

Interferences from icterus, lipemia, hemolysis and ascorbic acid were evaluated for this creatinine method on an ADVIA® 1650 analyzer using a significance criterion of >10% variance from control. Interference data was collected in serum and urine. Plasma is expected to be similar.

| Concentration of Analyte in Serum | | Substance Tested | Concentration of Interferent Where Interference is Insignificant | |
|-----------------------------------|-------------|-------------------|--|---|
| Conventional Units | SI Units | | | |
| 0.79 mg/dL | 69.4 µmol/L | Hemoglobin | 1000 mg/dL | 155.0 µmol/L |
| 0.76 mg/dL | 67.2 µmol/L | Ascorbic Acid | 3000 µg/dL | 170 µmol/L |
| 0.75 mg/dL | 66.3 µmol/L | Unconj. Bilirubin | 16 mg/dL | 273.6 µmol/L |
| 1.08 mg/dL | 94.9 µmol/L | Conj. Bilirubin | 40 mg/dL | 684 µmol/L |
| 0.75 mg/dL | 66.3 µmol/L | Intralipid | 1000 mg/dL | 3000 mg/dL (33.9 mmol/L) Simulated Triglycerides |

| Concentration of Analyte in Urine | | Substance Tested | Concentration of Interferent Where Interference is Insignificant | |
|-----------------------------------|----------------|-------------------|--|---|
| Conventional Units | SI Units | | | |
| 71.7 mg/dL | 6338.3 µmol/L | Hemoglobin | 1000 mg/dL | 155.0 µmol/L |
| 137.4 mg/dL | 12148.0 µmol/L | Ascorbic Acid | 3000 µg/dL | 170 µmol/L |
| 75.7 mg/dL | 6691.9 µmol/L | Unconj. Bilirubin | 40 mg/dL | 684 µmol/L |
| 95.9 mg/dL | 8477.6 µmol/L | Conj. Bilirubin | 40 mg/dL | 684 µmol/L |
| 31.7 mg/dL | 2802.3 µmol/L | Intralipid | 1000 mg/dL | 3000 mg/dL (33.9 mmol/L) Simulated Triglycerides |

The information presented above is based on results from Genzyme Diagnostics studies and is current at the date of publication.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S.⁽³⁾

ANALYTICAL PROCEDURE

MATERIALS PROVIDED

Genzyme Diagnostics' enzymatic creatinine reagents.

MATERIALS REQUIRED (BUT NOT PROVIDED)

1. Automated analyzer capable of accurately measuring absorbance at appropriate wavelengths as per instrument application.
2. Calibration material.
3. Quality Control materials.

TEST CONDITION

For data presented in this insert, studies using this reagent were performed on an automated analyzer using an endpoint test mode, with a sample to reagent ratio of 1:15:5 and a wavelength reading 545 nm. For assistance with applications on automated analyzers within Canada and the U.S., please contact Genzyme Diagnostics Technical Services at (800)565-0265. Outside Canada and the U.S., please contact your local distributor.

CALIBRATION

Calibration material should be used to calibrate the procedure. The frequency of calibration, if necessary, using an automated system is dependent on the system and the parameters used.

QUALITY CONTROL

A normal and abnormal concentration control should be analyzed as required. The results should fall within the quality control range established by the individual laboratory.

CALCULATION

The analyzer automatically calculates the creatinine concentration of each sample.

TEST LIMITATIONS

A sample with a creatinine concentration exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

REFERENCE INTERVALS⁽¹⁾

| | | |
|--------------------------------|---------|----------------------------------|
| Serum/Plasma | Male: | ≤1.2 mg/dL (≤104 µmol/L) |
| | Female: | ≤1.0 mg/dL (≤84 µmol/L) |
| Urine 1 st morning: | Male: | 40-280 mg/dL (3500-25000 µmol/L) |
| | Female: | 30-230 mg/dL (2600-20000 µmol/L) |

These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

PERFORMANCE CHARACTERISTICS

Data presented was collected on an Advia 1650 analyzer unless otherwise stated.

RESULTS

Serum, plasma, and urine creatinine concentration are reported as mg/dL (µmol/L).

REPORTABLE RANGE (CLSI EP6)⁽²⁾

Serum and Plasma - The linearity of the procedure described is 30.00 mg/dL (2652 µmol/L). The low limit of detection is 0 mg/dL (0 µmol/L) and the limit of quantitation is 0.03 mg/dL (3 µmol/L). This data results in a reportable range of 0.03-30.0 mg/dL (3-2652 µmol/L).

