RANDOX 0086 CE

CONTRÔLE DE CHIMIE TITRÉE LIQUIDE PREMIUM - NIVEAU 3 (LIQ CHEM ASY PREMIUM 3)

N° CAT. LAE 4217 **N° LOT** 1021UE
TAILLE : 12 x 5 ml **EXPIRATION :** 28/06/2020

GTIN : 05055273208993

UTILISATION PRÉVUE
Ce produit est prévu pour une utilisation diagnostique *in-vitro* dans le contrôle de la qualité des tests de diagnostic. Le contrôle de chimie titrée liquide Premium est destiné au contrôle de la précision.

DESCRIPTION DU DISPOSITIF
Le contrôle de chimie titrée liquide Premium est fourni sur 2 niveaux : les niveaux 2 et 3. Les valeurs cibles et les plages sont fournies pour les analytes répertoriés dans la section sur les valeurs en 2 niveaux.

PRÉCAUTIONS DE SÉCURITÉ ET MISES EN GARDE
Réservé au diagnostic *in vitro*. Ne pas pipeter à la bouche. Observer les précautions habituelles requises pour manipuler les réactifs de laboratoire.

Le matériel d'origine humaine dont est issu ce produit a été testé chez des donneurs possédant des anticorps du virus VIH (VIH 1, VIH 2), un antigène de surface de l'hépatite B (HbsAg) et des anticorps du virus de l'hépatite C (HCV) et s'est avéré NON RÉACTIF. Des méthodes approuvées par la FDA ont été utilisées pour effectuer ces tests.
Cependant, étant donné qu'aucune méthode ne peut offrir une assurance complète de l'absence d'agents infectieux, ce matériel et tous les échantillons de patients doivent être manipulés comme des produits potentiellement infectieux et éliminés en conséquence.

Des fiches de données sur la santé et la sécurité sont disponibles sur demande.

STOCKAGE ET STABILITÉ
APRÈS OUVERTURE : Conserver dans un endroit réfrigéré (entre +2 °C et +8 °C). Le sérum décongelé est stable pendant 7 jours entre +2 °C et +8 °C, avec les exceptions suivantes : La troponine T est stable pendant 3 jours entre +2 °C et +8 °C. Seule la quantité de produit requise doit être prélevée. Après utilisation, le produit résiduel NE DOIT PAS ÊTRE REPLACÉ dans le flacon d'origine.

AVANT OUVERTURE : Stocker gelé entre -20 °C et -70 °C. Stable jusqu'à la date d'expiration imprimée sur les flacons individuels (voir Restrictions).

RESTRICTIONS
Pour la phosphatase acide totale, le matériel doit être stabilisé en ajoutant 1 goutte (25 - 30 µl) de solution d'acide acétique à 0,7M à 1 ml de sérum après décongélation. Après la stabilisation, la phosphatase acide totale est stable pendant 1 jour entre +2 °C et +8 °C.
La bilirubine dans le sérum est sensible à la lumière. Il est recommandé de conserver le sérum dans l'obscurité.
Les valeurs d'ALT, de phosphatase acide totale, de phosphatase alcaline et de bilirubine totale et directe peuvent diminuer progressivement pendant la durée de conservation du produit.
La contamination bactérienne du sérum décongelé provoquera une réduction de la stabilité de nombreux composants.
Le contrôle ne doit pas être utilisé comme matériel d'étalonnage.

PRÉPARATION
1. Laisser le contrôle congelé décongeler à température ambiante (entre +15 °C et +25 °C) jusqu'à décongélation complète. Secouer les contenus pour garantir son homogénéité.
2. Consulter la section sur le contrôle de l'application d'analyseur individuel.
3. Réfrigérer tout matériel inutilisé. Avant toute réutilisation, mélanger soigneusement les contenus.

MATÉRIEL FOURNI
Contrôle de chimie titrée liquide Premium, Niveau 3 12 x 5 ml

MATÉRIEL REQUIS MAIS NON FOURNI
Aucun.

VALEURS ASSIGNÉES
Chaque lot de sérum est soumis à plusieurs laboratoires externes. Les valeurs sont assignées à partir d'un consensus de résultats obtenus par ces laboratoires et les tests internes conduits au sein de Randox Laboratories Ltd. Chaque lot de plage de contrôle est donné pour des paramètres individuels et chaque méthode de paramètres.

Si une valeur spécifique à un instrument n'est pas disponible, se reporter à la Moyenne de toutes les sections sur les instruments. Si nécessaire, contacter Laboratoires Randox - Services techniques, Irlande du Nord, par téléphone au : +44 (0) 28 9445 1070 envoyer un e-mail à Technical.Services@randox.com.

31 Oct 19 bm

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	28.4	24.1	32.7	2.15	4.30	Bromocresol Green
	g/dl	2.84	2.41	3.27	0.22	0.43	
Alkaline Phosphatase	U/l	370	315	425	27.50	55.00	AMP optimised to IFCC 37℃
ALT (GPT)	U/l	133	106	160	13.50	27.00	Tris buffer without P5P 37℃
Amylase Total	U/l	275	234	316	20.50	41.00	Beckman Coulter - blocked pNPG7 37℃
AST (GOT)	U/l	145	116	174	14.50	29.00	Tris buffer without P5P 37℃
Bicarbonate	mmol/l	29.8	23.6	36.0	3.10	6.20	Enzymatic
Bilirubin Direct	µmol/l	24.5	19.4	29.6	2.55	5.10	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.43	1.13	1.73	0.15	0.30	
Bilirubin Total	µmol/l	85.1	67.2	103	8.95	17.90	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.98	3.93	6.03	0.53	1.05	
Calcium	mmol/l	3.04	2.74	3.34	0.15	0.30	Cresolphthalein complexone
	mg/dl	12.2	11.0	13.4	0.60	1.20	
	mmol/l	2.91	2.62	3.20	0.15	0.29	Arsenazo III
	mg/dl	11.7	10.5	12.9	0.60	1.20	
Chloride	mmol/l	115	106	123	4.35	8.70	ISE indirect
Cholesterol	mmol/l	6.78	5.90	7.66	0.44	0.88	Cholesterol Oxidase
	mg/dl	262	228	296	17.00	34.00	
CK Total	U/l	577	473	681	52.00	104.00	CK-NAC (IFCC) 37℃
Creatinine	µmol/l	358	286	430	36.00	72.00	Jaffe rate blanked
	mg/dl	4.05	3.23	4.87	0.41	0.82	

