidera kepala	(120/80) Normal		Normal
120	L	39	17	16	21.4	0.93	85	181	115	Negatif	Negatif	DHF/Demam berdarah	(130/80) Normal		Sinus bradycardia.

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
121	L	40	16	23	18.3	0.85	93	192	99	Negatif	Negatif	Tidak ada	120	80	Normo sinus rhythm Normal ECG HR : 66 bpm
122	L	40	17	22	26.6	0.94	94	157	117	Negatif	Negatif	-	(120/60) Normal		Normo sinus rhythm Right axis deviation Other parameters are within normall limits HR : 68 bpm
123	L	40	19	24	19.1	0.94	90	179	103	Negatif	Negatif	TBC (10 tahun yang lalu), Gastritis	(110/70) Normal		- Normal resting ECG - Normal sinus rhytm - Normal axis - No ST-T Changes
124	L	41	18	16	19.8	0.92	92	152	64	Negatif	Negatif	Tidak ada	110	70	Normo sinus ritme HR : 68 bpm
125	L	41	14	15	23.5	0.76	93	191	102	Negatif	Negatif	Gastritis (maag), Operasi saluran pencernaan, Tuberculosa (TBC), Kacamata Minus	(120/70) Normal		Normal sinus rhythm.
126	L	41	18	18	15.4	1.04	86	188	89	Negatif	Negatif	Nyeri otot dan sendi	(100/70) Normal		Sinus bradikardia
127	L	41	17	28	19.3	0.80	90	173	81	Negatif	Negatif	-	(120/80) Normal		Normal Sinus Rhythm
128	L	42	18	27	30.9	0.88	100	168	136	Negatif	Negatif	Kacamata (+), Lain-lain (Penyakit lainnya)	120	80	Normal ECG
129	L	42	15	10	19.0	0.90	97	185	96	Negatif	Negatif	Memakai kacamata	120	80	Irama sinus 80 x/m, aksis frontal Normal - EKG Normal
130	L	42	16	18	22.4	0.96	91	182	62	Negatif	Negatif	Alergi (Debu).	130	70	Sinus ritme, HR 73x/menit, Normoaxis,
131	L	42	16	22	20.6	0.90	88	158	145	Negatif	Negatif	Tidak Ada	110	80	Normal ECG
132	L	42	27	18	24.0	0.83	82	196	94	Negatif	Negatif	-	110	70	Normal ECG
133	L	42	39	43	17.7	0.94	84	187	73	Negatif	Negatif	Allergi Makanan, Lain-lain (Allergi)	(120/70) Normal		Normal ECG
134	L	42	21	20	22.1	0.90	88	186	111	Negatif	Negatif	-	Normal		Normal sinus rhythm.
135	L	43	15	17	20.3	1.16	79	138	100	Negatif	Negatif	Stroke	(120/80) Normal		Dalam batas normal
136	L	44	20	28	19.1	1.01	100	192	147	Negatif	Negatif	Pernah Operasi (Caesar Tahun 2015 e.c Ketuban pecah dini).	120	80	Sinus Ritme, HR 74x/menit, Normoaxis
137	L	45	22	29	21.2	0.83	84	194	128	Negatif	Negatif	Kacamata Minus, Kacamata (+)	120	80	Normal ECG
138	L	45	16	18	19.3	0.90	89	163	89	Negatif	Negatif	Kacamata Minus	110	70	Normal Sinus Rhythm
139	L	45	29	44	27.8	0.58	91	170	82	Negatif	Negatif	Gastritis (maag), Kacamata (+)	(100/60) Normal		Normal sinus rhythm.
140	L	45	16	19	15.9	0.92	99	177	99	Negatif	Negatif	Cidera kepala, gangguan penglihatan	(110/70) NOrmal		Normal

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			L: < 37	L: < 50	12,8 - 42,8	L: 0,67 - 1,17	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
141	L	46	18	21	20.5	0.90	88	186	92	Negatif	Negatif	Kacamata (+), Allergi Obat	120	80	Dalam batas normal
142	L	46	28	40	15.0	0.90	79	187	143	Negatif	Negatif	Kacamata plus, Nyeri punggung/back pain	100	70	Normal sinus ritmis
143	L	46	18	18	21.0	0.96	101	199	143	Negatif	Negatif	(-)	130	80	Normal ECG
144	L	47	14	19	19.3	0.90	95	168	84	Negatif	Negatif	Kacamata Minus, Kacamata (+)	120	70	Normal Sinus Rhythm
145	L	48	20	27	24.2	0.90	85	139	132	Negatif	Negatif	Dirawat di RS (2015) karena demam thypoid, memakai kacamata minus : 1.25D ODS	130	90	Normal ECG
146	L	49	18	17	19.0	1.12	93	178	105	Negatif	Negatif	Gastritis (maag), Kacamata (+), Kecelakaan / cidera / trauma /luka parah, DHF/Demam berdarah	100	70	Normal ECG
147	L	49	17	18	19.9	1.15	106	154	64	Negatif	Negatif	Alergi	120	80	Normo sinus rhythm Normal ECG HR : 75 bpm
148	L	50	24	20	19.3	1.03	88	126	79	Negatif	Negatif	Kacamata (+), Lain-lain (Penyakit lainnya)	110	70	Normal
149	L	50	15	16	17.7	0.83	86	152	95	Negatif	Negatif	-	(90/70) Normal		- Normal sinus ritme - Normal ECG
150	L	51	13	10	21.5	0.93	102	185	97	Negatif	Negatif	-	110	80	Normal
151	L	51	15	14	17.1	1.00	89	190	80	Negatif	Negatif	Kacamata Minus, Kacamata (+), Kacamata Silender	130	80	Normal Sinus Rhythm
152	L	52	15	13	23.6	1.09	103	148	85	Negatif	Negatif	Pneumonia & TB paru (1992), Pernah operasi hernia (2016)	120	70	Normal
153	L	52	18	12	21.5	0.86	83	170	65	Negatif	Negatif	Tidak ada	100	60	Normo sinus ritme HR : 64 bpm
154	L	53	15	16	28.5	1.10	111	186	67	Negatif	Negatif	Haemorrhoid (wasir/ambeien), Kacamata (+), Amandel/tonsilitis, Lain-lain (Sistem Penglihatan)	130	80	Normal
155	L	54	16	13	25.8	1.00	95	186	87	Pos 1 (25 mg/dL)	Negatif	Kacamata (+), Kacamata Silender	110	70	Dalam batas normal