Urine - The linearity of the procedure described is 175.00 mg/dL (15470 µmol/L). The low limit of detection is 0 mg/dL (0 µmol/L) and the limit of quantitation is 0.02 mg/dL (2 µmol/L). This results in a reportable range of 0.02-175.00 mg/dL (2-15470 µmol/L). It is recommended that urine samples be diluted 1 part urine to 4 parts saline prior to assay. Incorporate the dilution calculation into the final result.

PRECISION STUDIES (CLSI EP5)⁽²⁾

Total precision was collected on three concentrations of serum controls and three concentrations of urine controls in 40 runs conducted over 20 days.

| Enzymatic Creatinine | N | Mean | | Standard Deviation | | Coefficient of Variation % |
|----------------------|----|-------|---------|--------------------|---------|----------------------------|
| | | mg/dL | µmol/L | mg/dL | µmol/L | |
| Serum 1 | 80 | 0.68 | 60.11 | 0.017 | 1.500 | 2.5 |
| Serum 2 | 80 | 1.32 | 115.80 | 0.032 | 2.830 | 2.4 |
| Serum 3 | 80 | 6.12 | 540.12 | 0.166 | 14.670 | 2.7 |
| Urine 1 | 80 | 22.01 | 1945.68 | 0.323 | 28.55 | 1.5 |
| Urine 2 | 80 | 44.66 | 3947.94 | 0.423 | 37.390 | 0.9 |
| Urine 3 | 80 | 93.31 | 8248.60 | 1.269 | 112.180 | 1.4 |

Within run precision was collected on three concentrations of serum controls and three concentrations of urine controls each run 20 times in a single assay.

| Enzymatic Creatinine | N | Mean | | Standard Deviation | | Coefficient of Variation % |
|----------------------|----|-------|---------|--------------------|--------|----------------------------|
| | | mg/dL | µmol/L | mg/dL | µmol/L | |
| Serum 1 | 20 | 0.62 | 54.81 | 0.004 | 0.35 | 0.6 |
| Serum 2 | 20 | 1.27 | 112.27 | 0.007 | 0.53 | 0.5 |
| Serum 3 | 20 | 5.85 | 517.14 | 0.018 | 1.59 | 0.3 |
| Urine 1 | 20 | 22.19 | 1961.60 | 0.049 | 4.15 | 0.2 |
| Urine 2 | 20 | 45.12 | 3988.61 | 0.083 | 7.16 | 0.2 |
| Urine 3 | 20 | 88.38 | 7812.79 | 0.221 | 19.54 | 0.2 |

ACCURACY (CLSI EP9)⁽²⁾

The performance of this method was compared with the performance of a similar method on an Advia 1650. 40 patient serum samples ranging from 0.7-31.2 mg/dL (61.88 - 2758.08 µmol/L) gave a correlation coefficient of 1.0000. Linear regression analysis gave the following equation:

$$\text{This method} = 1.03 (\text{Comparison Method}) - 0.13 \text{ mg/dL (11.49 } \mu\text{mol/L)}.$$

The performance of this method was compared with the performance of a similar method on an Advia 1650. 40 patient urine samples ranging from 13.5-141.7 mg/dL (1193.40 - 12526.28 µmol/L) gave a correlation coefficient of 0.9995. Linear regression analysis gave the following equation:

$$\text{This method} = 1.04 (\text{Comparison Method}) + 1.06 \text{ mg/dL (93.70 } \mu\text{mol/L)}.$$










The performance of this plasma method was compared with the performance of this serum method on an Advia 1650. 33 patient serum samples ranging from 0.61 - 27.04 mg/dL (53.92 - 2390.34 µmol/L) gave a correlation coefficient of 0.9997. Linear regression analysis gave the following equation:

$$\text{This method (Plasma)} = 1.01 (\text{This Method- Serum}) - 0.03 \text{ mg/dL (2.92 } \mu\text{mol/L)}.$$

The information presented above is based on results from Genzyme Diagnostics studies and is current at the date of publication.

LITERATURE REFERENCES

1. Heil, W., Koberstein, R., Zawta, B. Reference Ranges for Adults and Children, Roche Diagnostics, Mannheim, 2002.
2. *CLSI Method Evaluation Protocols*, Clinical and Laboratory Standards Institute, Wayne, PA.
3. Young, D.S., *Effects of Drugs on Clinical Laboratory Tests*, AACC Press, Washington, Third Edition, 1990.

| Definitions for Symbols | |
|--|---|
|  | This product fulfills the requirements of the European Directive for In Vitro Diagnostic Medical Devices. |
|  LOT | Batch code |
|  | Manufacturer |
|  i | Consult instructions for use |
|  IVD | In vitro diagnostic medical device |
|  | Use by YYYY-MM-DD or YYYY-MM |
|  REF | Catalog number |
|  EC REP | Authorized representative in the European Community |
|  | Temperature limitation |

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