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Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
gamma-GT	U/l	167	142	192	12.50	25.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37℃
Glucose	mmol/l	14.8	12.6	17.0	1.10	2.20	Hexokinase
	mg/dl	267	227	307	20.00	40.00	
Iron	µmol/l	35.9	29.4	42.4	3.25	6.50	Colorimetric without ppt.
	µg/dl	201	164	238	18.50	37.00	
LD (LDH)	U/l	354	301	407	26.50	53.00	L->P IFCC 37℃
	U/l	762	648	876	57.00	114.00	P->L Scandinavian & Dutch 37℃
Magnesium	mmol/l	1.68	1.48	1.88	0.10	0.20	Xylidyl Blue
	mg/dl	4.08	3.60	4.56	0.24	0.48	
Phosphate Inorganic	mmol/l	2.30	1.96	2.64	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.13	6.08	8.18	0.53	1.05	
Potassium	mmol/l	6.04	5.56	6.52	0.24	0.48	ISE indirect
Protein Total	g/l	43.3	34.6	52.0	4.35	8.70	Biuret reaction end point
	g/dl	4.33	3.46	5.20	0.44	0.87	
Sodium	mmol/l	157	149	165	4.00	8.00	ISE indirect
Triglycerides	mmol/l	3.00	2.52	3.48	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	266	223	309	21.50	43.00	
Urea	mmol/l	19.1	16.2	22.0	1.45	2.90	Urease kinetic
	mg/dl	115	97.4	133	8.80	17.60	
	mmol/l	19.1	16.2	22.0	1.45	2.90	BUN
	mg/dl	53.6	45.6	61.6	4.00	8.00	
Uric Acid (Urate)	mmol/l	0.56	0.49	0.63	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.36	8.15	10.6	0.61	1.21	

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MEAN OF ALL INSTRUMENTS (Elec.)

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin (electrophoresis)		62.0	55.9	68.1	3.05	6.10	% of total Protein (Beckman Capillary)
alpha-1-globulin		6.4	4.9	7.9	0.77	1.54	% of total Protein (Beckman Capillary)
alpha-2-globulin		7.7	5.9	9.6	0.93	1.85	% of total Protein (Beckman Capillary)
beta-globulin		11.5	8.7	14.3	1.38	2.76	% of total Protein (Beckman Capillary)
gamma-globulin		12.4	9.4	15.4	1.49	2.98	% of total Protein (Beckman Capillary)

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ASSAYED HUMAN SERA LEVEL 3

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			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Acid Phosphatase (Total)	U/l	30.8	20.6	41.0	5.10	10.20	1-Naphthyl Phosphate substrate Kinetic 37℃
Albumin	g/l	28.4	24.1	32.7	2.15	4.30	Bromocresol Green
	g/dl	2.84	2.41	3.27	0.22	0.43	
	g/l	25.5	21.7	29.3	1.90	3.80	Bromocresol Purple
	g/dl	2.55	2.17	2.93	0.19	0.38	
Alkaline Phosphatase	U/l	362	308	416	27.00	54.00	AMP optimised to IFCC 37℃
	U/l	282	240	324	21.00	42.00	AMP optimised to IFCC 30℃
	U/l	231	197	265	17.00	34.00	AMP optimised to IFCC 25℃
	U/l	568	483	653	42.50	85.00	Diethanolamine buffer DEA 37°C
	U/l	442	376	508	33.00	66.00	Diethanolamine buffer DEA 30°C
	U/l	363	309	417	27.00	54.00	Diethanolamine buffer DEA 25°C
Alpha-1-Acid Glycoprotein	g/l	0.29	0.23	0.35	0.03	0.06	Immunoturbidimetric
	mg/dl	29.3	23.4	35.2	2.95	5.90	
Alpha-1-Antitrypsin	g/l	0.72	0.57	0.86	0.07	0.14	Immunoturbidimetric
	mg/dl	71.7	57.4	86.0	7.15	14.30	
Alphafoetoprotein	KIU/l =	1.06	0.85	1.27	0.11	0.21	Roche Cobas E411
	ng/ml	1.28	1.03	1.53	0.13	0.25	
ALT (GPT)	U/l	168	134	202	17.00	34.00	Tris buffer with P5P 37℃
	U/l	124	99	149	12.50	25.00	Tris buffer with P5P 30℃
	U/l	95	75	115	10.00	20.00	Tris buffer with P5P 25℃
	U/l	144	115	173	14.50	29.00	Tris buffer without P5P 37℃
	U/l	107	85	129	11.00	22.00	Tris buffer without P5P 30℃
	U/l	81	65	97	8.00	16.00	Tris buffer without P5P 25℃

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Amylase Pancreatic	U/l	263	224	302	19.50	39.00	Randox Liquid Ethylidene pNPG7 37℃
	U/l	230	196	264	17.00	34.00	Roche liquid stable pNPG7 37°C
	U/l	257	218	296	19.50	39.00	Immunoinhibition EPS substrate 37℃
Amylase Total	U/l	275	234	316	20.50	41.00	Beckman Coulter - blocked pNPG7 37℃
	U/l	251	213	289	19.00	38.00	Roche liquid stable pNPG7 37°C
	U/l	288	245	331	21.50	43.00	Randox Liquid Ethylidene pNPG7 37℃
	U/l	278	236	320	21.00	42.00	Siemens - blocked pNPG7 37℃
	U/l	323	275	371	24.00	48.00	Siemens 2-chloro-pNPG3 37℃
	U/l	213	181	245	16.00	32.00	Randox Lyo. Ethylidene pNPG7 37℃
Apolipoprotein A-1	g/l	0.84	0.69	0.99	0.08	0.15	Immunoturbidimetric
	mg/dl	84.0	68.9	99.1	7.55	15.10	
Apolipoprotein B	g/l	0.56	0.46	0.66	0.05	0.10	Immunoturbidimetric
	mg/dl	56.0	45.9	66.1	5.05	10.10	
AST (GOT)	U/l	192	154	230	19.00	38.00	Tris buffer with P5P 37℃
	U/l	130	104	156	13.00	26.00	Tris buffer with P5P 30℃
	U/l	91	73	109	9.00	18.00	Tris buffer with P5P 25℃
	U/l	154	123	185	15.50	31.00	Tris buffer without P5P 37℃
	U/l	104	83	125	10.50	21.00	Tris buffer without P5P 30℃
	U/l	73	59	87	7.00	14.00	Tris buffer without P5P 25℃
Bicarbonate	mmol/l	29.7	23.6	35.8	3.05	6.10	Enzymatic
Bile Acids	µmol/l	39.4	31.5	47.3	3.95	7.90	4th Generation Colorimetric
	µmol/l	40.3	32.2	48.4	4.05	8.10	5th Generation Colorimetric
Bilirubin Direct	µmol/l	29.8	23.5	36.1	3.15	6.30	Oxidation to Biliverdin/Vanadate
	mg/dl	1.74	1.37	2.11	0.19	0.37	