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
1	P	24	14	11	13.0	0.70	79	163	67	Negatif	Negatif	Gastritis	(110/70) Normal		Normal
2	P	25	13	12	27.0	0.74	102	136	83	Negatif	Negatif	Gastritis (maag)	100	70	Normal
3	P	25	16	15	15.0	0.70	89	172	110	Negatif	Negatif	Haemorroid (wasir/ambeien)	100	60	Normal sinus ritmis.
4	P	25	19	18	19.3	0.60	80	193	81	Negatif	Negatif	Gasritis (maag), Rhinitis Alergika, Cidera tulang belakang, nyeri punggung, Gangguan tiroid, Alergi udara dingin	100	70	Normal sinus ritmis
5	P	25	13	12	19.3	0.60	76	143	62	Negatif	Negatif	Gastritis (Maag), Alergi Kontak	120	70	Normal sinus ritmis.
6	P	25	20	27	19.3	0.60	98	212	78	Negatif	Negatif	Gastritis (Maag), Kacamata minus dan silinder, Alergi makanan dan alkohol	110	80	Normal Sinus Ritmis.
7	P	26	19	30	20.5	0.70	119	195	92	Negatif	Negatif	Gastritis (maag), Haemorrhoid (wasir/ambeien), Kacamata Minus, Kacamata Silender, Infeksi saluran kemih, Pernah	100	70	Dalam batas normal
8	P	26	16	11	25.6	0.80	78	126	41	Negatif	Negatif	Kacamata Minus, Pernah operasi	110	70	Normal ECG
9	P	26	18	19	12.8	0.60	81	146	76	Negatif	Negatif	-	120	80	Normal Sinus Rhythm
10	P	26	16	11	17.5	0.70	79	192	69	Negatif	Negatif	Pernah opname karena DB, maag , insomnia	(90/60) Normal		Normal
11	P	26	14	11	17.1	0.70	78	140	76	Negatif	Negatif	-	(110/80) Normal		Normal Sinus Rhythm
12	P	26	14	12	14.2	0.63	79	140	73	Negatif	Negatif	Kacamata Minus, Kacamata Silender	(100/80) Normal		Dalam batas normal
13	P	27	14	11	19.6	0.68	98	172	77	Negatif	Negatif	Gastritis (maag), Kacamata Minus, Kacamata Silender, Lain-lain (Allergi), Pernah operasi	110	80	Dalam batas normal
14	P	27	16	10	17.1	0.70	76	171	44	Negatif	Negatif	-	120	80	Normal Sinus Rhythm
15	P	27	11	12	15.0	0.70	95	168	91	Negatif	Negatif	-	110	70	Normal Sinus Rhythm
16	P	27	19	16	15.0	0.70	70	192	38	Pos 1 (25 mg/dl)	Negatif	Vertigo, Kacamata minus, Low Back Pain, Operasi SC	100	70	Normal sinus ritmis
17	P	27	16	16	18.4	0.72	90	181	64	Negatif	Negatif	Tidak ada	100	80	Normal ECG
18	P	27	16	11	16.2	0.56	75	122	51	Negatif	Negatif	Amandel, maag, sedang hamil 6 minggu	(100/70) Normal		Sinus arrhythmia 75-85 bpm
19	P	27	17	15	20.2	0.68	89	164	50	Negatif	Negatif	-	(120/80) Normal		Normo sinus rhythm. HR : 77 bpm
20	P	27	20	15	18.3	0.66	83	173	55	Negatif	Negatif	-	(90/60) Normal		Normo sinus ritme HR :73 bpm

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
21	P	27	15	14	24.0	0.53	89	137	41	Negatif	Negatif	Kacamata Minus, Pernah operasi	(120/80) Normal		- Normal sinus ritme - Normal ECG
22	P	28	20	14	13.9	0.70	75	191	113	Negatif	Negatif	Kacamata Minus	110	80	Dalam batas normal
23	P	28	19	18	10.0	0.80	101	171	84	Negatif	Negatif	Kacamata Minus, Kacamata Silender	110	70	Dalam batas normal
24	P	28	18	10	13.3	0.63	83	194	72	Negatif	Negatif	Kacamata Minus, Lain-lain (Allergi)	110	80	SR, HR 55x/m, normoECG
25	P	28	15	32	19.3	0.60	88	178	85	Negatif	Negatif	-	110	80	Normal Sinus Rhythm
26	P	28	21	33	21.4	0.50	92	124	91	Pos 1 (25 mg/dl)	Negatif	Gastritis (Maag), asma, rheumatik, hiperiroid	130	80	Normal sinus ritmis
27	P	28	10	9	16.5	0.50	82	150	70	Negatif	Negatif	Pernah operasi Kista, kacamata minus, maag	(110/70) Normal		Normal
28	P	28	16	12	22.1	0.86	88	193	72	Negatif	Negatif	-	(120/80) Normal		Normal ECG
29	P	28	14	13	13.7	0.70	76	186	127	Negatif	Negatif	Gastritis (maag)	(100/70) Normal		- Normal sinus ritme - Normal ECG
30	P	28	17	19	14.4	0.90	92	197	144	Negatif	Negatif	Gastritis (maag), Kacamata Minus, Pernah operasi	(120/70) Normal		Normal sinus rhythm.
31	P	28	20	23	19.2	0.70	83	154	106	Negatif	Negatif	Gastritis (maag), Demam typoid, Haemorrhoid, Vertigo, Kacamata minus, Infeksi saluran kemih, Nyeri	(90/60) Normal		Normal sinus rhythm.
32	P	28	14	9	10.8	0.55	73	136	40	Negatif	Negatif	-	(100/60) Normal		Dalam batas normal
33	P	28	20	11	21.5	0.90	90	183	105	Negatif	Negatif	kacamata minus	(120/80) Normal		Dalam batas normal
34	P	29	14	13	23.5	0.60	92	187	150	Negatif	Negatif	Kacamata Minus, Kacamata Silender, Allergi Makanan	130	80	Dalam batas normal
35	P	29	15	16	24.9	0.80	81	194	57	Negatif	Negatif	-	130	90	Dalam batas normal
36	P	29	15	19	15.9	0.74	107	182	91	Negatif	Negatif	Kacamata Minus	110	70	SR. HR 60x/m, normoECG
37	P	29	15	11	22.0	0.65	79	130	40	Negatif	Negatif	Hipotensi, riwayat SC 2016,2019	100	70	Normal ECG
38	P	29	14	16	12.8	0.70	81	181	36	Negatif	Negatif	-	110	80	Normal Sinus Rhythm
39	P	29	21	16	27.8	0.60	76	176	36	Negatif	Negatif	Pernah operasi	100	70	Normal sinus ritmis.
40	P	29	13	11	17.8	0.54	89	178	37	Negatif	Negatif	Alergi : udang, Olahraga : Gym 1x/minggu	110	70	Normal

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
41	P	29	17	13	20.5	0.60	92	136	109	Negatif	Negatif	Maag, ambein	(100/70) Normal		EKG dalam batas normal
42	P	29	12	9	17.8	0.66	85	182	90	Negatif	Negatif	Pernah opname karena tifus dan operasi melahirkan (Janua	(100/70) Normal		Normal
43	P	29	22	22	19.3	0.59	93	184	112	Negatif	Negatif	Pernah opname karena tifus. Riwayat ambein.	(100/60) Normal		Normal
44	P	29	15	16	21.4	0.71	77	176	61	Negatif	Negatif	Riwayat alergi seafood	(120/70) Normal		Normo sinus rhythm Normal ECG
45	P	29	16	14	16.9	0.62	92	179	51	Negatif	Negatif	Allergi Makanan	(120/70) Normal		Normal ECG
46	P	29	27	20	27.5	0.64	88	170	61	Negatif	Negatif	Allergi Makanan	(110/80) Normal		Normal
47	P	29	14	13	15.9	0.71	98	168	66	Negatif	Negatif	DHF/Demam berdarah	(90/60) Normal		Normal
48	P	29	18	14	14.4	0.53	79	159	51	Negatif	Negatif	Pernah operasi	(100/70) Normal		Normal ECG
49	P	29	15	13	15.0	0.68	91	197	80	Negatif	Negatif	Gastritis (maag), Haemorrhoid (wasir/ambeien), Kacamata Silender, Lain-lain (Sistem Penglihatan), Lain-lain (Kulit	(120/70) Normal		Normal sinus rhythm.
50	P	29	29	21	17.0	0.65	80	154	47	Negatif	Negatif	Gastritis (maag), Allergi Obat, Allergi Makanan, Lain-lain (Allergi)	(110/70) Normal		Normal sinus rhythm
51	P	29	18	22	15.0	0.71	96	171	89	Negatif	Negatif	Tuberculosa (TBC), Kacamata Minus, Allergi Makanan, Lain-lain (Allergi), Pernah operasi	(92/70) Normal		ECG dalam batas normal
52	P	29	22	27	19.5	0.62	84	157	56	Negatif	Negatif	pernah operasi SC	(100/70) Normal		Dalam batas normal
53	P	29	16	16	15.4	0.62	90	183	93	Negatif	Negatif	Gastritis (maag), asma, gangguan penglihatan, alergi debu, pernah operasi SC & amandel	(110/70) Normal		Incomplete RBBB
54	P	29	13	10	13.8	0.52	87	179	49	Negatif	Negatif	Post op sinus-polip (2008),	(110/70) Normal		- NSR 66 bpm, axis N - Normal Resting ECG
55	P	29	15	10	22.0	0.60	76	177	50	Negatif	Negatif	Asma	(110/70) Normal		Normal sinus rhythm
56	P	29	11	10	18.2	0.68	82	192	113	Negatif	Negatif	Allergi Makanan, Typoid, Pernah operasi	(110/70) Normal		Dalam batas normal
57	P	29	26	17	17.3	0.70	81	167	36	Negatif	Negatif	kacamata minus	(120/80) Normal		Sinus Bradicardia 40x/menit
58	P	30	20	10	20.4	0.79	75	196	92	Negatif	Negatif	-	120	80	SR, HR 55x/m, normoECG
59	P	30	19	12	21.4	0.60	88	170	41	Negatif	Negatif	-	110	70	Normal Sinus Rhythm
60	P	30	13	24	19.3	0.70	97	144	55	Negatif	Negatif	Pernah operasi	110	80	Normal Sinus Rhythm

