

# DRIED URINE TEST SPECIFICATIONS

## Creatinine

### Clinical Information

Creatinine is a normal breakdown product of creatine phosphate in muscle. It is produced at a fairly predictable rate depending on gender, age, and muscle mass; men tend to produce more creatinine than women because of their larger skeletal muscle mass.

Urinary creatinine is used as a determinant of urine dilution, for example in urine drug tests, where levels below normal can indicate that the sample has been diluted to manipulate the test result. Inadequate fluid intake concentrates urine, giving higher than normal urinary creatinine, while diuretics such as coffee and tea dilute the urine and give lower creatinine levels. Urinary creatinine is therefore used in conjunction with tests for analytes in dried urine (e.g., elements and steroid metabolites) to correct for hydration status of the individual.

The reference range for urinary creatinine is 0.3-2.0 mg/mL.

### References:

Zava TT, Kapur S, Zava DT. Iodine and creatinine testing in urine dried on filter paper. *Anal Chim Acta* 2013;764:64-9.  
Kim HK, Lee SY, Lee JI, et al. Usefulness of iodine/creatinine ratio from spot-urine samples to evaluate the effectiveness of low-iodine diet preparation for radioiodine therapy. *Clin Endocrinol (Oxf)*. 2010;73:114-8.  
Barr DB, Wilder LC, Caudill SP, et al. Urinary creatinine concentrations in the U.S. population: implications for urinary biologic monitoring measurements. *Environ Health Perspect*. 2005;113:192-200.  
Knudsen N, Christiansen E, Brandt-Christensen M, et al. Age- and sex-adjusted iodine/creatinine ratio. A new standard in epidemiological surveys? Evaluation of three different estimates of iodine excretion based on casual urine samples and comparison to 24 h values. *Eur J Clin Nutr*. 2000;54:361-3.

### Assay Method: Colorimetric

#### Intra-assay Precision

Intra-assay precision was determined by choosing three dried urine samples spanning the reference range for creatinine, and analyzing them 20 times within the same run. Results are shown below:

Mean Creatinine Concentration (mg/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
0.40	0.02	3.8
1.66	0.05	3.2
2.60	0.08	3.0

#### Inter-assay Precision

Inter-assay precision was determined by choosing three samples spanning the reference range for creatinine, and analyzing them in 12 different runs. Results are shown below:

Mean Creatinine Concentration (mg/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
0.39	0.02	6.1
1.54	0.10	6.2
2.41	0.14	5.9

### Accuracy

To test the accuracy of the dried urine assay for creatinine, external urine controls containing known concentrations of creatinine were analyzed. An inter-laboratory comparison was also performed with matching samples. Results are shown below:

External Control	Expected Creatinine (mg/mL)	ZRT Creatinine (mg/mL)	Inter-Laboratory Comparison	Other Lab Result (mg/mL)	ZRT Result (mg/mL)
BioRad 376 Lyphocheck Level 1	0.8	0.79	Sample 1	1.18	1.12
BioRad 377 Lyphocheck Level 2	2.34	2.43	Sample 2	1.00	0.93
BioRad 397 Liquichek Level 1	0.638	0.63			
BioRad 398 Liquichek Level 2	1.49	1.35			

### Analyte Stability

The dried urine creatinine samples are stable for more than one month at room temperature and for more than six months when stored at  $-80^{\circ}\text{C}$ . Three freeze-thaw cycles did not cause a significant change in concentration.

### Specimen Collection

Kits for dried urine collection contain two (elements testing) or four (metabolites testing) filter paper collection strips, easy-to-follow instructions, and a mailer to return the sample for analysis.