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Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Direct	µmol/l	31.9	25.2	38.6	3.35	6.70	Diazo with Sulphanilic Acid
	mg/dl	1.87	1.47	2.27	0.20	0.40	
	µmol/l	30.6	24.2	37.0	3.20	6.40	Modified Jendrassik
	mg/dl	1.79	1.42	2.16	0.19	0.37	
Bilirubin Total	µmol/l	83.7	66.1	101	8.80	17.60	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.90	3.87	5.93	0.52	1.03	
	µmol/l	82.7	65.3	100	8.70	17.40	Diazo with Sulphanilic Acid
	mg/dl	4.84	3.82	5.86	0.51	1.02	
	µmol/l	86.6	68.4	105	9.10	18.20	Diazo with Dichloroaniline (DCA)
	mg/dl	5.07	4.00	6.14	0.54	1.07	
	µmol/l	91.2	72.0	110	9.60	19.20	Oxidation to Biliverdin/Vanadate
	mg/dl	5.34	4.21	6.47	0.57	1.13	
	µmol/l	92.9	73.4	112	9.75	19.50	Modified Jendrassik
	mg/dl	5.43	4.29	6.57	0.57	1.14	
C-Reactive Protein	mg/l	5.23	4.18	6.28	0.53	1.05	Immunoturbidimetric
Caeruloplasmin	g/l	0.209	0.157	0.261	0.03	0.05	Immunoturbidimetric
	mg/dl	20.9	15.7	26.1	2.60	5.20	
Calcium	mmol/l	3.04	2.74	3.34	0.15	0.30	Cresolphthalein complexone
	mg/dl	12.2	11.0	13.4	0.60	1.20	
	mmol/l	3.01	2.71	3.31	0.15	0.30	NM-BAPTA
	mg/dl	12.1	10.9	13.3	0.60	1.20	
	mmol/l	2.99	2.69	3.29	0.15	0.30	Arsenazo III
	mg/dl	12.0	10.8	13.2	0.60	1.20	
Carbamazepine	µmol/l	62.6	50.1	75.1	6.25	12.50	Immunoturbidimetric
	µg/ml	14.8	11.8	17.8	1.50	3.00	

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Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Carcinoembryonic Antigen (CEA)	ng/ml =	0.86	0.69	1.03	0.09	0.17	Roche Cobas E411
Chloride	mmol/l	108	99.5	117	4.35	8.70	Colorimetric
	mmol/l	115	106	124	4.50	9.00	ISE indirect
	mmol/l	114	105	123	4.50	9.00	ISE direct
Cholesterol	mmol/l	6.98	6.07	7.89	0.46	0.91	Cholesterol Oxidase
	mg/dl	269	234	304	17.50	35.00	
Cholinesterase	U/l	4817	3854	5780	481.50	963.00	Colorimetric Butyrylthiocholine 37℃
CK Total	U/l	565	463	667	51.00	102.00	CK-NAC (IFCC) 37℃
	U/l	354	290	418	32.00	64.00	CK-NAC (IFCC) 30℃
	U/l	240	197	283	21.50	43.00	CK-NAC (IFCC) 25℃
	U/l	547	449	645	49.00	98.00	CK-NAC substrate start (DGKC) 37℃
	U/l	342	281	403	30.50	61.00	CK-NAC substrate start (DGKC) 30℃
	U/l	232	191	273	20.50	41.00	CK-NAC substrate start (DGKC) 25℃
Complement C3	g/l	0.67	0.53	0.80	0.07	0.13	Immunoturbidimetric
	mg/dl	66.5	53.2	79.8	6.65	13.30	
Complement C4	g/l	0.15	0.12	0.18	0.01	0.03	Immunoturbidimetric
	mg/dl	14.6	11.7	17.5	1.45	2.90	
Copper	µmol/l	26.4	21.1	31.7	2.65	5.30	Colorimetric
	µg/dl	168	134	202	17.00	34.00	
Cortisol	nmol/l	975	731	1219	122.00	244.00	Roche Cobas E411
	µg/dl	35.1	26.3	43.9	4.40	8.80	
Creatinine	µmol/l	351	281	421	35.00	70.00	Alkaline picrate no deproteinization
	mg/dl	3.97	3.18	4.76	0.40	0.79	
	µmol/l	358	286	430	36.00	72.00	Jaffe rate blanked
	mg/dl	4.05	3.23	4.87	0.41	0.82	