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
61	P	30	15	10	13.8	0.78	94	167	68	Negatif	Negatif	Tidak ada	110	70	SB, HR 58x/m, RBBB Incomplete
62	P	30	16	9	14.4	0.71	92	148	63	Negatif	Negatif	Pernah operasi SC. Riwayat amandel, ambein, kontrasepsi	(120/70) Normal		Normal
63	P	30	20	13	21.3	0.62	80	191	88	Negatif	Negatif	Riwayat alergi secar tahun 2017	(120/70) Normal		Normo sinus ritme HR : 87 bpm
64	P	30	12	10	20.7	0.71	88	162	42	Negatif	Negatif	-	(120/80) Normal		Normal ECG
65	P	30	15	14	28.8	0.58	83	177	61	Negatif	Negatif	Gastritis (maag)	(90/70) Normal		Sinus bradikardi
66	P	30	12	12	12.8	0.61	89	176	75	Negatif	Negatif	Demam typoid, Haemorrhoid (wasir/ambeien), Pernah operasi, Lain-lain (Tulang, Sendi & Otot)	(110/70) Normal		Normal sinus rhythm.
67	P	30	15	9	22.4	0.67	97	171	51	Negatif	Negatif	Gastritis (maag), Kacamata Minus, Pernah operasi	(90/60) Normal		Normal sinus rhythm.
68	P	30	19	16	21.0	0.77	92	196	74	Negatif	Negatif	Gastritis (maag), Asma, Kacamata Minus, Kacamata Silender, Infeksi saluran kemih, Allergi Obat, Allergi	(110/70) Normal		Normal sinus rhythm
69	P	30	15	20	17.0	0.59	89	168	130	Negatif	Negatif	Kacamata Minus, Kacamata Silender, Pernah operasi	(100/70) Normal		ECG dalam batas normal
70	P	30	13	9	14.2	0.80	78	158	67	Negatif	Negatif	Gastritis (maag), Vertigo, dan Kacamata minus	(120/80) Normal		Normal sinus rhythm.
71	P	30	24	29	25.0	0.70	88	191	74	Negatif	Negatif	Asma, Nyeri punggung/back pain, DHF/Demam berdarah, Pernah operasi (usus buntu dan caesar)	(110/70) Normal		Normal sinus ritme
72	P	30	14	10	19.8	0.70	78	163	68	Negatif	Negatif		(90/70) Normal		Within Normal Limit Findings Within Normal Limit ECG
73	P	30	22	18	18.5	0.70	75	157	59	Negatif	Negatif	Alergi seafood, & debu, operasi amandel (2017)	(110/70) Normal		Within Normal Limit Findings Within Normal Limit ECG
74	P	30	13	9	11.6	0.58	65	194	118	Negatif	Negatif	Pernah operasi	(120/80) Normal		Normal ECG
75	P	30	20	22	16.6	0.61	85	168	105	Negatif	Negatif	Gastritis (maag), Kacamata Minus, Kacamata Silender, Infeksi saluran kemih, DHF/Demam berdarah, Pernah	(100/60) Normal		Dalam batas normal
76	P	31	17	15	14.4	0.65	91	195	71	Negatif	Negatif	Allergi Makanan	105	70	Dalam batas normal
77	P	31	14	11	21.1	0.70	79	198	50	Negatif	Negatif	Kacamata Silender	100	80	Dalam batas normal
78	P	31	16	10	22.6	0.61	86	157	52	Negatif	Negatif	Lain-lain (Allergi), Pernah operasi, Lain-lain (Penyakit lainnya), Lain-lain (Sistem Cardiovaskuler)	100	70	SR, HR 60x/m, normoECG
79	P	31	13	14	22.2	0.68	96	164	65	Negatif	Negatif	Pernah operasi	100	70	Normal ECG
80	P	31	15	18	21.4	0.80	89	176	112	Negatif	Negatif	Kacamata Minus	120	70	Normal Sinus Rhythm

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
81	P	31	18	24	17.1	0.70	91	164	101	Negatif	Negatif	-	110	80	Normal Sinus Rhythm
82	P	31	17	10	30.0	0.70	89	164	59	Negatif	Negatif	-	110	80	Normal Sinus Ritmis
83	P	31	17	20	15.0	0.60	106	155	67	Negatif	Negatif	Kacamata minus	105	70	Normal sinus ritmis.
84	P	31	18	17	29.9	0.60	97	150	58	Negatif	Negatif	Tidak ada	110	70	Normal
85	P	31	13	11	19.3	0.60	96	181	75	Negatif	Negatif	Gastritis (maag), Haemorrhoid (wasir/ambeien), Kacamata Minus	(100/70) Normal		Normal sinus rhythm.
86	P	31	21	27	24.0	0.70	81	160	76	Negatif	Negatif	Gangguan tiroid (gondok, hipo, hipertiroid)	(100/60) Normal		Normal sinus rhythm.
87	P	31	15	21	19.5	0.80	92	194	123	Negatif	Negatif	Gastritis (maag), Kacamata minus dan silender, Kista, dan pernah operasi laparaskopi pcos (myomauteri kista	(100/60) Normal		Normal sinus rhythm.
88	P	31	24	27	15.7	0.67	90	166	86	Negatif	Negatif	Gangguan penglihatan (minus), Pernah dioperasi	(100/90) Normal		Normal ECG
89	P	31	13	10	13.8	0.67	90	167	115	Negatif	Negatif	Gastritis (maag), Demam typoid, Asma, Kacamata Minus, Kacamata Silender, Allergi Makanan, Typoid, Pernah	(100/80) Normal		Dalam batas normal
90	P	32	12	11	15.6	0.77	81	171	50	Negatif	Negatif	Gastritis (maag), Kacamata Minus	110	70	Normal ECG
91	P	32	14	11	21.4	0.70	90	193	49	Pos 1 (25 mg/dl)	Negatif	Pernah operasi	110	70	Normal sinus ritmis.
92	P	32	15	13	21.2	0.60	78	166	71	Negatif	Negatif	Pernah opname karena operasi SC dan patah tulang, DBD, tifus, SLE, migran.	(100/70) Normal		Sinus bradycardia.
93	P	32	16	11	22.1	0.70	80	147	43	Negatif	Negatif	Pernah operasi kista	(90/60) Normal		Sinus aritmia (varian normal) HR : 57 bpm
94	P	32	27	11	16.8	0.55	85	154	45	Negatif	Negatif	Gastritis (maag)	(100/70) Normal		- Normal sinus ritme - Normal ECG
95	P	32	16	13	15.0	0.65	88	181	43	Negatif	Negatif	Gastritis (maag), Kacamata Silender, Lain-lain (Allergi)	(100/70) Normal		Sinus bradycardia.
96	P	32	19	19	20.9	0.73	92	150	97	Negatif	Negatif	Gastritis, Post op SC (2012), Alergi debu dan dingin	(110/80) Normal		- NSR 73 bpm, axis N - Normal resting ECG
97	P	33	14	11	17.1	0.60	83	184	84	Negatif	Negatif	Pernah operasi	110	80	Normal Sinus Rhythm
98	P	33	14	14	15.4	0.61	90	196	42	Negatif	Negatif	Alergi : debu	120	70	NORMAL ECG
99	P	33	17	22	10.9	0.50	87	165	88	Negatif	Negatif	Kacamata Minus, maag	(110/70) Normal		Normal
100	P	33	17	15	30.2	0.80	84	176	56	Negatif	Negatif	-	(110/70) Normal		Sinus bradycardia. HR : 56 bpm.

