

# PARACETAMOL

## KEY POINTS:

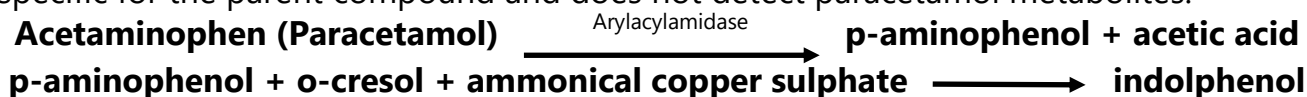
- **Paracetamol (Acetaminophen) 3 Reagent Assay Kit**
- **Easy Enzyme reconstitution**
- **Adaptable to multiple clinical chemistry platforms**
- **No interference from up to 1g/L N-acetyl cysteine or Paracetamol metabolites**
- **Serum and plasma samples**

## INDICATION:

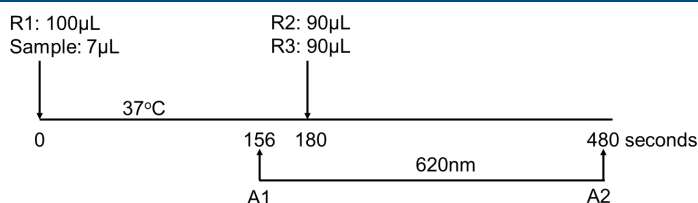
Quantitative measurement of paracetamol as an aid to monitor and diagnose paracetamol overdose.

## PRINCIPLE OF THE ASSAY:

The method is based on the use of an enzyme specific for the amide bond of acylated aromatic amines. It cleaves the paracetamol molecule, yielding p-aminophenol, which reacts specifically with o-cresol in ammoniacal copper solution to produce a blue colour. The assay is specific for the parent compound and does not detect paracetamol metabolites.



## ASSAY SCHEME:



## REFERENCE RANGE:

Paracetamol result	Result Interpretation
66 - 199 µmol/L (10 - 30 mg/L)	Therapeutic level
>1990 µmol/L (>300 mg/L)	Toxic at 4 hours after ingestion
>330 µmol/L (> 50 mg/L)	Toxic at 12 hours after ingestion

## ORDERING INFORMATION

### PARACETAMOL (Acetaminophen) ASSAY KIT



98/79/EC  
For in vitro diagnostic use and  
Professional Use only.

## CONFIGURATION

3 x Lyophilised Enzyme (**R1**)  
1 x 45mL Enzyme Diluent (**R1**)  
1 x 65mL Colour Reagent A (**R2**)  
1 x 65mL Colour Reagent B (**R3**)  
2 x 3mL 302mg/L Aqueous Calibrator

## PART NUMBER

**K8002**

K8100  
Sera Calibrators Kit  
available separately

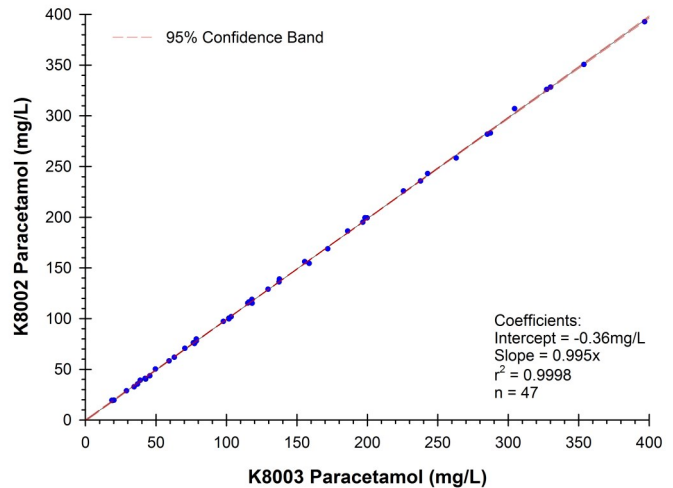
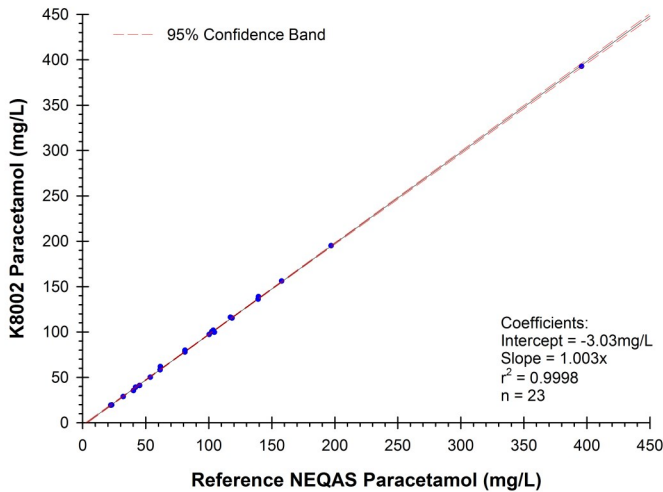
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# PERFORMANCE:

## Accuracy

### Regression Analysis



K8002 Paracetamol method performance on Pentra C400 was compared to the external quality scheme (NEQAS) results

## Precision

		Conc (mmol/L)	Std Dev. (mmol/L)	Conc (mg/L)	Std. Dev. (mg/L)	%CV
Intra Assay	Sample 1	0.145	0.0050	21.93	0.748	3.4
	Sample 2	0.260	0.0045	39.31	0.677	1.7
	Sample 3	0.736	0.0066	111.18	0.992	0.9
Inter Assay	Sample 1	0.054	0.0028	8.14	0.42	5.1
	Sample 2	0.243	0.0044	36.67	0.67	1.8
	Sample 3	0.700	0.0069	105.78	1.04	1.0

Intra-assay precision n = 20  
Inter-assay precision n = 15 days

## Interference

Interferent	Concentration
Ascorbic Acid	1.76g/L (10.0mmol/L)
Total Bilirubin (unconjugated)	300.0mg/L (513µmol/L)
Direct Bilirubin (conjugated)	300.0mg/L (513µmol/L)
Haemoglobin	5.0g/L (77.6µmol/L)
Triglycerides	10.0 g/L (11.3mmol/L)
N-acetyl cysteine	1 g/L

## Recovery

Target (mmol/L)	Mean (mmol/L)	Difference (mmol/L)	Target (mg/L)	Mean (mg/L)	Difference (mg/L)	Recovery %
0.31	0.320	0.010	46.87	48.36	1.49	103.2
0.62	0.626	0.006	93.74	94.49	0.75	100.8
1.26	1.235	-0.025	190.51	186.51	-4.01	97.9
2.52	2.541	0.021	381.02	383.74	2.72	100.7
3.00	3.011	0.011	453.60	454.71	1.11	100.2

## Linearity

0.02 - 3.00 mmol/L (3 - 454 mg/L)

## Limit of Detection

0.02 mmol/L (3 mg/L) Drug free sera

## Calibrator Standardisation

Paracetamol calibrators are manufactured using primary calibration material, Acetaminophen (99.5% - 100.5%) that meets USP specifications. They are manufactured gravimetrically and tested against independent controls.