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Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Creatinine	µmol/l	361	289	433	36.00	72.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.08	3.27	4.89	0.41	0.81	
	µmol/l	358	286	430	36.00	72.00	Enzymatic UV method
	mg/dl	4.05	3.23	4.87	0.41	0.82	
D-3-Hydroxybutyrate	mmol/l	1.05	0.89	1.21	0.08	0.16	Tris buffer 100mmol pH 8.5
Digoxin	nmol/l	3.70	2.96	4.44	0.37	0.74	Immunoturbidimetric
	ng/ml	2.89	2.31	3.47	0.29	0.58	
Ethanol	mg/dl	175	140	210	17.50	35.00	Enzyme Immunoassay
Ferritin	ng/ml =	33.3	26.6	40.0	3.35	6.70	Immunoturbidimetric
Folate	nmol/l	7.48	5.68	9.28	0.90	1.80	Roche Cobas 6000/8000
	ng/ml	3.30	2.50	4.10	0.40	0.80	
Free T3	pmol/l	18.7	14.0	23.4	2.35	4.70	Roche Cobas E411
	ng/dl	1.22	0.910	1.53	0.16	0.31	Roche Cobas E411
	pg/ml	12.2	9.11	15.3	1.55	3.09	Roche Cobas E411
Free T4	pmol/l	201	151	251	25.00	50.00	Roche Cobas E411
	ng/dl	15.7	11.8	19.6	1.95	3.90	Roche Cobas E411
	pg/ml	157	118	196	19.50	39.00	Roche Cobas E411
Gentamicin	µmol/l	15.9	12.7	19.1	1.60	3.20	Immunoturbidimetric
	µg/ml	7.60	6.07	9.13	0.77	1.53	
gamma-GT	U/l	172	146	198	13.00	26.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 37℃
	U/l	136	115	157	10.50	21.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 30℃
	U/l	106	90	122	8.00	16.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 25℃
	U/l	181	154	208	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37℃
	U/l	143	121	165	11.00	22.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30℃
	U/l	112	95	129	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25℃

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RANDOX

MEAN OF ALL INSTRUMENTS

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
GLDH	U/l	30	24	36	3.00	6.00	Triethanolamine buffer 50 mmol 37℃
	U/l	23	18	28	2.50	5.00	Triethanolamine buffer 50 mmol 30°C
	U/l	19	15	23	2.00	4.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	15.0	12.8	17.2	1.10	2.20	Hexokinase
	mg/dl	270	231	309	19.50	39.00	
	mmol/l	15.4	13.1	17.7	1.15	2.30	Glucose oxidase
	mg/dl	278	236	320	21.00	42.00	
Haptoglobin	g/l	0.62	0.50	0.74	0.06	0.12	Immunoturbidimetric
	mg/dl	62.0	49.6	74.4	6.20	12.40	
HDL - Cholesterol	mmol/l	3.19	2.71	3.67	0.24	0.48	Direct Clearance Method
	mg/dl	123	105	141	9.00	18.00	
Immunoglobulin A	g/l	1.25	0.94	1.56	0.16	0.31	Immunoturbidimetric
	mg/dl	125	93.8	156	15.60	31.20	
Immunoglobulin E	KIU/l =	38.8	31.0	46.6	3.90	7.80	Immunoturbidimetric
Immunoglobulin G	g/l	5.15	4.22	6.08	0.47	0.93	Immunoturbidimetric
	mg/dl	515	422	608	46.50	93.00	
Immunoglobulin M	g/l	0.60	0.48	0.72	0.06	0.12	Immunoturbidimetric
	mg/dl	60.0	48.0	72.0	6.00	12.00	
Iron	µmol/l	36.5	29.9	43.1	3.30	6.60	Colorimetric without ppt.
	µg/dl	204	167	241	18.50	37.00	
Lactate	mmol/l	5.16	4.23	6.09	0.47	0.93	Colorimetric Lactate Oxidase
	mg/dl	46.5	38.1	54.9	4.20	8.40	
LAP	U/l	13	11	16	1.20	2.40	NAGEL 37℃
LD (LDH)	U/l	762	648	876	57.00	114.00	P->L Scandinavian & Dutch 37℃
	U/l	550	468	632	41.00	82.00	P->L Scandinavian & Dutch 30°C
	U/l	386	329	443	28.50	57.00	P->L Scandinavian & Dutch 25°C

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MEAN OF ALL INSTRUMENTS

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
LD (LDH)	U/l	343	292	394	25.50	51.00	L->P IFCC 37℃
	U/l	248	211	285	18.50	37.00	L->P IFCC 30℃
	U/l	174	148	200	13.00	26.00	L->P IFCC 25℃
	U/l	734	624	844	55.00	110.00	P->L German methods 37℃
	U/l	530	451	609	39.50	79.00	P->L German methods 30℃
	U/l	372	316	428	28.00	56.00	P->L German methods 25℃
LDL - Cholesterol	mmol/l	2.40	2.04	2.76	0.18	0.36	Direct Clearance Method
	mg/dl	92.6	78.7	107	6.95	13.90	
Lipase	U/l	72	58	86	7.00	14.00	Randox Colorimetric 37℃
Lipoprotein (a)	mg/dl	11.1	8.88	13.3	1.11	2.22	Immunoturbidimetric
	nmol/l	24.1	19.3	28.9	2.40	4.80	
Lithium	mmol/l	2.02	1.78	2.26	0.12	0.24	Randox Colorimetric
	mg/dl	1.40	1.24	1.56	0.08	0.16	
Magnesium	mmol/l	1.70	1.50	1.90	0.10	0.20	Xylidyl Blue
	mg/dl	4.13	3.65	4.61	0.24	0.48	
	mmol/l	1.56	1.37	1.75	0.10	0.19	Methylthymol blue
	mg/dl	3.79	3.33	4.25	0.23	0.46	
Myoglobin	ng/ml =	302	211	393	45.50	91.00	Immunoturbidimetric
Osmolality	mOsm/kg	791	633	949	79.00	158.00	Freezing point depression
Paracetamol	mmol/l	0.52	0.41	0.62	0.05	0.10	Colorimetric
	mg/l	78.4	62.6	94.2	7.90	15.80	
Phenobarbital	µmol/l	206	164	247	20.80	41.60	Immunoturbidimetric
	µg/ml	47.7	38.0	57.4	4.85	9.70	