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
101	P	33	16	13	14.5	0.76	88	155	94	Negatif	Negatif	Riwayat GERD (+)	(120/70) Normal		SR, HR 74x/m
102	P	33	24	25	15.7	0.57	87	194	135	Negatif	Negatif	Alergi dingin, maag	(102/66) Normal		Sinus Rhythm HR : 80x/m
103	P	33	22	21	17.0	0.77	71	156	42	Negatif	Negatif	Typoid	(110/70) Normal		Normal sinus rhythm.
104	P	33	21	20	13.9	0.70	84	172	130	Negatif	Negatif	Gastritis (maag), Demam typoid, Anemia, Vertigo, Kacamata minus, Nyeri punggung/back pain,	(100/60) Normal		Normal sinus rhythm.
105	P	34	15	10	17.0	0.80	94	152	82	Negatif	Negatif	Riwayat : Gastritis. Kebiasaan : olahraga 6 kali/minggu.	110	70	Normal Sinus Rhythm
106	P	34	21	23	20.0	0.80	87	156	46	Negatif	Negatif	Riwayat : Gangguan penglihatan (ODS : -6.50), infeksi saluran kencing tahun 2015. Kebiasaan : Olahraga 3	100	60	Normal Sinus Rhythm
107	P	34	16	10	20.9	0.57	89	178	34	Negatif	Negatif	Pernah operasi	110	80	Normal
108	P	34	16	10	23.5	0.60	88	199	59	Negatif	Negatif	Kacamata Minus, Lainlain (Sistem Penglihatan)	100	80	Normal Sinus Rhythm
109	P	34	12	9	24.0	0.64	72	113	48	Negatif	Negatif	Pernah operasi SC	(100/60) Normal		Sinus arrythmia 75-90 bpm
110	P	34	15	9	13.4	0.68	91	199	57	Negatif	Negatif	Lain-lain (Allergi)	(90/60) Normal		Normal
111	P	34	13	11	17.1	0.74	83	141	45	Negatif	Negatif	Gastritis (maag), Kacamata Minus, Kacamata Silender, DHF/Demam berdarah, Typoid, Pernah operasi	(110/70) Normal		Normal sinus rhythm.
112	P	34	15	9	26.0	0.85	84	172	61	Negatif	Negatif	Gastritis (maag), Vertigo (pusing memutar), Kacamata Minus, Kacamata Silender, Allergi Obat, Lain-lain (Allergi	(110/80) Normal		Normal sinus rhythm
113	P	34	12	9	19.0	0.60	92	183	72	Negatif	Negatif	Gastritis (maag), Allergi Makanan, Lain-lain (Allergi), Lain-lain (Penyakit lainnya)	(102/70) Normal		ECG dalam batas normal
114	P	35	26	21	14.0	0.60	82	179	67	Negatif	Negatif	Riwayat : Gangguan penglihatan (ODS : -5.50), pernah di operasi SC tahun 2009 dan 2012. Kebiasaan : Olahraga 4	110	70	Normal Sinus Rhythm
115	P	35	30	30	12.0	0.70	97	179	105	Negatif	Negatif	Riwayat : Infeksi saluran kencing (1 kali), riwayat alergi (dermatitis). Kebiasaan : Olahraga 3 kali/minggu.	110	70	Normal Sinus Rhythm
116	P	35	17	14	17.1	0.60	80	115	76	Negatif	Negatif	Haemorrhoid (wasir/ambeien), Kacamata Minus, Gangguan tiroid (gondok, hipo/hipertiroid), Allergi	100	60	Dalam batas normal
117	P	35	11	15	13.5	0.80	78	179	146	Negatif	Negatif	Kacamata Minus	100	70	Dalam batas normal
118	P	35	15	12	16.2	0.64	86	161	88	Negatif	Negatif	Pernah operasi SC, Maag, demam berdarah, tipus.	(100/70) Normal		Normo sinus rhytm HR : 76 bpm
119	P	35	17	15	22.3	0.77	83	180	75	Negatif	Negatif	Thypus, demam berdarah	(120/60) Normal		Normo sinus ritme HR : 60 bpm
120	P	35	21	20	14.1	0.71	88	165	67	Negatif	Negatif	-	(110/80) Normal		Normal

No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
121	P	35	12	20	27.8	0.45	91	142	64	Negatif	Negatif	Pernah operasi	(110/70) Normal		Normal sinus rhythm.
122	P	35	15	11	23.0	0.88	81	187	64	Negatif	Negatif	Gastritis (maag), Asma, Kacamata Silender, Lain-lain (Allergi), Lain-lain (Penyakit lainnya)	(120/80) Normal		Normal sinus rhythm
123	P	35	17	14	19.2	0.67	82	144	87	Negatif	Negatif	Asma, gangguan penglihatan	(90/60) Normal		Dalam batas normal
124	P	35	16	12	16.9	0.62	69	163	45	Negatif	Negatif	Gastritis (maag), Vertigo (pusing memutar), Typoid, Lain-lain (Penyakit lainnya)	(90/60) Normal		Normal ECG
125	P	36	16	19	17.6	0.69	89	189	60	Negatif	Negatif	Alergi : dingin, Appendiktomi 7 tahun yang lalu	120	70	Normal ECG
126	P	36	20	12	21.3	0.67	86	154	89	Negatif	Negatif	Tidak ada	120	70	Normal
127	P	36	16	11	12.8	0.69	90	163	47	Negatif	Negatif	Gastritis (maag)	(90/60) Normal		Normal sinus rhythm.
128	P	37	15	10	21.8	0.73	88	151	59	Negatif	Negatif	Gastritis (maag), Haemorrhoid (wasir/ambeien), Lain-lain (Allergi), Pernah operasi	110	70	Dalam batas normal
129	P	37	15	17	18.6	0.55	83	183	36	Negatif	Negatif	Alergi : Alkohol	100	70	Normal ECG
130	P	37	19	17	18.0	0.78	77	152	64	Negatif	Negatif	Appendiktomi (2013)	100	70	Normal ECG
131	P	38	12	11	21.0	0.60	93	179	75	Negatif	Negatif	-	100	60	Dalam batas normal
132	P	38	15	14	13.4	0.60	89	187	124	Negatif	Negatif	Kacamata Minus, Kacamata Silender, Allergi Obat, Pernah operasi	100	70	Dalam batas normal
133	P	38	22	36	15.0	0.80	97	156	120	Negatif	Negatif	Asma, Kacamata Minus, Allergi Hirupan, Pernah operasi	110	70	Normal Sinus Rhythm
134	P	38	17	16	17.1	0.71	70	147	71	Negatif	Negatif	Gastritis (maag), Haemorrhoid (wasir/ambeien), Asma, Kacamata Minus, Amandel/tonsilitis	(110/70) Normal		Normal sinus rhythm.
135	P	38	14	11	10.7	0.57	87	167	93	Negatif	Negatif	Lain-lain (Allergi), DHF/Demam berdarah	(100/60) Normal		Normal sinus rhythm.
136	P	38	15	13	19.9	0.70	83	195	96	Negatif	Negatif	-	(100/60) Normal		Normal sinus rhythm.
137	P	38	14	15	11.1	0.80	90	191	136	Negatif	Negatif	Alergi udang & debu, Gastritis	(90/60) Normal		Within Normal Limit Findings Within Normal Limit ECG
138	P	38	22	19	20.2	0.74	82	186	101	Negatif	Negatif	-	(110/70) Normal		- NSR 86 bpm - Normal resting ECG
139	P	39	17	11	14.6	0.65	77	142	52	Negatif	Negatif	Tidak ada	110	80	Normal
140	P	39	20	9	18.7	0.75	78	158	38	Negatif	Negatif	Allergi Makanan	(120/80) Normal		- Normal sinus ritme - Normal ECG

