

Urea

Test strips for the determination of urea in blood, serum and plasma

Cat. No.	Package content
1 3129 99 90 350	60 Test strips

Principle

The test strip contains a reaction zone and an indicator zone with a scale. In the reaction zone, urea is specifically splitted into carbon dioxide and ammonia by urease. After diffusion through the gas phase, ammonia colours part of the pH indicator blue. The length of the blue zone depends on

$$\text{Urea concentration} - \text{temperature} - \text{reaction time}$$

The temperature and the reaction time are constant so that the length of the blue zone indicates the urea concentration directly.

Storage instructions for the test strips

The test strips can be used up to the expiry date if stored in a closed container below 30 °C.

Warnings and precautions

Take note of the necessary precautions for the handling with specimen.

Test strip preparation

The test strips are ready to use.

Specimen

Capillary blood, full blood, serum and plasma (heparin, oxalate and citrate are suitable for obtaining plasma while EDTA and fluoride are not suitable). Discard contaminated specimens!

Assay procedure

Application of the samples

By dipping in the test strip*	With a pipette
Dip the reaction zone into the liquid to be tested for 2 sec (do not wet the indicator zone!)	
On removal, wipe off excess liquid against the edge of the vessel.	
Place the test strip in the slider from above (Fig. 1)	
	Pipette 10 µL of the liquid to be tested onto the reaction zone (distribute evenly!)
Immediately push the slider containing the test strip, closed end and reaction zone first, into the cell (Fig. 2)	

* When capillary blood is used, ensure that the reaction zone is completely saturated.

Reaction conditions

Storage of the reaction vessel: Horizontal at constant temperature (avoid direct sunlight)
Temperature: approx. 22 °C
Reaction time: normal method 30 min.
 rapid method 10 min.
 emergency diagnosis 5 min.

Assessment

Emergency diagnosis

For rough estimation of the urea concentration in full blood, the length of the blue zone can be read after only 5 min. Lengths of 10 mm or more indicate concentrations of over 300 mg/dL (50 mmol/L) of urea equivalent to 140 mg/dL of urea-N.

Rapid method 10 min, approx. 22 °C*

Serum, Plasma				Full blood			
Blue zone	Urea		Urea-N	Blue zone	Urea		Urea-N
mm	mg/dL	mmol/L	mg/dL	mm	mg/dL	mmol/L	mg/dL
2	50	8	25	2	70	12	35
6	100	17	45	6	140	24	65
10	150	25	70	10	210	35	100
15	220	37	105	15	300	50	140
20	290	48	135	20	390	65	180

Normal method

30 min, approx. 22 °C*

Serum, Plasma				Full blood			
Blue zone	Urea		Urea-N	Blue zone	Urea		Urea-N
mm	mg/dL	mmol/L	mg/dL	mm	mg/dL	mmol/L	mg/dL
0.0	14	2	7	0.0	17	3	8
0.5	17	3	8	0.5	21	4	10
1.0	19	3	9	1.0	25	4	12
1.5	22	4	10	1.5	29	5	14
2.0	25	4	12	2.0	33	6	15
2.5	28	5	13	2.5	38	6	18
3.0	31	5	14	3.0	42	7	20
3.5	34	6	16	3.5	46	8	22
4.0	37	6	17	4.0	50	8	23
4.5	41	7	19	4.5	54	9	25
5.0	44	7	20	5.0	58	10	27
5.5	48	8	22	5.5	63	10	29
6.0	51	8	24	6.0	67	11	31
6.5	55	9	26	6.5	71	12	33
7.0	59	10	28	7.0	75	13	35
7.5	62	10	29	7.5	79	13	37
8.0	66	11	31	8.0	83	14	39
8.5	70	12	33	8.5	88	15	41
9.0	73	12	34	9.0	92	15	43
9.5	77	13	36	9.5	96	16	45
10.0	80	13	37	10.0	100	17	47
10.5	84	14	40	10.5	104	17	49
11.0	88	15	41	11.0	108	18	50
11.5	91	15	42	11.5	113	19	53
12.0	95	16	44	12.0	117	20	55
12.5	99	16	46	12.5	121	20	56
13.0	102	17	48	13.0	125	21	58
13.5	106	18	50	13.5	129	21	60
14.0	109	18	51	14.0	133	22	62
14.5	113	19	53	14.5	138	23	64
15.0	117	19	55	15.0	142	24	66
15.5	120	20	56	15.5	146	24	68
16.0	124	21	58	16.0	150	25	70
16.5	128	21	60	16.5	154	26	72
17.0	131	22	61	17.0	158	26	74
17.5	135	22	63	17.5	163	27	76
18.0	138	23	64	18.0	167	28	78
18.5	142	24	66	18.5	171	28	80
19.0	146	24	68	19.0	175	29	82
19.5	149	25	70	19.5	179	30	84
20.0	153	25	72	20.0	183	30	86
20.5	157	26	73	20.5	188	31	88
21.0	160	27	75	21.0	192	32	90
21.5	164	27	77	21.5	196	33	92
22.0	167	28	78	22.0	200	33	94
22.5	171	28	80	22.5	204	34	95
23.0	175	29	82	23.0	208	35	97
23.5	178	29	83	23.5	213	36	100
24.0	182	30	85	24.0	217	36	101
24.5	186	31	87	24.5	221	37	103