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Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Phenytoin	µmol/l	79.2	63.4	95.0	7.90	15.80	Immunoturbidimetric
	µg/ml	20.0	16.0	24.0	2.00	4.00	
Phosphate Inorganic	mmol/l	2.28	1.94	2.62	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.07	6.01	8.13	0.53	1.06	
Potassium	mmol/l	6.01	5.53	6.49	0.24	0.48	Enzymatic
	mmol/l	6.05	5.57	6.53	0.24	0.48	ISE indirect
	mmol/l	6.17	5.59	6.57	0.25	0.49	ISE direct
Prealbumin	g/l	0.14	0.11	0.17	0.01	0.03	Immunoturbidimetric
	mg/dl	14.0	11.2	16.8	1.40	2.80	
Prolactin	µU/ml	141	113	169	14.00	28.00	Roche Cobas E411
Protein Total	g/l	43.8	35.0	52.6	4.40	8.80	Biuret reaction end point
	g/dl	4.38	3.50	5.26	0.44	0.88	
PSA Total	ng/ml =	20.2	15.2	25.2	2.50	5.00	Roche Cobas E411
Salicylate	mmol/l	0.87	0.70	1.04	0.09	0.17	Gravimetric
	mg/dl	12.0	9.59	14.4	1.21	2.41	
Sodium	mmol/l	161	153	169	4.00	8.00	ISE direct
	mmol/l	157	149	165	4.00	8.00	ISE indirect
	mmol/l	156	148	164	4.00	8.00	Enzymatic
Theophylline	µmol/l	139	111	166	13.85	27.70	Gravimetric
	µg/ml	25.0	20.0	30.0	2.50	5.00	
Thyroid Stimulating Hormone	µU/ml =	11.9	9.52	14.3	1.19	2.38	Roche Cobas E411
TIBC	µmol/l	42.4	33.5	51.3	4.45	8.90	Randox Direct
	µg/dl	237	187	287	25.00	50.00	
Total Beta hCG	mU/ml=IU	259	207	311	26.00	52.00	Roche Cobas E411
	IU/ml	0.259	0.207	0.311	0.03	0.05	

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ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Total T3	nmol/l	4.37	3.28	5.46	0.55	1.09	Roche Cobas E411
	ng/ml	2.84	2.14	3.54	0.35	0.70	Roche Cobas E411
	ng/dl	284	214	354	35.00	70.00	Roche Cobas E411
Total T4	nmol/l	259	194	324	32.50	65.00	Roche Cobas E411
	µg/dl	20.2	15.1	25.3	2.55	5.10	Roche Cobas E411
	ng/ml	202	151	253	25.50	51.00	Roche Cobas E411
Transferrin	g/l	1.62	1.30	1.94	0.16	0.32	Immunoturbidimetric
	mg/dl	162	130	194	16.00	32.00	
Triglycerides	mmol/l	2.92	2.45	3.39	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	258	217	299	20.50	41.00	
Troponin T	ng/ml =	0.24	0.17	0.31	0.04	0.07	Roche Cobas E411
	ng/l = p	238	167	309	35.50	71.00	
Urea	mmol/l	19.1	16.2	22.0	1.45	2.90	Urease kinetic
	mg/dl	115	97.4	133	8.80	17.60	
	mmol/l	19.1	16.2	22.0	1.45	2.90	BUN
	mg/dl	53.6	45.6	61.6	4.00	8.00	
Uric Acid (Urate)	mmol/l	0.56	0.49	0.63	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.36	8.15	10.6	0.61	1.21	
	mmol/l	0.56	0.48	0.63	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.32	8.11	10.5	0.61	1.21	
	mmol/l	0.53	0.46	0.60	0.03	0.07	Spectrophotometric at 280-290
	mg/dl	8.93	7.76	10.1	0.59	1.17	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.21	8.01	10.4	0.60	1.20	
Valproic Acid	µmol/l	880	704	1056	88.00	176.00	Immunoturbidimetric
	µg/ml	127	102	152	12.50	25.00	

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MEAN OF ALL INSTRUMENTS

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Vancomycin	µmol/l	20.2	16.2	24.2	2.00	4.00	Gravimetric
	µg/ml	30.0	24.1	35.9	2.95	5.90	
Vitamin B12	pmol/l	195	156	234	19.50	39.00	Roche Cobas E411
	pg/ml	264	211	317	26.50	53.00	
Zinc	µmol/l	32.6	26.1	39.1	3.25	6.50	Colorimetric with deproteinisation
	µg/dl	213	170	256	21.50	43.00	

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ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	28.8	24.5	33.1	2.15	4.30	Bromocresol Green
	g/dl	2.88	2.45	3.31	0.22	0.43	
Alkaline Phosphatase	U/l	293	249	337	22.00	44.00	Roche Integra AMP buffer 37℃
	U/l	228	194	262	17.00	34.00	Roche Integra AMP buffer 30℃
	U/l	187	159	215	14.00	28.00	Roche Integra AMP buffer 25℃
ALT (GPT)	U/l	138	110	166	14.00	28.00	Tris buffer without P5P 37℃
	U/l	102	81	123	10.50	21.00	Tris buffer without P5P 30℃
	U/l	78	62	94	8.00	16.00	Tris buffer without P5P 25℃
Amylase Pancreatic	U/l	230	196	264	17.00	34.00	Roche liquid stable pNPG7 37°C
Amylase Total	U/l	251	213	289	19.00	38.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	152	122	182	15.00	30.00	Tris buffer without P5P 37℃
	U/l	103	82	124	10.50	21.00	Tris buffer without P5P 30℃
	U/l	72	58	86	7.00	14.00	Tris buffer without P5P 25℃
Bicarbonate	mmol/l	27.7	22.0	33.4	2.85	5.70	Enzymatic
Bilirubin Direct	µmol/l	32.4	25.6	39.2	3.40	6.80	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.90	1.50	2.30	0.20	0.40	
Bilirubin Total	µmol/l	80.8	63.8	97.8	8.50	17.00	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.73	3.73	5.73	0.50	1.00	
Calcium	mmol/l	3.01	2.71	3.31	0.15	0.30	NM-BAPTA
	mg/dl	12.1	10.9	13.3	0.60	1.20	
Chloride	mmol/l	113	104	122	4.40	8.80	ISE indirect

