Uric acid FS* TOOS

Order Information

Cat. No.	Kit size	Instrument	Σ
1 3001 99 10 972	R1 3 x 16.8 mL	BX-3010	375 (3 x 125)
		BX-4000	279 (3 x 93)
	R2 3 x 6.7 mL	BX-3010	375 (3 x 125)
		BX-4000	279 (3 x 93)

Intended Use

Diagnostic reagent for quantitative in vitro determination of uric acid in human serum, heparin plasma or urine on automated Sysmex BX-Series.

Summary

Uric acid and its salts are end products of the purine metabolism. In gout, the most common complication of hyperuricemia, increased serum levels of uric acid lead to formation of monosodium urate crystals around the joints. Further causes of elevated blood concentrations of uric acid are renal diseases with decreased excretion of waste products, starvation, drug abuse and increased alcohol consume as well as use of certain medicaments. High uric acid levels also constitute a indirect risk factor for coronary heart disease. [1,2]

Method

Enzymatic photometric test using TOOS (N-ethyl-N-(hydroxy-3-sulfopropyl)-m-toluidin)

Uric acid is oxidized to allantoin by uricase. The generated hydrogen peroxide reacts with 4-aminoantipyrine and N-ethyl-N-(hydroxy-3-sulfopropyl)-m-toluidin (TOOS) to a blue violet dye. Ascorbate oxidase avoids interference by ascorbic acid.

$$\text{Uric acid} + H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$\text{TOOS} + \text{4-Aminoantipyrine} + 2\,H_2O_2 \xrightarrow{\text{POD}} \text{Indamine} + 3\,H_2O$$

Reagents

Components and Concentrations

R1:	Phosphate buffer	pH 7.0	100 mmol/L
	TOOS		1.25 mmol/L
	Ascorbate oxidase		≥ 1.2 kU/L
R2:	Phosphate buffer	pH 7.0	100 mmol/L
	4-Aminoantipyrine		1.5 mmol/L
	$K_4[Fe(CN)_6]$		50 µmol/L
	Peroxidase	(POD)	≥ 5 kU/L
	Uricase		≥ 250 U/L

Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Protect the reagents from light.

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
4. In very rare cases, samples of patients with gammopathy might give falsified results [3].
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only.

Waste Management

Refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum, heparin plasma or urine

Stability in serum/plasma [4]:

3 days	at	20 – 25°C
7 days	at	4 – 8°C
6 months	at	–20°C

Only freeze once. Discard contaminated specimens.

Stability in urine [5]:

4 days	at	20 – 25°C

Dilute urine 1 + 10 with dist. water and multiply results by 11.

Discard contaminated specimens.

Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the reference method gas chromatography-isotope dilution mass spectrometry (GC-IDMS). Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal U	5 9100 99 10 063	20 x 3 mL
	5 9100 99 10 064	6 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL
TruLab Urine Level 1	5 9170 99 10 062	20 x 5 mL
	5 9170 99 10 061	6 x 5 mL
TruLab Urine Level 2	5 9180 99 10 062	20 x 5 mL
	5 9180 99 10 061	6 x 5 mL

Performance Characteristics

Exemplary data mentioned below may slightly differ in case of deviating measurement conditions.

Measuring range up to 20 mg/dL (1190 µmol/L) in serum. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	0.05 mg/dL (3.00 µmol/L)
Onboard stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration [mg/dL]
Ascorbic acid	30 mg/dL	5.70 mg/dL (339 µmol/L)
Bilirubin (conjugated)	15 mg/dL	5.06 mg/dL (301 µmol/L)
Bilirubin (unconjugated)	15 mg/dL	6.26 mg/dL (372 µmol/L)
Hemoglobin	500 mg/dL	5.25 g/dL (312 µmol/L)
Lipemia (triglycerides)	2000 mg/dL	5.90 mg/dL (351 µmol/L)
For further information on interfering substances refer to Young DS [6,7].		