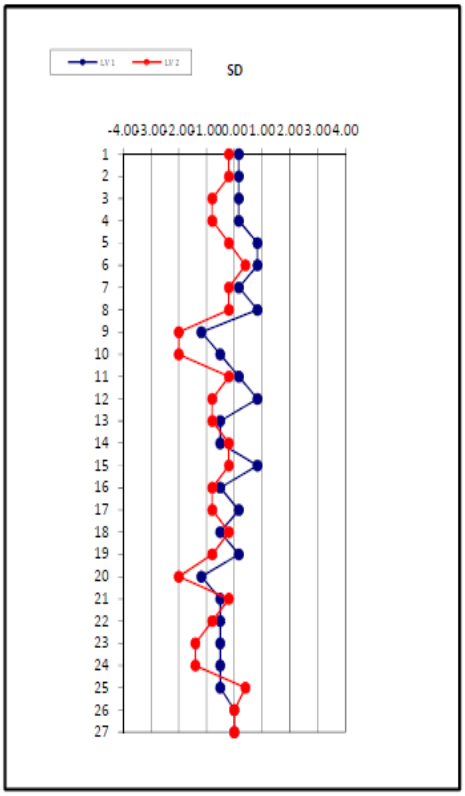
No.	Gender	Age	Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
			SGOT	SGPT	Ureum	Creatinin	Gluk. P	Koles. T	Trig	Protein	Glukosa		Sistolik	Diastolik	
			P: < 31	P: < 35	12,8 - 42,8	P: 0,51 - 0,95	< 100 Diagnosis DM ≥ 126	< 200	< 150	Negatif	Negatif				
141	P	40	17	15	19.3	0.70	88	167	63	Negatif	Negatif	-	110	80	Normal Sinus Rhythm
142	P	41	14	12	24.5	0.67	91	164	52	Negatif	Negatif	Lain-lain (Allergi), Pernah operasi, Lain-lain (Penyakit lainnya)	110	70	Normal ECG
143	P	41	11	14	20.7	0.55	79	167	69	Negatif	Negatif	Kacamata Minus	120	80	Normal sinus rhytm
144	P	41	14	10	17.1	0.70	91	181	59	Negatif	Negatif	-Pernah operasi	120	80	Normal Sinus Rhythm
145	P	41	22	22	19.3	0.70	95	188	69	Negatif	Negatif	Kacamata minus silinde, Alergi makanan	110	80	Normal Sinus Ritmis
146	P	41	13	12	36.4	0.45	93	189	40	Negatif	Negatif	Kacamata (+)	(120/80) Normal		Normal sinus rhythm.
147	P	41	16	13	34.2	0.74	86	164	89	Negatif	Negatif	Gastritis (maag), Kacamata Minus	(130/70) Normal		Normal sinus rhythm.
148	P	41	16	13	19.4	0.74	96	141	58	Negatif	Negatif	Haemorrhoid (wasir/ambeien), Kacamata Minus	(100/70) Normal		Normal
149	P	42	20	12	18.0	0.70	93	180	129	Negatif	Negatif	Riwayat : Gangguan pendengaran, gangguan penglihatan (ODS : -2.00, cyl : -2.00), gangguan alat reproduksi	110	70	Normal Sinus Rhythm
150	P	42	27	20	19.3	0.70	74	192	100	Negatif	Negatif	-	120	80	Normal Sinus Rhythm
151	P	42	17	24	21.4	0.70	104	197	144	Negatif	Negatif	Pernah operasi	120	80	Normal Sinus Rhythm
152	P	43	19	11	13.1	0.80	87	192	82	Negatif	Negatif	-	110	70	Normal Sinus Rhythm
153	P	43	13	12	15.0	0.60	82	182	66	Pos 1 (25 mg/dl)	Negatif	Kacamata minus, Riwayat IUFD	120	80	Normal sinus ritmis
154	P	43	19	19	38.5	0.70	87	167	40	Negatif	Negatif	Gastritis (maag), Demam typoid, Mengalami cidera kepala, Kacamata Minus	(110/70) Normal		Normal sinus rhythm.
155	P	43	29	17	17.1	0.67	85	173	43	Negatif	Negatif	Haemorrhoid (wasir/ambeien), Hipertensi, Kacamata (+), Lain-lain (Penyakit daerah tropis)	(120/70) Normal		Normal sinus rhythm.
156	P	44	20	20	16.6	0.85	88	164	41	Negatif	Negatif	Kacamata (+)	110	70	Normal ECG
157	P	44	26	40	19.9	0.68	75	192	60	Negatif	Negatif	Gastritis (maag), Kacamata Minus	(100/60) Normal		Normal sinus rhythm.
158	P	45	18	16	15.0	0.60	93	186	98	Negatif	Negatif	Kacamata (+), Pernah operasi	100	80	Normal Sinus Rhythm
159	P	45	22	14	10.5	0.53	94	198	90	Negatif	Negatif	Kacamata Minus	(110/70) Normal		Normal
160	P	46	16	10	16.0	0.51	94	172	67	Negatif	Negatif	Lain-lain (Allergi), Pernah operasi, Lain-lain (Penyakit lainnya)	130	90	NORMAL

			Fungsi Hati		Faal Ginjal		DM	Profil Lipid		Urinalisa		Riwayat Kesehatan	Tensi (mmHg)		EKG
	Gender	Age	SGOT P: <31	SGPT P: <35	Ureum 12,8 -42,8	Creatinin P: 0,51 - 0,95	Gluk. P <140 Diagnosis DM > 126	Kolest. T <200	Trig <150	Protein Negatif	Glukosa Negatif	Riwayat Kesehatan	Sistolik	Diastolik	EKG
161															
162	P	47	17	25	15.0	0.80	90	166	55	Negatif	Negatif	-	(110/70)		Within Normal Limit Findings
													Normal		Within Normal Limit ECG
163	P	48	23	13	22.4	0.98	78	198	43	Negatif	Negatif	Kacamata (+), Pernah operasi	120	80	Normal sinus rhytm
164	P	48	14	13	15.0	0.70	84	177	65	Negatif	Negatif	Kacamata (+), Lain-lain (Tulang, Sendi & Otot)	110	80	Normal Sinus Rhytdm
165	P	48	16	18	21.8	0.70	95	175	100	Negatif	Negatif	Alergi obat : golongan sulfa	120	80	Normal ECG
166	P	49	18	23	21.4	0.80	97	185	71	Negatif	Negatif	-	120	80	Normal Sinus Rhytdm
167	P	49	17	21	15.0	0.60	81	174	84	Negatif	Negatif	Lain-lain (Allergi), Pernah operasi	110	80	Normal Sinus Rhytdm
168	P	50	17	15	15.0	0.80	95	168	74	Negatif	Negatif	Kacamata Minus, Kacamata Silender	120	80	- Sinus Rhythm - Incomplete RBBB pattern
169	P	54	18	15	24.6	0.90	84	199	88	Negatif	Negatif	Pnah tulang, Pernah operasi	130	70	Dalam batas normal