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			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	6.57	5.72	7.42	0.43	0.85	Cholesterol Oxidase
	mg/dl	254	221	287	16.50	33.00	
CK Total	U/l	575	472	678	51.50	103.00	CK-NAC (IFCC) 37℃
	U/l	360	295	425	32.50	65.00	CK-NAC (IFCC) 30℃
	U/l	244	201	287	21.50	43.00	CK-NAC (IFCC) 25℃
Creatinine	µmol/l	361	289	433	36.00	72.00	Roche Creatinine Plus
	mg/dl	4.08	3.27	4.89	0.41	0.81	
gamma-GT	U/l	177	150	204	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37℃
	U/l	139	118	160	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30℃
	U/l	109	93	125	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25℃
Glucose	mmol/l	14.8	12.6	17.0	1.10	2.20	Hexokinase
	mg/dl	267	227	307	20.00	40.00	
Iron	µmol/l	36.8	30.2	43.4	3.30	6.60	Colorimetric without ppt.
	µg/dl	206	169	243	18.50	37.00	
Magnesium	mmol/l	1.64	1.44	1.84	0.10	0.20	Xylidyl Blue
	mg/dl	3.99	3.50	4.48	0.25	0.49	
Phosphate Inorganic	mmol/l	2.24	1.90	2.58	0.17	0.34	Phosphomolybdate UV
	mg/dl	6.94	5.89	7.99	0.53	1.05	
Potassium	mmol/l	6.08	5.59	6.57	0.25	0.49	ISE indirect
Protein Total	g/l	44.4	35.5	53.3	4.45	8.90	Biuret reaction end point
	g/dl	4.44	3.55	5.33	0.45	0.89	
Sodium	mmol/l	158	150	166	4.00	8.00	ISE indirect
Triglycerides	mmol/l	2.97	2.49	3.45	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	263	220	306	21.50	43.00	
Urea	mmol/l	18.6	15.8	21.4	1.40	2.80	Urease kinetic
	mg/dl	112	95.0	129	8.50	17.00	

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ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	18.6	15.8	21.4	1.40	2.80	BUN
	mg/dl	52.2	44.4	60.0	3.90	7.80	
Uric Acid (Urate)	mmol/l	0.56	0.49	0.63	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.39	8.16	10.6	0.62	1.23	

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ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	29.7	25.2	34.2	2.25	4.50	Bromocresol Green
	g/dl	2.97	2.52	3.42	0.23	0.45	
Alkaline Phosphatase	U/l	568	483	653	42.50	85.00	Diethanolamine buffer DEA 37°C
	U/l	375	319	431	28.00	56.00	AMP optimised to IFCC 37℃
ALT (GPT)	U/l	132	106	158	13.00	26.00	Tris buffer without P5P 37℃
Amylase Pancreatic	U/l	263	224	302	19.50	39.00	Randox Liquid Ethylidene pNPG7 37℃
Amylase Total	U/l	288	245	331	21.50	43.00	Randox Liquid Ethylidene pNPG7 37℃
AST (GOT)	U/l	153	122	184	15.50	31.00	Tris buffer without P5P 37℃
Bicarbonate	mmol/l	30.5	24.2	36.8	3.15	6.30	Enzymatic
Bile Acids	µmol/l	40.3	32.2	48.4	4.05	8.10	5th Generation Colorimetric
Bilirubin Direct	µmol/l	35.8	28.3	43.3	3.75	7.50	Diazo with Sulphanilic Acid
	mg/dl	2.09	1.66	2.52	0.22	0.43	
	µmol/l	31.7	25.0	38.4	3.35	6.70	Oxidation to Biliverdin/Vanadate
	mg/dl	1.85	1.46	2.24	0.20	0.39	
Bilirubin Total	µmol/l	85.9	67.9	104	9.00	18.00	Diazo with Sulphanilic Acid
	mg/dl	5.03	3.97	6.09	0.53	1.06	
	µmol/l	93.9	74.2	114	9.85	19.70	Oxidation to Biliverdin/Vanadate
	mg/dl	5.49	4.34	6.64	0.58	1.15	
Calcium	mmol/l	3.07	2.76	3.38	0.16	0.31	Arsenazo III
	mg/dl	12.3	11.1	13.5	0.60	1.20	
Chloride	mmol/l	114	105	123	4.50	9.00	ISE direct

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Size 12 x 5ml Expiry 2020-06-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Cholesterol	mmol/l	7.28	6.33	8.23	0.48	0.95	Cholesterol Oxidase
	mg/dl	281	244	318	18.50	37.00	
CK Total	U/l	587	481	693	53.00	106.00	CK-NAC (IFCC) 37℃
	U/l	547	449	645	49.00	98.00	CK-NAC substrate start (DGKC) 37℃
Creatinine	µmol/l	319	255	383	32.00	64.00	Alkaline picrate no deproteinization
	mg/dl	3.60	2.88	4.32	0.36	0.72	
	µmol/l	358	286	430	36.00	72.00	Enzymatic UV method
	mg/dl	4.05	3.23	4.87	0.41	0.82	
gamma-GT	U/l	172	146	198	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37℃
Glucose	mmol/l	15.0	12.8	17.2	1.10	2.20	Hexokinase
	mg/dl	270	231	309	19.50	39.00	
	mmol/l	15.9	13.5	18.3	1.20	2.40	Glucose oxidase
	mg/dl	287	243	331	22.00	44.00	
Iron	µmol/l	36.9	30.3	43.5	3.30	6.60	Colorimetric without ppt.
	µg/dl	206	169	243	18.50	37.00	
Lactate	mmol/l	5.16	4.23	6.09	0.47	0.93	Colorimetric Lactate Oxidase
	mg/dl	46.5	38.1	54.9	4.20	8.40	
LD (LDH)	U/l	734	624	844	55.00	110.00	P->L German methods 37℃
	U/l	345	293	397	26.00	52.00	L->P IFCC 37℃
Lipase	U/l	72	58	86	7.00	14.00	Randox Colorimetric 37℃
Lithium	mmol/l	2.02	1.78	2.26	0.12	0.24	Colorimetric
	mg/dl	1.40	1.24	1.56	0.08	0.16	
Magnesium	mmol/l	1.76	1.55	1.97	0.11	0.21	Xylidyl Blue
	mg/dl	4.28	3.77	4.79	0.26	0.51	
Phosphate Inorganic	mmol/l	2.32	1.97	2.67	0.18	0.35	Phosphomolybdate UV
	mg/dl	7.19	6.11	8.27	0.54	1.08	

