CAMBRIDGE Life Sciences

Clinical Chemistry Reagents: Toxicology

PARACETAMOL

KEY POINTS:

- **Paracetamol (Acetaminophen) 2 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.

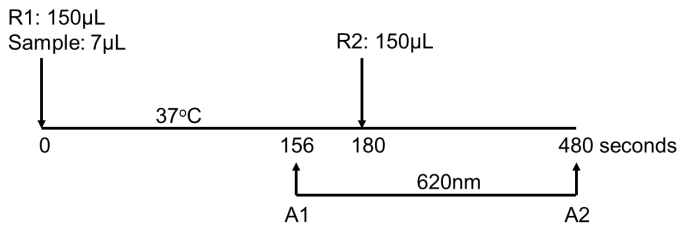
PRINCIPLE OF THE ASSAY:

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.

Acetaminophen (Paracetamol) $\xrightarrow{\text{Arylacylamidase}}$ **p-aminophenol + acetic acid**

p-aminophenol + o-cresol + ammonical copper sulphate $\longrightarrow$ **indolphenol**

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

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

CONFIGURATION

5 x Lyophilised Enzyme (**R1**)
5 x 20mL Enzyme Diluent (**R1**)
1 x 100mL Colour Reagent (**R2**)
2 x 0.5mL 0mg/L Sera Calibrator
2 x 0.5mL 302mg/L Sera Calibrator
1 x 3mL 302mg/L Aqueous Calibrator (option)

PART NUMBER

K8003

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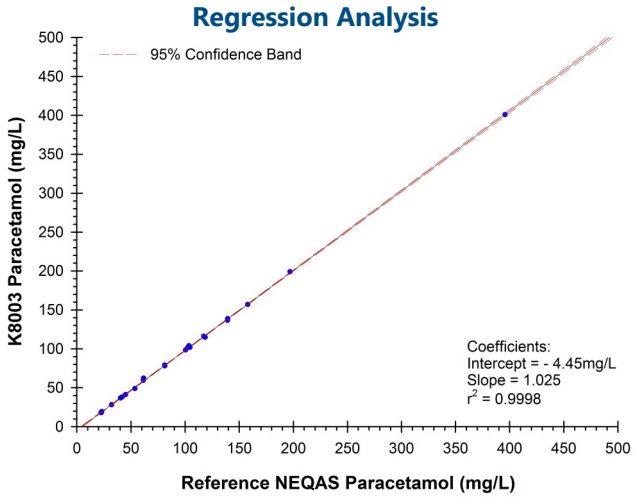
LRQA CERTIFIED ISO 13485 UKAS MANAGEMENT SYSTEMS 0001

PERFORMANCE:

Accuracy



Linearity

0.02 - 5.00 mmol/L (3 - 756 mg/L) using sera calibrators

K8003 Paracetamol method performance on Pentra C400 was compared to the external quality scheme (NEQAS) results

Precision

Sample		Level 1	Level 2	Level 3
N		46	46	46
Mean (mmol/L)		**0.0857**	**0.2869**	**0.9003**
Mean (mg/L)		**12.94**	**43.32**	**135.95**
Repeatability	**SD**	0.0023	0.0032	0.0075
	%CV	**2.68**	**1.12**	**0.83**
Between Day	**SD**	0.0007	0.0039	0.0090
	%CV	**0.82**	**1.36**	**1.00**
Between Run	**SD**	0.0027	0.0040	0.0091
	%CV	**3.15**	**1.39**	**1.01**
Total	**SD**	0.0032	0.0060	0.0137
	%CV	**3.73**	**2.09**	**1.52**

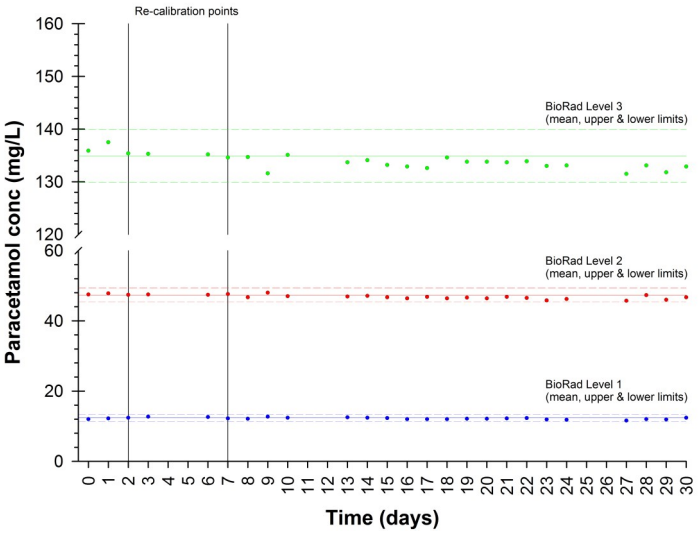
Interference

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)
Intralipids	1% (w/v)
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	**0.313**	0.003	**46.87**	**47.32**	0.44	**100.9**
0.62	**0.632**	0.012	**93.74**	**95.49**	1.75	**101.9**
1.26	**1.252**	-0.008	**190.51**	**189.03**	-1.48	**99.2**
2.52	**2.522**	0.002	**381.02**	**380.89**	-0.13	**100.0**
3.00	**3.052**	0.052	**453.60**	**458.81**	5.21	**101.6**
5.00	**5.152**	0.028	**756.00**	**779.00**	23.00	**103.0**

On-board Reagent Stability



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.