

Infinity™











Creatinine Liquid Stable Reagent

PRODUCT SUMMARY

Stability	:	Until Expiry at 2-8°C
Linear Range	:	0 - 1800 µmol/L (0 - 20 mg/dL)
Specimen Type	:	Serum
Method	:	Rate
Reagent Preparation	:	Supplied ready to use.

IVD

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Temperature Limitation
	For in vitro diagnostic use		Use by/Expiration Date
	Batch code/Lot number		CAUTION: CONSULT INSTRUCTIONS FOR USE.
	Catalogue number		Manufactured by
	Consult instructions for use		Xi - Irritant

INTENDED USE

This reagent is intended for the in vitro quantitative determination of Creatinine in human serum on automated clinical chemistry analysers.

CLINICAL SIGNIFICANCE

Creatinine is a waste product formed in muscle from the high energy storage compound, creatine phosphate. The amount of creatinine produced is fairly constant (unlike urea) and is primarily a function of muscle mass. It is not greatly affected by diet, age, sex or exercise. Creatinine is removed from plasma by glomerular filtration and then excreted in urine without any appreciable resorption by the tubules.

Creatinine is used to assess renal function, however serum creatinine levels do not start to rise until renal function has decreased by at least 50%.

METHODOLOGY

Creatinine reacts with alkaline picrate to produce a reddish colour complex (Jaffe reaction). Specificity of the assay has been improved by the introduction of a kinetic method¹ however, the cephalosporin antibiotics are still major interferants.²

The red colour formed is directly proportional to the creatinine concentration and is measured spectrophotometrically at 500 nm.

REAGENT COMPOSITION

Active Ingredients

	<u>Concentration</u>
Picric Acid	10 mmol/L
Sodium Hydroxide	260 mmol/L
Surfactants	
pH 13.0 ± 0.2 at 25°C.	

WARNING: Do not ingest. This reagent contains picric acid which is explosive when dry. The reagent also contains alkali. If spilt, thoroughly wash affected areas with water. Flush with plenty of water when disposing. For further information consult the Infinity Creatinine Liquid Stable Reagent Material Safety Data Sheet.

R38 Irritating to skin.

R41 Risk of serious damage to eyes.

S24/25 Avoid contact with skin and eyes.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

REAGENT PREPARATION

The reagent is supplied ready to use.

STABILITY AND STORAGE

When stored refrigerated (2 - 8°C) the reagent is stable until the expiration date stated on the bottle and kit box label.

Indications of Reagent Deterioration:

- Turbidity;
- Blank Absorbance of > 0.6 AU at 500nm (1cm) ; and/or
- Failure to recover control values within the assigned range.

SPECIMEN COLLECTION AND HANDLING³

Serum: Use non-haemolysed serum.

Storage: Serum Creatinine samples are stable for at least 2 days at room temperature (18-25°C) or for 1 week at 2-8°C.

ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED

- If required, pipettes for accurately dispensing measured volumes.
- A clinical chemistry analyser capable of maintaining constant temperature (37°C) and measuring absorbance between 500 and 520nm.
- Analyser specific consumables, eg: sample cups.
- Normal and abnormal assayed control material.
- Calibrator or a suitable aqueous Creatinine standard.

ASSAY PROCEDURE

The following system parameters are recommended. Individual instrument applications are available upon request from the Technical Support Group.

SYSTEM PARAMETERS

Temperature	37°C
Primary Wavelength	500 nm (500 - 520nm)
Secondary Wavelength	550 nm - 600nm
Assay Type	Fixed Rate
Direction	Increase
Sample : Reagent Ratio	1 : 10
eg: Sample Vol	30 µL
Reagent Vol	300 µL
First Read Time	60 Seconds
Delay Time	120 Seconds
Last Read Time	180 Seconds
Reagent Blank Limits	Low 0.0 AU
(500nm, 1cm lightpath)	High 0.6 AU
Linearity	0 - 1800 µmol/L
(refer to linearity section)	(0 - 20 mg/dL)
Analytical Sensitivity	0.14 ΔmA/min per µmol/L
(500nm, 1cm lightpath)	0.012 ΔA/min per mg/dL

CALCULATIONS

Results are calculated, usually automatically by the instrument, as follows:

$$\text{Creatinine} = \frac{\Delta\text{Abs/min of Unknown}}{\Delta\text{Abs/min of Calibrator}} \times \text{Calibrator Value}$$

$$\Delta\text{Abs} / \text{min} = \frac{(A2 - A1)}{2}$$

Where:

A1 = Absorbance at First Read time

A2 = Absorbance at Last Read time

Example:

ΔAbs/min of calibrator = 0.062

ΔAbs/min of unknown = 0.038

Value of calibrator = 440 µmol/L (5.0 mg/dL)

$$\text{Creatinine} = \frac{0.038}{0.062} \times 440 = 270 \mu\text{mol/L}$$

$$\text{Creatinine} = \frac{0.038}{0.062} \times 5.0 = 3.1 \text{ mg/dL}$$

NOTES

1. The reagent and sample volumes may be altered proportionally to accommodate different spectrophotometer requirements.
2. Specimens with creatinine values above 1800 µmol/L should be diluted with isotonic saline and reassayed. Multiply results by the dilution factor.
3. Unit conversion: µmol/L x 0.0113 = mg/dL.