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RANDOX

RX SERIES®

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Potassium	mmol/l	6.17	5.68	6.66	0.25	0.49	ISE direct
	mmol/l	6.01	5.53	6.49	0.24	0.48	Enzymatic
Protein Total	g/l	43.7	35.0	52.4	4.35	8.70	Biuret reaction end point
	g/dl	4.37	3.50	5.24	0.44	0.87	
Sodium	mmol/l	161	153	169	4.00	8.00	ISE direct
	mmol/l	156	148	164	4.00	8.00	Enzymatic
TIBC	µmol/l	42.4	33.5	51.3	4.45	8.90	Direct Colorimetric
	µg/dl	237	187	287	25.00	50.00	
Triglycerides	mmol/l	2.85	2.39	3.31	0.23	0.46	Lipase/GPO-PAP no correction
	mg/dl	252	212	292	20.00	40.00	
Urea	mmol/l	19.1	16.2	22.0	1.45	2.90	Urease kinetic
	mg/dl	115	97.4	133	8.80	17.60	
	mmol/l	19.1	16.2	22.0	1.45	2.90	BUN
	mg/dl	53.6	45.6	61.6	4.00	8.00	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.21	8.01	10.4	0.60	1.20	
	mmol/l	0.56	0.49	0.63	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.37	8.15	10.6	0.61	1.22	

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RANDOX

SIEMENS ATELLICA / ADVIA 1200/1650/1800/240 | ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28 **Range**

Analyte	unit	Target	low	high	1SD	2SD	methods
Albumin	g/l	26.7	22.7	30.7	2.00	4.00	Bromocresol Green
	g/dl	2.67	2.27	3.07	0.20	0.40	
Alkaline Phosphatase	U/l	373	317	429	28.00	56.00	AMP optimised to IFCC 37℃
ALT (GPT)	U/l	152	122	182	15.00	30.00	Tris buffer without P5P 37℃
Amylase Pancreatic	U/l	257	218	296	19.50	39.00	Immunoinhibition EPS substrate 37℃
Amylase Total	U/l	278	236	320	21.00	42.00	Siemens - blocked pNPG7 37℃
AST (GOT)	U/l	164	131	197	16.50	33.00	Tris buffer without P5P 37℃
Bilirubin Direct	µmol/l	27.8	22.0	33.6	2.90	5.80	Oxidation to Biliverdin/Vanadate
	mg/dl	1.63	1.29	1.97	0.17	0.34	
Bilirubin Total	µmol/l	88.4	69.8	107	9.30	18.60	Oxidation to Biliverdin/Vanadate
	mg/dl	5.17	4.08	6.26	0.55	1.09	
Calcium	mmol/l	3.13	2.82	3.44	0.16	0.31	Cresolphthalein complexone
	mg/dl	12.5	11.3	13.7	0.60	1.20	
	mmol/l	2.99	2.69	3.29	0.15	0.30	Arsenazo III
	mg/dl	12.0	10.8	13.2	0.60	1.20	
Cholesterol	mmol/l	7.29	6.34	8.24	0.48	0.95	Cholesterol Oxidase
	mg/dl	281	245	317	18.00	36.00	
CK Total	U/l	558	458	658	50.00	100.00	CK-NAC (IFCC) 37℃
Creatinine	µmol/l	361	289	433	36.00	72.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.08	3.27	4.89	0.41	0.81	
gamma-GT	U/l	173	147	199	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37℃

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SIEMENS ATELLICA / ADVIA 1200/1650/1800/240 | ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28 **Range**

Analyte	unit	Target	low	high	1SD	2SD	methods
Glucose	mmol/l	14.9	12.7	17.1	1.10	2.20	Glucose oxidase
	mg/dl	268	229	307	19.50	39.00	
	mmol/l	15.2	12.9	17.5	1.15	2.30	Hexokinase
	mg/dl	274	232	316	21.00	42.00	
Iron	µmol/l	38.4	31.5	45.3	3.45	6.90	Colorimetric without ppt.
	µg/dl	215	176	254	19.50	39.00	
Magnesium	mmol/l	1.71	1.50	1.92	0.11	0.21	Xylidyl Blue
	mg/dl	4.16	3.65	4.67	0.26	0.51	
Phosphate Inorganic	mmol/l	2.29	1.95	2.63	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.10	6.05	8.15	0.53	1.05	
Protein Total	g/l	44.7	35.8	53.6	4.45	8.90	Biuret reaction end point
	g/dl	4.47	3.58	5.36	0.45	0.89	
Triglycerides	mmol/l	3.01	2.53	3.49	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	266	224	308	21.00	42.00	
Urea	mmol/l	19.5	16.6	22.4	1.45	2.90	Urease kinetic
	mg/dl	117	99.8	134	8.60	17.20	
	mmol/l	19.5	16.6	22.4	1.45	2.90	BUN
	mg/dl	54.7	46.5	62.9	4.10	8.20	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.19	8.00	10.4	0.60	1.19	

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RANDOX

SIEMENS DIMENSION SERIES®

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	25.5	21.7	29.3	1.90	3.80	Bromocresol Purple
	g/dl	2.55	2.17	2.93	0.19	0.38	
Alkaline Phosphatase	U/l	329	280	378	24.50	49.00	AMP optimised to IFCC 37℃
ALT (GPT)	U/l	147	118	176	14.50	29.00	Siemens Dade Standard Non IFCC Correlated 37℃
Amylase Total	U/l	323	275	371	24.00	48.00	Siemens 2-chloro-pNPG3 37℃
AST (GOT)	U/l	168	134	202	17.00	34.00	Siemens Dade Standard Non IFCC Correlated 37℃
Bicarbonate	mmol/l	30.9	24.5	37.3	3.20	6.40	Enzymatic
Bilirubin Total	µmol/l	81.9	64.7	99.1	8.60	17.20	Diazo with Sulphanilic Acid
	mg/dl	4.79	3.78	5.80	0.51	1.01	
Calcium	mmol/l	2.94	2.65	3.23	0.15	0.29	Cresolphthalein complexone
	mg/dl	11.8	10.6	13.0	0.60	1.20	
Cholesterol	mmol/l	6.89	5.99	7.79	0.45	0.90	Dimension-Siemens reagents
	mg/dl	266	231	301	17.50	35.00	
CK Total	U/l	529	434	624	47.50	95.00	CK-NAC (IFCC) 37℃
Creatinine	µmol/l	383	306	460	38.50	77.00	Alkaline picrate no deproteinization
	mg/dl	4.33	3.46	5.20	0.44	0.87	
gamma-GT	U/l	205	174	236	15.50	31.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37℃
Glucose	mmol/l	15.0	12.8	17.2	1.10	2.20	Hexokinase
	mg/dl	270	231	309	19.50	39.00	
Iron	µmol/l	34.3	28.1	40.5	3.10	6.20	Colorimetric without ppt.
	µg/dl	192	157	227	17.50	35.00	