LAMPIRAN 4. Pemantapan Mutu Bahan Kontrol ALT Bulan Maret 2020

TEST NAME	SGPT	BIORAD LEVEL 1			BIORAD LEVEL 2				
REAGENT	ABBOT	No.LOT 26461			No.LOT 26462				
METHOD	IFCC WITHOUT P5P	-3S	MEAN	+3S	-3S	MEAN	+3S	TEa	16.0
INSTRUMENT	ALINITY	24.3	28.76	33.2	93.3	98.3	103.3	TE (Lev 1)	12.80
CONTROL LIMIT	Target Value	29.48			100.6			TE (Lev 2)	5.65
	Bias / (%)	0.72		2.44	2.27		2.26	UNIT	U/L
	SD / CV (%)	1.49		5.18	1.67		1.70		
	Sigma	2.62			8.09				
QC RULE	1-3s/2of3-2s/R4s/3-1s/6x N=6								

NO	TGL	LV 1	LV 2	Flag
1	2 Maret 20	29	98	
2	3 Maret 20	29	98	
3	4 Maret 20	29	97	
4	5 Maret 20	29	97	
5	6 Maret 20	30	98	
6	7 Maret 20	30	99	
7	9 Maret 20	29	98	
8	10 Maret 20	30	98	
9	11 Maret 20	27	95	
10	12 Maret 20	28	95	
11	13 Maret 20	29	98	
12	14 Maret 20	30	97	
13	16 Maret 20	28	97	
14	17 Maret 20	28	98	
15	18 Maret 20	30	98	
16	19 Maret 20	28	97	
17	20 Maret 20	29	97	
18	21 Maret 20	28	98	
19	23 Maret 20	29	97	
20	24 Maret 20	27	95	
21	26 Maret 20	28	98	
22	27 Maret 20	28	97	
23	28 Maret 20	28	96	
24	30 Maret 20	28	96	
25	31 Maret 20	28	99	

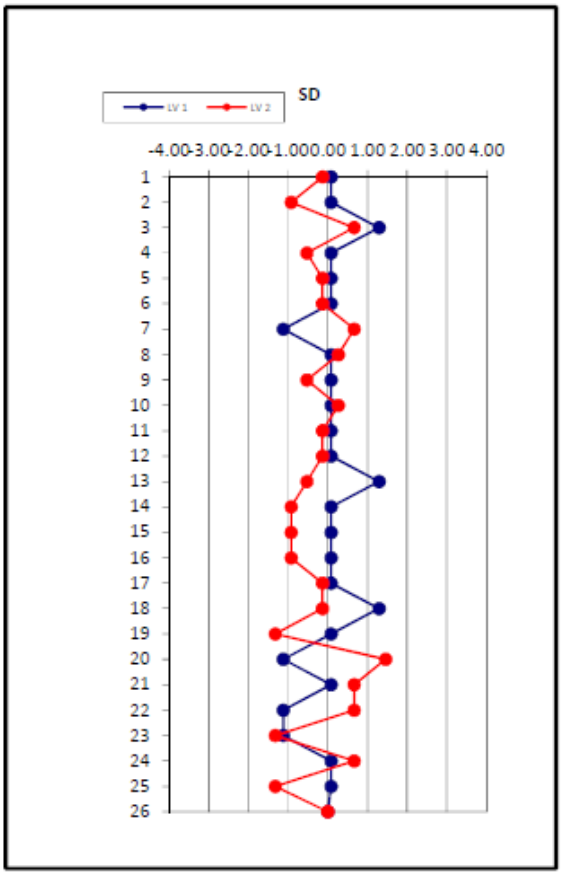


MEAN	28.64	97.24
SD	0.91	1.13
CV %	3.17	1.16
Bias	0.84	3.36
Bias (%)	2.85	3.34
% TE	9.19	5.66
Sigma	4.15	10.91

LAMPIRAN 5. Pemantapan Mutu Bahan Kontrol AST Bulan Februari 2020

TEST NAME	SGOT	BIORAD LEVEL 1			BIORAD LEVEL 2				
REAGENT	ABBOT	No.LOT 26461			No.LOT 26462				
METHOD	IFCC WITHOUT P5P	-3S	MEAN	+3S	-3S	MEAN	+3S	Tea (%)	15.2
INSTRUMENT	ALINITY	33.4	35.9	38.4	172.8	180.3	187.9	TE (Lev 1)	11.46
CONTROL LIMIT	Target Value	38.6			194.1			TE (Lev 2)	9.89
	Bias / (%)	2.64		6.84	13.77		7.09	UNIT	U/L
	SD / CV (%)	0.83		2.31	2.52		1.40		
	Sigma	3.62			5.80				
QC RULE	1-3s/2of3-2s/R4s/3-1s/6x N=6								

NO	TGL	LV 1	LV 2	Flag
1	1 feb 20	36	180	
2	3 Feb 20	36	178	
3	4 Feb 20	37	182	
4	5 Feb 20	36	179	
5	6 Feb 20	36	180	
6	7 Feb 20	36	180	
7	8 Feb 20	35	182	
8	10 Feb 20	36	181	
9	11 Feb 20	36	179	
10	12 Feb 20	36	181	
11	13 Feb 20	36	180	
12	14 Feb 20	36	180	
13	15 Feb 20	37	179	
14	17 Feb 20	36	178	
15	18 Feb 20	36	178	
16	19 Feb 20	36	178	
17	20 Feb 20	36	180	
18	21 Feb 20	37	180	
19	22 Feb 20	36	177	
20	24 Feb 20	35	184	
21	25 Feb 20	36	182	
22	26 Feb 20	35	182	
23	27 Feb 20	35	177	
24	28 Feb 20	36	182	
25	29 Feb 20	36	177	



MEAN	35.96	179.84
SD	0.54	1.86
CV %	1.50	1.04
Bias	2.61	14.26
Bias (%)	6.77	7.35
% TE	9.76	9.42
Sigma	5.63	7.58

LAMPIRAN 6. Kit Insert

Alinity c

Alanine Aminotransferase Reagent Kit

en
ALT
07P98
G71193R04
B7P980

Read Highlighted Changes: Revised February 2018.

REF 07P9820

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NAME

Alinity c Alanine Aminotransferase Reagent Kit (also referred to as ALT)

INTENDED USE

The Alinity c Alanine Aminotransferase assay is used for the quantitation of alanine aminotransferase in human serum or plasma on the Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Alanine Aminotransferase (ALT), also referred to as glutamate pyruvate transaminase (GPT), is an enzyme involved in amino acid metabolism. It is found in many tissues, but the highest levels are found in liver and kidney tissues. Tissue destruction leads to the release of the intracellular enzyme into the circulating blood. Markedly elevated serum ALT levels may be found in a variety of diseases which involve the liver, such as hepatitis, mononucleosis, and cirrhosis. These very high levels of ALT are not usually observed in other disease processes, e.g., myocardial infarction; thus, ALT is regarded as a reasonably specific indicator of liver disease.

PRINCIPLES OF THE PROCEDURE

ALT present in the sample catalyzes the transfer of the amino group from *L*-alanine to α-ketoglutarate, forming pyruvate and *L*-glutamate. Pyruvate in the presence of NADH and lactate dehydrogenase (LD) is reduced to *L*-lactate. In this reaction NADH is oxidized to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due to the oxidation of NADH to NAD.

Methodology: Enzymatic: NADH (without P-5'-P)

For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Alinity c Alanine Aminotransferase Reagent Kit 07P98

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	07P9820
Tests per cartridge	360
Number of cartridges per kit	10
Tests per kit	3600
R1	68.1 mL
R2	21.0 mL

R1 Active ingredients: β-NADH (0.16 mg/mL), Lactate dehydrogenase (2.57 U/mL), *L*-Alanine (392 mmol/L).

R2 Active ingredients: α-Ketoglutaric acid (77 mmol/L), *L*-Alanine (1000 mmol/L).

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[1-4]

The following warnings and precautions apply to R2*:	
Contains tris hydroxymethyl aminomethane.	
H316	Causes mild skin irritation.
Response	
P332+P313	If skin irritation occurs: Get medical advice / attention.