*Temperature correction factor

Temperature (°C)	14	16	18	20	25	27	29	31
Factor	1.2	1.15	1.1	1.05	0.95	0.9	0.85	0.8

Dilution limit

If the concentration exceeds the measuring range, the sample material can be diluted 1 + 2 with distilled water. The values obtained from the conversion table (normal method) must then be multiplied by 3.

Reference range

	Urea		Urea-N
	mg/dL	mmol/L	mg/dL
Serum	20 – 40	3.3 – 6.7	10 – 20
Full blood	18 - 36	3.0 – 6.0	9 - 18

Dependence of the normal range on protein intake

Protein intake g/kg body weight and day	Normal range urea (serum)	
	mg/dL	mmol/L
0.5	13 – 23	2.2 – 3.8
1.5	24 – 52	4.0 – 8.7
2.5	31 – 59	5.2 – 9.8

Literature

1. Richterich R, Colombo JP. In: Karger S, Klinische Chemie. 4 th edition. Basel: 1978, p. 323
2. F. Dunsbach, Seiffert UB. Prüfung von Merckognost Harnstoff unter Routinebedingungen. Med. Lab. 1974; 11: p. 263-65.
3. Appel W. Medizin 3, 1975; 9: p. 778 - 779

Performance characteristics

Measuring range

The test has been developed to determine Urea concentrations up to 180 mg/dL. When values exceed this range samples should be diluted 1+2 with distilled water and the result multiplied by 3.

Specificity

Because of the reaction principle the test is specific for urea.

Limit of detection

The lower limit of detection is 14 mg/dL.

Precision

Intra assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	24	2.22	9.39
Sample 2	83	3.22	3.87
Sample 3	127	3.04	2.39

Inter assay n = 20	Mean [mg/dL]	SD [mg/dL]	CV [%]
Sample 1	24	1.49	6.31
Sample 2	82	3.01	3.69
Sample 3	130	3.76	2.90

Method comparison

A comparison between DiaSys Urea Test strips (y) and the GLDH method (x) using 222 samples gave following results: $y = 1.00 x + 2.61$ mg/dL; $r = 0.981$.

Waste management

Please refer to the local legal requirements.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Evaluation

Scale divisions of the indicator zone: Millimeters with thicker lines for 0, 5, 10, 15, 20 mm. The bottom thick line indicates the zero line. Reading off: Read the transition from blue to yellow at the bottom of the meniscus (arrow in fig. 3).

Fig. 1

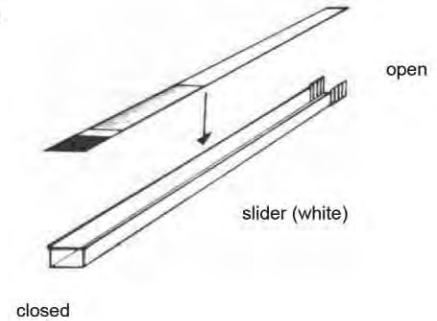


Fig. 2

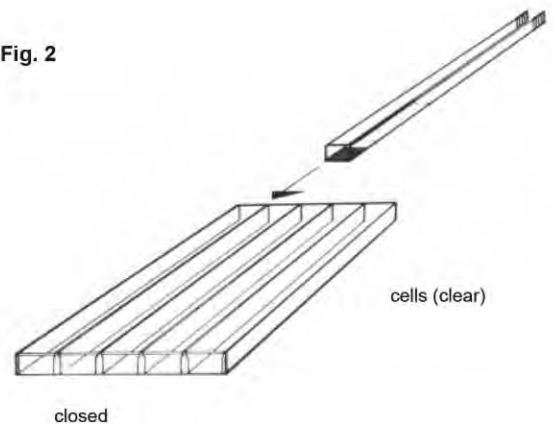
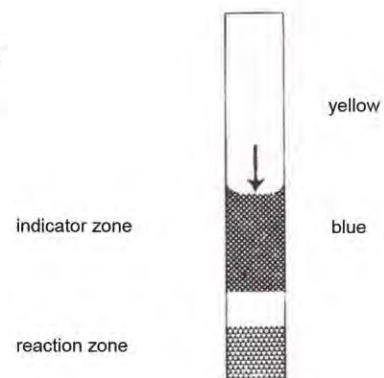


Fig. 3



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