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SIEMENS DIMENSION SERIES®

ASSAYED HUMAN SERA LEVEL 3

Lot. No. 1021UE Cat. No. LAE4217

Size 12 x 5ml Expiry 2020-06-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
LD (LDH)	U/l	331	281	381	25.00	50.00	L->P IFCC 37℃
Magnesium	mmol/l	1.56	1.37	1.75	0.10	0.19	Methylthymol blue
	mg/dl	3.79	3.33	4.25	0.23	0.46	
Phosphate Inorganic	mmol/l	2.23	1.90	2.56	0.17	0.33	Phosphomolybdate UV
	mg/dl	6.91	5.89	7.93	0.51	1.02	
Protein Total	g/l	42.7	34.2	51.2	4.25	8.50	Biuret reaction end point
	g/dl	4.27	3.42	5.12	0.43	0.85	
Triglycerides	mmol/l	2.78	2.34	3.22	0.22	0.44	Lipase/GPO-PAP no correction
	mg/dl	246	207	285	19.50	39.00	
Urea	mmol/l	19.3	16.4	22.2	1.45	2.90	Urease kinetic
	mg/dl	116	98.6	133	8.70	17.40	
	mmol/l	19.3	16.4	22.2	1.45	2.90	BUN
	mg/dl	54.2	46.1	62.3	4.05	8.10	
Uric Acid (Urate)	mmol/l	0.53	0.46	0.60	0.03	0.07	Spectrophotometric at 280-290
	mg/dl	8.93	7.76	10.1	0.59	1.17	

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RANDOX

Avis urgent de sécurité sur le terrain

Randox Laboratories Ltd
55 Diamond Road, Crumlin
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Tél : +44 (0) 28 9445 1070

Date d'émission : 11 décembre 2019

Référence de la réclamation : REC430 **Type d'action** : Modification du dispositif

Détail sur les dispositifs concernés :

Nos systèmes de traçabilité indiquent que votre établissement est susceptible d'avoir reçu le produit suivant.

Nom du dispositif	Référence catalogue	GTIN	Numéro de lot	Date d'expiration	Date de fabrication
Contrôle de chimie clinique liquide	LAE4217	05055273208993	1021UE	30 juin 2020	21 oct. 2018

Motif de l'action :

Une erreur de transcription a été constatée dans la valeur colorimétrique de la lipase de Randox dans le contrôle de chimie clinique liquide, lot 1021UE. La cible et la plage mentionnées, 50 U/L (40 – 60), doivent être remplacées par 72 U/L (58 – 86).

Risque pour la santé :

Le contrôle hors plage peut entraîner un retard dans les résultats du patient.

Action à entreprendre :

- Mettez à jour les kits concernés avec les valeurs cibles appropriées fournies.
- Parlez du contenu de cet avis avec votre directeur médical.
- Complétez et renvoyez le formulaire de réponse 12187-QA à technical.services@randox.com dans les cinq jours ouvrables.

Formulaire n° 6307-TS
RÉVISION (10)
4 février 2019

Dernière impression : 11 décembre 2019

RANDOX

Avis urgent de sécurité sur le terrain

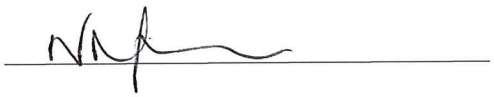
Randox Laboratories Ltd
55 Diamond Road, Crumlin
BT29 4QY, Royaume-Uni
technical.services@randox.com
Tél : +44 (0) 28 9445 1070

Transmission de l'avis de sécurité sur le terrain :

Envoyez une copie de l'avis de sécurité sur le terrain à tous les clients concernés, ainsi qu'au personnel concerné de votre entreprise .

Veuillez accepter nos excuses pour les gênes occasionnées. Merci de votre patience et de votre compréhension. Si vous avez des questions ou rencontrez des problèmes, veuillez contacter le service d'assistance technique de Randox.

Je soussigné confirme que cet avis a été notifié à l'agence réglementaire appropriée



Dernière impression : 11 décembre 2019

Formulaire n° 6307-TS
RÉVISION (10)
4 février 2019

RANDOX

Response Form

Randox Laboratories Ltd
55 Diamond Road, Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Please complete this form *even if you do not have any affected stock*.

Date Issued: 11 December 2019

Complaint Reference: REC430 **Action Type:** Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry Date	Manufacturing Date
Liquid Clinical Chemistry Control	LAE4217	05055273208993	1021UE	30 Jun 2020	21 Oct 2018

Please check ALL appropriate boxes.

- ❑ I have read and understand the instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and identified the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ Field Safety Notice is not applicable to my use of the product.

Indicate disposition of affected product:

- ❑ no affected stock
- ❑ returned (*specify quantity, date and method*)/held for return;
- ❑ destroyed (*specify quantity, date and method*);
- ❑ relabelled (*specify quantity and date*);
- ❑ quarantined pending correction (*specify quantity*);

Customer Details

Company Name	
Address	

RANDOX

Response Form

Randox Laboratories Ltd
55 Diamond Road, Crumlin
United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Total Quantity

Received	
Distributed	

Completed By	Print Name: Signature:	Date	
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@randox.com within five working days.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

RANDOX

Response Form

Randox Laboratories Ltd
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PART 2 (To be completed by Distributors and Randox Offices only)

Area of Distribution

- ❑ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*);

  OR

- ❑ Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

Have your customers notified you of any adverse events associated with recalled product?

- ❑ YES
- ❑ NO

If yes, please explain: _____