* Not applicable where regulation EU 1272/2008 (CLP) or OSHA Hazard Communication 29CFR 1910.1200 (HCS) 2012 have been implemented.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2-8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	27 days	
Opened	2-8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

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Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity c Alanine Aminotransferase assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay. Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

Specimen Types	Collection Tubes	Special Conditions
Serum	Serum tubes (with or without gel barriers)	
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin EDTA	Do not use ammonium heparin.[5]

Hemolysis in serum or plasma can increase test results.

CAUTION: Erythrocytes contain approximately 3 to 5 times more ALT than does serum.[6]

- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross-contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Specimen Storage

Numerous publications have defined storage conditions for ALT.[6-15] Examples are shown below.

Specimen Type	Temperature	Maximum Storage Time	Special Instructions
Serum/ Plasma	30°C	3 days[10]	Remove serum or plasma from the clot, red blood cells, or separator gel.
	2 to 8°C	7 days[10]	
	-40°C	60 days[15]	

It is recommended that specimens be assayed on the day of collection.[16, 17]

When samples were stored at -20°C for 8 days, an 11% reduction in ALT activity was observed; a 20% reduction in ALT activity was observed when specimens were stored at -20°C for 1 month.[18]

Avoid multiple freeze/thaw cycles.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

PROCEDURE

Materials Provided

07P98 Alinity c Alanine Aminotransferase Reagent Kit

Materials Required but not Provided

- Alinity c Alanine Aminotransferase assay file
- Commercially available controls containing alanine aminotransferase
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 5.3 µL.
    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.
- Refer to the commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Samples with an alanine aminotransferase value exceeding 3899 U/L are flagged with the code "> 3899 U/L" and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

The system performs a 1:5 dilution of the sample and automatically calculates the concentration by multiplying the result by the dilution factor.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the concentration of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is less than the lower value of the measuring interval of 5 U/L, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration is stable for approximately 27 days (648 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[19]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity c Alanine Aminotransferase assay utilizes the Factor data reduction method to generate a calibration curve and results. The calibration factor for the Alinity c Alanine Aminotransferase assay is 8141.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in U/L which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity c Alanine Aminotransferase assay is 5 to 3899 U/L.

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Range

Serum/Plasma[20, 21]

	Range (U/L)
Adult	0 to 55

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c analyzer, and the ARCHITECT c System and AEROSET System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 1 lot of Alinity c Alanine Aminotransferase Reagent Kit, water calibrator, and 1 lot of commercially available controls, and 1 instrument. Three controls were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.[22]

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	n	Mean (U/L)	SD	%CV	SD	%CV
Control Level 1	120	30	0.5	1.8	0.9	2.8
Control Level 2	120	138	0.7	0.6	1.0	1.0
Control Level 3	120	230	0.7	0.3	1.4	0.6

[a] Includes within-run, between-run, and between-day variability.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2 and was replicated on 3 reagent lots and 2 instruments over a minimum of 3 days on each instrument/reagent lot combination. The maximum observed Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) values are reported in the table.[23]

	U/L
LoB[a]	1
LoD[b]	2
LoQ[c]	5

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

Linearity

A study was performed based on guidance from CLSI EP06-A.[24]

This assay is linear across the measuring interval of 5 to 3899 U/L.

Interference

This study was performed on the AEROSET System.

Potentially Interfering Endogenous Substances

Interference studies were conducted using NCCLS EP7-P.[25] Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.

Potentially Interfering Substance	Interferent Level		Target U/L	Recovery (% of Target)
	Default Units	Alternate Units		
Bilirubin	30 mg/dL	513 µmol/L	53.1	95.3
	60 mg/dL	1026 µmol/L	53.1	88.1
Hemoglobin	750 mg/dL	7.5 g/L	47.4	107.9
	1000 mg/dL	10.0 g/L	47.4	111.0
Intralipid	550 mg/dL	5.5 g/L	50.6	97.2
	625 mg/dL	6.25 g/L	50.6	96.8

The following drugs were tested on the ARCHITECT system for interference at the concentrations indicated using an acceptance criteria of ± 10% from the target value.

Potentially Interfering Substance	Interferent Level		Target U/L	Recovery (% of Target)
	Default Units	Alternate Units		
Sulfapyridine	60 mg/L	241.0 µmol/L	43.1	95.1
Sulfasalazine	20 mg/L	50.3 µmol/L	43.1	92.8
Temozolomide	20 mg/L	103.1 µmol/L	58.2	105.0

Interferences from medications or endogenous substances may affect results.[26]

Method Comparison

A study was performed based on guidance from CLSI EP9-A3 using the Passing-Bablok regression method.[27]

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Alanine Aminotransferase vs ARCHITECT Alanine Aminotransferase	Serum	U/L	130	1.00	1.11	0.97	6-3727

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Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
DISTRIBUTED IN THE USA BY	Distributed in the USA by
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCED FOR ABBOTT BY	Produced for Abbott by
PRODUCT OF CANADA	Product of Canada
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

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Revised February 2018.

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Alinity c

Aspartate Aminotransferase Reagent Kit

en
AST
08P17
G71194R06
B8P170

Read Highlighted Changes: Revised February 2018.

REF 08P1720

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NAME

Alinity c Aspartate Aminotransferase Reagent Kit (also referred to as AST)

INTENDED USE

The Alinity c Aspartate Aminotransferase assay is used for the quantitation of aspartate aminotransferase in human serum or plasma on the Alinity c analyzer.

SUMMARY AND EXPLANATION OF THE TEST

Aspartate aminotransferase (AST), also referred to as glutamate oxaloacetate transaminase (GOT), is one of a group of enzymes which catalyzes the interconversion of amino acids and α-keto acids by transfer of amino groups. Both AST and alanine aminotransferase (ALT) are normally found in most body fluids, but not in urine except in instances of kidney lesions. The greatest concentrations of AST are found in heart, liver, muscle, and kidney tissues. Damage to these tissues can greatly elevate serum AST levels. Following myocardial infarction, AST in serum begins to increase within 6 to 8 hours of onset of pain, reaching a peak within 18 to 24 hours and falling to normal by the fourth or fifth day. Serum values may increase to 10 to 15 times normal levels and the increase is roughly proportional to the degree of tissue damage.[1, 2]

PRINCIPLES OF THE PROCEDURE

AST present in the sample catalyzes the transfer of the amino group from *L*-aspartate to α-ketoglutarate, forming oxaloacetate and *L*-glutamate. Oxaloacetate in the presence of NADH and malate dehydrogenase (MDH) is reduced to *L*-malate. In this reaction, NADH is oxidized to NAD. The reaction is monitored by measuring the rate of decrease in absorbance at 340 nm due to the oxidation of NADH to NAD.

Methodology: Enzymatic (NADH (without P-5'-P))

For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Alinity c Aspartate Aminotransferase Reagent Kit 08P17

Volumes (mL) listed in the table below indicate the volume per cartridge.

REF	08P1720
Tests per cartridge	360
Number of cartridges per kit	10
Tests per kit	3600
R1	68.1 mL
R2	21.0 mL

R1 Active ingredients: β-NADH (0.16 mg/mL), Malate Dehydrogenase (0.64 U/mL), Lactate Dehydrogenase (0.64 U/mL), *L*-Aspartate (232 mmol/L).

R2 Active ingredients: α-Ketoglutarate (51.3 mmol/L), *L*-Aspartate (100 mmol/L).

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[3-6]

The following warnings and precautions apply to: R2*	
H316	Causes mild skin irritation.
P332+P313	If skin irritation occurs: Get medical advice / attention.

* Not applicable where regulation EU 1272/2008 (CLP) or OSHA Hazard Communication 29CFR 1910.1200 (HCS) 2012 have been implemented.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Reagents are shipped refrigerated or on wet ice.
- Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	30 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

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Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 8°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Alinity c Aspartate Aminotransferase assay file must be installed on the Alinity c analyzer prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay. Other specimen types, collection tube types, and anticoagulants have not been verified with this assay.

