



## TEST TRUE™ CHROMATE ASSAY

### INTENDED USE-LABORATORY

For the quantitative determination of chromate in urine as a means of determining sample adulteration.

### SUMMARY AND EXPLANATION OF ASSAY

TEST TRUE™ Chromate Assay is for use on automatic Analyzers to detect the presence of chromate added to urine specimens submitted for DAU Testing. According to the Public Health Service Notice<sup>1</sup> (PD 035), the Administration's Drug Testing Advisory Board now defines a urine specimen as being "ADULTERATED" if an exogenous substance (i.e., a substance which is not a normal constituent of urine)...is present in the specimen. One commercially available product "URINE LUCK™" contains Pyridinium Chlorochromate as the active ingredient. It is the chlorochromate which is reported to interfere with some THC and opiate assays, or their confirmation in positive urine samples<sup>2</sup>. The Urine Luck™ formula 5.4, added to urine as directed, will range from 480 to 1470 mg/L (e.g. ½ vial to 30-90 mLs urine). Klear II will range from 200 to 1000 mg/L when added as directed to urine (e.g., contents of vial to 30-120 mLs urine).

### PRINCIPLE

TEST TRUE™ Chromate Assay Reagents contain a diazonium salt which yields a colored complex when mixed with chromate alone or in urine samples. The color intensity is proportional to the concentration of chromate present providing quantitative results.

#### Cat No.

#### Item

#### Test True™ Chromate Assay Kit

M-1150K R1 Reagent and Calibrators below

#### REAGENT

M-1150L, M-1170/100, M-1170/500 R1 Reagent

#### CALIBRATORS

Z-1001, Z-1071 Zero Cal ( 0 mg/L )  
M-1151, M-1171 Chromate (VI) Cal ( 50 mg/L )

### REAGENT COMPONENTS

TEST TRUE™ Chromate Assay Reagents contain a diazonium salt which yields a colored complex when mixed with chromate alone or in urine samples.

### PRECAUTIONS

1. TEST TRUE™ Chromate 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 and calibrators are ready for use upon receipt.

### REAGENT STABILITY AND STORAGE

Unopened and open reagents are stable until expiration date when stored tightly capped at 2-10° 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 2-10° C.

### INSTRUMENTATION

TEST TRUE™ Chromate 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 plastic or glass containers to collect urine specimens. Protect sample from heat and light. Testing may be performed on samples at room temperature and samples may be stored refrigerated at 2-10° C. Handle all urine samples as if potentially infected!

**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 Nos T-3001, T-3002, T-3003, T-3004 and T-3005) to meet your program needs.

### ADDITIONAL REQUIRED MATERIALS NOT PROVIDED

Automated Analyzer or spectrophotometer. Tri-level Controls.

### SPECIFICITY, LIMITATIONS AND INTERFERENCES

The TEST TRUE™ Chromate Assay is for the detection of chromate (VI) in urine. The test is linear from 0 to 1500 mg/L without sample dilution. In contrast, urine samples spiked with up to 2000 mg/L of chromate (III) gave no reaction.

### 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™ Chromate Assay on samples spiked with Pyridinium Chlorochromate at 50, 100, 500 and 1500 µg/mL (mg/L). 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/L)	Conf (99%)	Mean ± S.D.(mg/L)	Conf (99%)
50.00 ± 0.45	0.0013	45.70 ± 0.64	0.0018
95.75 ± 0.54	0.0015	92.53 ± 1.77	0.0050
468.34 ± 3.20	0.0090	439.42 ± 4.97	0.0139
1367.18 ± 7.47	0.0209	1268.91 ± 10.55	0.0296

### EXPECTED VALUES

Chromate may be present in urine in amounts of 0.04 to 1.0 ng/mL. Extreme situations may result in chromate values up to 62 ng/mL.<sup>3</sup> Addition of Urine Luck results in chromate levels of 100 mg/L to 1200 mg/L.<sup>2</sup> Chromate values above 100 mg/L should be considered abnormal (adulterated).

### 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. Wu, Alan H.B., et al., Adulteration of Urine by "Urine Luck". Clin. Chem. Vol. 45:7, 1051-1057, 1999.
3. Baselt, R. C. and R.H. Cravey, "Disposition of Toxic Drugs and Chemicals in Man". pp. 168-170.
4. National Laboratory Certification Program. General Laboratory Inspection Checklist / Report. OMB No. 0930-0158. November, 2002.

### TRADEMARKS

1. Hitachi™ is a registered trademark of Roche.
2. TEST TRUE™ is a registered trademark of Axiom Diagnostics, Inc.
3. URINE LUCK™ is a registered trademark of Spectrum Laboratories, Inc.

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