TEST TRUE™ CREATININE ASSAY

INTENDED USE-LABORATORY ONLY

For the quantitative determination of creatinine in urine specimens as a means of detecting sample adulteration.

SUMMARY AND EXPLANATION OF ASSAY

TEST TRUE™ Creatinine Assay is for use on automatic analyzers to quantitatively determine the creatinine level of urine specimens submitted for Drugs-of-Abuse-Urine (DAU) Testing.

Modification of drug test results may be altered via dilution of the urine specimen, or "flushing" by the donor, prior to submitting the specimen. According to the Public Health Service Notice[1] (PD 035), the Administration's Drug Testing Advisory Board defines a urine specimen as being "DILUTE" if the creatinine concentration is <20 mg/dL AND the specific gravity is <1.003; and as being "SUBSTITUTED" if the creatinine concentration is ≤5 mg/dL AND the specific gravity is ≤1.001 or ≥1.020.

PRINCIPLE

TEST TRUE™ Creatinine Assay is a modified Jaffe[2] method in which the specimen reacts with hydroxide and picric acid to yield a colored complex read spectrophotometrically at 505 nm. The color intensity is proportional to the concentration of creatinine present to provide quantitative results.

Cat No.	Item
	Test True™ Creatinine Assay Kits
C-1250K	R1 & R2 Reagents and 0 & 2 mg/dL Calibrators
C-1260K	R1 & R2 Reagents and 0 & 20 mg/dL Calibrators
	REAGENTS
C-1250,C-1270	R1 Reagent & R2 Reagent
	CALIBRATORS
Z-1001,Z-1071	Zero Cal (0 mg/dL)
C-1251,C-1271	Creatinine Cal (20 mg/dL)
C-1252,C-1272	Creatinine Cal (5 mg/dL)
C-1253,C-1273	Creatinine Cal (400 mg/dL)
C-1254,C-1274	Creatinine Cal (2 mg/dL)
C-1255,C-1275	Creatinine Cal (500 mg/dL)
C-1256,C-1276	Creatinine Cal (100 mg/dL)
C-1257,C-1277	Creatinine Cal (200 mg/dL)
C-1258,C-1278	Creatinine Cal (300 mg/dL)

REAGENT COMPONENTS

TEST TRUE™ Creatinine Assay Reagents contain sodium hydroxide and picric acid.

PRECAUTIONS

1. TEST TRUE™ Creatinine Reagents are For Laboratory Use Only. May be harmful if inhaled or swallowed. Do not pipette by mouth.
2. Avoid contact with skin and eyes. In case of contact, flush area with water. Seek immediate medical attention for eyes.

PREPARATIONS OF WORKING REAGENTS

All reagents (NaOH and Picric Acid) and calibrators are ready for use upon receipt.

REAGENT STABILITY AND STORAGE

Unopened and opened reagents are stable until expiration date when stored tightly capped at room temperature. Reagents may also be stored tightly capped at 2-10º C. The stability of reagents stored uncapped on-board the analyzer may be affected in that environment. Axiom recommends capping on-board reagents when not in use. Controls and calibrators are stable until expiration date when stored tightly capped at 2-10º C.

INSTRUMENTATION

TEST TRUE™ Creatinine Reagents and Calibrators are for use on automated analyzers. Refer to instrument procedure instructions in the instrument manual provided with the specific analyzer.

SPECIMEN COLLECTION AND HANDLING

Use clean containers to collect urine specimens. Protect sample from heat and light. Testing may be performed on sample stored at room temperature for up to 96 hours but is best stored refrigerated at 2-10º C. [6]

Handle all urine samples as if potentially infectious!

QUALITY CONTROL

Store and handle all reagents and calibrators properly before and during use. Every laboratory should establish its own test requirements using 5-level controls. Axiom Diagnostics, Inc., provides a 5-level control set (Catalog No.s T-3001, T-3002, T-3003, T-3004 and T-3005) to meet your program needs and which conform to NLCP Guidelines[5].

ADDITIONAL REQUIRED MATERIALS NOT PROVIDED

Automated Analyzer or spectrophotometer. 5-level Controls.

SPECIFICITY, LIMITATIONS AND INTERFERENCES

The TEST TRUE™ Creatinine Assay is for the determination of creatinine in urine. The test is linear up to 300 mg/dL and is run without sample dilution.

TYPICAL PERFORMANCE CHARACTERISTICS

The following performance data was obtained using a Hitachi 717 Automated Analyzer. Other instruments may yield different performance data.

PRECISION

The following Within-Run and Run-to-Run results were obtained on a Hitachi 717 Analyzer using the TEST TRUE™ Creatinine Assay on samples containing creatinine at 3, 5, 20, and 300 mg/dL. The table below includes mean, standard deviation and 99% confidence interval for each value.

Within-Run (n =20):		Run-to-Run (n=20):	
Mean ± S.D. (mg/dL)	Conf (99%)	Mean ± S.D.(mg/dL)	Conf (99%)
3.00 ± 0.00	0.0000	3.00 ± 0.00	0.0000
5.00 ± 0.00	0.0000	5.00 ± 0.00	0.0000
20.00 ± 0.00	0.0000	20.44 ± 0.50	0.0014
307.00 ± 2.82	0.0079	304.29 ± 2.74	0.0077

EXPECTED VALUES

Creatinine is usually found in normal urine in amounts ranging from 22 mg/dL to 250 mg/dL[2]. Specimens with urine creatinine values of 20 mg/dL, or less, should be considered abnormal or diluted. By their oxidation in a strong base to colorless compounds, bilirubin and other hemoglobin degradation products may cause a negative bias, decreasing measured absorbance and is interpreted as a lower creatinine concentration.[3] Bacterial contamination may also produce falsely lower creatinine values using the Jaffe reaction.[4]

BIBLIOGRAPHY

1. Notice to HHS Certified and Applicant Laboratories. Subject: Guidance for Reporting Specimen Validity Test Results. Department of Health and Human Services. Public Health Service Notice PD 035. September 28, 1998.
2. Burtis, C.A. and E.R. Ashwood, Eds: Tietz Textbook of Clinical Chemistry, 2nd ed., Philadelphia, Saunders, 1994.
3. Weber, JA, van Zanten AP: Interferences in current methods for measurement of creatinine. Clin Chem 37:965-700, 1991.
4. Dilena, BA: Bacterial interference with measurement of creatinine in stored plasma. Clin Chem 34: 1007-1008, 1988.
5. National Laboratory Certification Program. General Laboratory Inspection Checklist / Report. OMB No. 0930-0158. November, 2002
6. Cooper RG, et.al., "Preanalytical, including biological variation in lipid and apolipoprotein measurements." Curr.Opin.Lipidol 1992;3:365-71.

TRADEMARKS

1. Hitachi is a registered trademark of Roche.
2. TEST TRUE™ is a registered trademark of Axiom Diagnostics, Incorporated.

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