CALIBRATION

Calibration is required. An aqueous standard or serum based calibrator, with assigned value traceable to a primary standard (eg NIST or IRMM) is recommended. For calibration frequency on automated instruments refer to the instrument manufacturers specifications. However, calibration stability is contingent upon optimum instrument performance and the use of reagents which have been stored as recommended in the stability and storage section of this package insert.

Recalibration is recommended at anytime if one of the following events occurs:-

- The lot number of reagent changes.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.

QUALITY CONTROL

To ensure adequate quality control, normal and abnormal control should be run as unknown samples:-

- At least once per day or as established by the laboratory.
- When a new bottle of reagent is used.
- After preventative maintenance is performed or a critical component is replaced.
- With every calibration.

Control results falling outside the upper or lower limits of the established ranges indicate the assay may be out of control.

The following corrective actions are recommended in such situations:-

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with freshly prepared reagent, then repeat the test.
- If results are still out of control, contact Technical Services or the local distributor.

LIMITATIONS

1. Studies to determine the level of interference from haemoglobin, bilirubin and lipaemia were carried out on an automated Clinical Chemistry system. The following results were obtained:
Haemoglobin: No interference from haemoglobin up to 1000 mg/dL.
Bilirubin: No interference from free bilirubin up to 170 µmol/L (10 mg/dL). No interference from conjugated bilirubin up to 86 µmol/L (5 mg/dL).
Lipaemia: No interference from lipaemia, measured as triglycerides, up to 6.8 mmol/L (600 mg/dL).
2. Young DS⁴ has published a comprehensive list of drugs and substances which may interfere with this assay.

EXPECTED VALUES⁵

Males: 80 - 115 µmol/L (0.9 - 1.3 mg/dL)
 Females: 53 - 97 µmol/L (0.6 - 1.1 mg/dL)

The quoted values should serve as a guide only. It is recommended that each laboratory verify this range or derive a reference interval for the population it serves.⁶

PERFORMANCE DATA

The following data was obtained using the Infinity Creatinine Liquid Stable Reagent on a well maintained automated clinical chemistry analyser. Users should establish product performance on their specific analyser used.

IMPRECISION

Imprecision was evaluated using two levels of commercial control and following the NCCLS EP5-T procedure.⁷

	LEVEL I	LEVEL II
Number of data points	40	40
Mean (µmol/L / mg/dL)	186 / 2.1	628 / 7.1
Within run: SD (µmol/L / mg/dL)	4 / 0.05	7 / 0.08
CV (%)	2.2	1.1
Between Day: SD (µmol/L / mg/dL)	8 / 0.09	13 / 0.15
CV (%)	4.4	2.1

METHOD COMPARISON

Comparison studies were carried out using a similar commercially available Creatinine reagent as a reference. Serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained.

Number of sample pairs	50
Range of sample results	60 - 1170 µmol/L (0.68-13.20 mg/dL)
Mean of reference method results	210 µmol/L (2.4 mg/dL)
Mean of Infinity Creatinine results	200 µmol/L (2.3 mg/dL)
Slope	0.95
Intercept	-4 µmol/L (-0.04 mg/dL)
Correlation coefficient	0.998

LINEARITY

When run as recommended the assay is linear between 0 and 1800 µmol/L (0 - 20 mg/dL).

Linearity on automated instruments may vary from the quoted value. It is recommended that the user refer to the appropriate Creatinine instrument application for the instrument specific linearity claim.

ANALYTICAL SENSITIVITY

When run as recommended the sensitivity of this assay is 0.14 ΔmAbs/min per µmol/L or approximately 0.012 ΔAbs/min per mg/dL (1cm light path, 500nm).

REFERENCES

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7. National Committee for Clinical Laboratory Standards. User evaluation of Precision Performance of Clinical Chemistry Devices NCCLS; 1984, NCCLS publication EP5-T.

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REF

Reorder Information

Catalogue No.	Configuration
TR35121	2 x 125 mL
TR35198	2 x 500 mL
TL35101	8 x 100 mL (ILab 600)
TH35101	4 x 100 mL (Hitachi)
TY35101	4 x 50 mL (Hitachi)