Specimen Type	Collection Vessel	Special Conditions
Serum	Serum tubes (with or without gel barrier)	
Plasma	Collection tubes Acceptable anticoagulants are: Lithium heparin (with or without gel barrier) Sodium heparin	Do not use ammonium heparin.[7]

- The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- For accurate results, plasma specimens should be free of platelets and other particulate matter. Ensure centrifugation is adequate to remove platelets.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross-contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	20 to 25°C	4 days[8]
	2 to 8°C	7 days[8, 9]
	-20°C	12 weeks[8]

Avoid multiple freeze/thaw cycles.

Guder et al. suggest storage of frozen specimens at -20°C for no longer than the time intervals cited above.[8]

Each laboratory may establish a range around -20°C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

PROCEDURE

Materials Provided

08P17 Alinity c Aspartate Aminotransferase Reagent Kit

Materials Required but not Provided

- Alinity c Aspartate Aminotransferase assay file
- Commercially available controls containing aspartate aminotransferase
- Saline (0.85% to 0.90% NaCl) for specimen dilution

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 5.3 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.
- Refer to the commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Samples with an aspartate aminotransferase value exceeding 4202 U/L are flagged with the code "> 4202 U/L" and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

If using an automated dilution protocol, the system performs a dilution of the sample and automatically calculates the enzyme activity value by multiplying the result by the dilution factor. For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Manual Dilution Procedure

Dilute the sample with saline (0.85% to 0.90% NaCl).

The operator must enter the dilution factor in the Specimen or Control tab of the Create Order screen. The system will use this dilution factor to automatically calculate the enzyme activity value of the sample and report the result.

If the operator does not enter the dilution factor, the result must be manually multiplied by the appropriate dilution factor before reporting the result. If a diluted sample result is flagged indicating it is less than the lower value of the measuring interval of 3 U/L, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration is stable for approximately 30 days (720 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- Two levels of controls (normal and abnormal) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Commercial controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to "Basic QC Practices" by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[10]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Alinity c Aspartate Aminotransferase assay utilizes the Factor data reduction method to generate a calibration and results.

The calibration factor for the Alinity c Aspartate Aminotransferase assay is 8141.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Measuring Interval

Measuring interval is defined as the range of values in U/L which meets the limits of acceptable performance for linearity, imprecision, and bias.

The measuring interval of the Alinity c Aspartate Aminotransferase assay is 3 U/L to 4202 U/L.

LIMITATIONS OF THE PROCEDURE

Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS and SPECIFIC PERFORMANCE CHARACTERISTICS sections of this package insert.

EXPECTED VALUES

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Range

Serum/Plasma[11]

	Range (U/L)
Adult	5 to 34

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c analyzer, and the ARCHITECT c System and AEROSET System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c analyzer.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A2. Testing was conducted using 1 lot of the Alinity c Aspartate Aminotransferase Reagent Kit, 1 lot of commercially available controls and 1 instrument. Three controls and one human serum panel were assayed in a minimum of 2 replicates at 2 separate times per day on 20 different days.[12]

			Within-Run (Repeatability)		Within-Laboratory (Total)[a]	
Sample	n	Mean (U/L)	SD	%CV	SD	%CV
Control Level 1	120	42	0.5	1.2	0.6	1.4
Control Level 2	120	122	0.7	0.6	1.3	1.1
Control Level 3	120	251	0.8	0.3	1.4	0.6
Panel	119	177	0.7	0.4	0.8	0.5

[a] Includes within-run, between-run, and between-day variability.

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Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2. Testing was conducted using 3 lots of the Alinity c Aspartate Aminotransferase Reagent Kit on each of 2 instruments over a minimum of 3 days. The maximum observed Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) values are summarized below.[13]

	U/L
LoB[a]	1
LoD[b]	3
LoQ[c]	3

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ was determined from n ≥ 60 replicates of low-analyte level samples and is defined as the lowest concentration at which a maximum allowable precision of 20 %CV was met.

Linearity

A study was performed based on guidance from CLSI EP06-A.[14] This assay is linear from 3 to 4202 U/L.

Interference

This study was performed on the AEROSET System.

Potentially Interfering Endogenous Substances

Interference studies were conducted using NCCLS EP7-P. Interference effects were assessed by Dose Response and Paired Difference methods, at the medical decision level of the analyte.[15]

Potentially Interfering Substance	Interferent Level		Target Level (U/L)	Recovery (% of Target)
	Default Units	Alternate Units		
Bilirubin	30 mg/dL	513 µmol/L	72.2	95.8
	60 mg/dL	1026 µmol/L	72.2	91.9
Hemoglobin	62 mg/dL	0.62 g/L	64.5	105.7
	125 mg/dL	1.25 g/L	64.5	111.6
Intralipid	550 mg/dL	5.5 g/L	69.0	95.4
	625 mg/dL	6.25 g/L	69.0	103.9

The following drugs were tested on the ARCHITECT system for interference at the concentrations indicated using an acceptance criteria of ± 10% from the target value.

Potentially Interfering Substance	Interferent Level		Target Level (U/L)	Recovery (% of Target)
	Default Units	Alternate Units		
Sulfapyridine	300 mg/L	1204.8 µmol/L	14.4	101.2
Sulfasalazine	300 mg/L	753.8 µmol/L	14.4	98.4
Temozolomide	20 mg/L	103.1 µmol/L	35.9	106.0

Interferences from medication or endogenous substances may affect results.[16]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3 using the Passing-Bablok regression method.[17]

		Units	n	Correlation Coefficient	Intercept	Slope	Concentration Range
Alinity c Aspartate Aminotransferase vs ARCHITECT Aspartate Aminotransferase	Serum	U/L	114	1.00	0.15	0.96	4 - 4025

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Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
DISTRIBUTED IN THE USA BY	Distributed in the USA by
INFORMATION FOR USA ONLY	Information needed for United States of America only
PRODUCED FOR ABBOTT BY	Produced for Abbott by
PRODUCT OF JAPAN	Product of Japan
R1	Reagent 1
R2	Reagent 2
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

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LAMPIRAN 7. Kaji Etik

KOMISI ETIK PENELITIAN KESEHATAN
HEALTH RESEARCH ETHICS COMMITTEE
POLTEKKES KEMENKES BANDUNG
MINISTRY OF HEALTH, BANDUNG HEALTH POLYTHECHNIC

KETERANGAN LAYAK ETIK
DESCRIPTION OF ETHICAL APPROVAL
"ETHICAL APPROVAL"

No. 24/KEPK/EC/V/2020

Protokol penelitian yang diusulkan oleh
The research protocol proposed by

Peneliti utama : Ridi Nurfitria
Principal In Investigator

Nama Institusi : Poltekkes Kemenkes Bandung
Name of the Institution

Dengan judul:
Title

"PENETAPAN NILAI RUJUKAN AKTIVITAS AST DAN ALT USIA DEWASA DI LABORATORIUM KLINIK PRAMITA"

"ESTABLISHMENT REFERENCE INTERVALS OF AST AND ALT ACTIVITIES IN ADULT AT PRAMITA CLINICAL LABORATORY"

Dinyatakan layak etik sesuai 7 (tujuh) Standar WHO 2011, yaitu 1) Nilai Sosial, 2) Nilai Ilmiah, 3) Pemerataan Beban dan, 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 14 Mei 2020 sampai dengan tanggal 14 Mei 2021
This declaration of ethics applies during the period May 14th, 2020 until May 14th, 2021.

May 14th , 2020
Professor and Chairperson,

KEMENTERIAN KESEHATAN RI
KOMITE ETIK PENELITIAN KESEHATAN
POLTEKKES BANDUNG

Dr. Suparman, SKM., M.Sc