Precision (Serum/Plasma) BX-3010			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	2.72	6.63	10.6
Mean [µmol/L]	162	394	632
CV [%]	1.91	1.47	0.712
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	3.37	6.64	10.9
Mean [µmol/L]	200	395	649
CV [%]	1.85	1.69	1.11

Method comparison (Serum/Plasma; n=110)	
Test x	Uric acid FS TOOS (BioMajesty 6010C)
Test y	Uric acid FS TOOS (BX-3010)
Slope	1.02
Intercept	0.084 mg/dL (5.00 µmol/L)
Coefficient of correlation	0.9995

Measuring range up to 300 mg/dL (17844 µmol/L) in urine.
In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Precision (Urine) BX-3010			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	6.55	11.5	25.9
Mean [µmol/L]	390	682	1538
CV [%]	3.57	2.17	1.75
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mg/dL]	6.27	11.4	25.4
Mean [µmol/L]	373	679	1509
CV [%]	4.17	2.58	6.99

Method comparison (Urine; n=82)	
Test x	Uric acid FS TOOS (BX-4000)
Test y	Uric acid FS TOOS (BX-3010)
Slope	0.989
Intercept	0.006 mg/dL (0.351 µmol/L)
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero; mean + 3 SD (n = 20) of an analyte free specimen.

Conversion Factor
Uric acid [mg/dL] x 59.48 = Uric acid [µmol/L]
Uric acid [mg/dL] x 0.05948 = Uric acid [mmol/L]

Reference Range

Serum/Plasma

	Female		Male	
	[mg/dL]	[µmol/L]	[mg/dL]	[µmol/L]
Adults [8]	2.6 – 6.0	155 – 357	3.5 – 7.2	208 – 428
Children [9]				
1 – 30 day(s)	1.0 – 4.6	59 – 271	1.2 – 3.9	71 – 230
31 – 365 days	1.1 – 5.4	65 – 319	1.2 – 5.6	71 – 330
1 – 3 year(s)	1.8 – 5.0	106 – 295	2.1 – 5.6	124 – 330
4 – 6 years	2.0 – 5.1	118 – 301	1.8 – 5.5	106 – 325
7 – 9 years	1.8 – 5.5	106 – 325	1.8 – 5.4	106 – 319
10 – 12 years	2.5 – 5.9	148 – 348	2.2 – 5.8	130 – 342
13 – 15 years	2.2 – 6.4	130 – 378	3.1 – 7.0	183 – 413
16 – 18 years	2.4 – 6.6	142 – 389	2.1 – 7.6	124 – 448

Urine [1]
≤ 800 mg/24h 4.76 mmol/24h assuming normal diet
≤ 600 mg/24h 3.57 mmol/24h assuming low purine diet

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 208-14.
2. Newman DJ, Price CP. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1204-70.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 48-9.
5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001. p. 52-3.
6. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
7. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, https://clinfx.wiley.com/aaccweb/aacc/, accessed in July 2021. Published by AACC Press and John Wiley and Sons, Inc.
8. Newman JD, Price PC. Renal function and nitrogen metabolites. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1250.
9. Soldin SJ, Brugnara C, Wong EC. Pediatric Reference Intervals, 6th ed. Washington DC; The American Association for Clinical Chemistry Press, 2007; p. 204-5.

IVD CE

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* Fluid Stable

Uric acid FS* TOOS

Chemistry Code 100 79

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	UA	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Uric acid	MethodColor		R1 UA	100	
Sample Type	Serum			R2 UA	25	
Unit	mg/dL			Diluent Disable		
Assay Type	End			Sample Ppt. Wash Disable		

Measuring points

	Start	End
1	22	23
2	45	46

Stirring Speed R1 Middle R2 Middle

Wave Length Prim. 546 Sec. 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal Sample Volume (µL) Low	Normal	High	Diluted Sample (µL)	Diluent (µL)
☐ Diluent	0.0 <	2.0 <	0.0		
Rerun (High/Prozone) ☐ Diluent	0.0 <	2.0 <	0.0		
Rerun (Low) ☐ Diluent	0.0 <	2.0 <	0.0		

Technical Range (Conc) 0.05 – 20 (mAbs/10) * – *

Previous Result Comparison (%) * * %

Abnormal Range (Conc) * – *

Panic Range (Conc) * –

Decimal Point 1 Profile SI Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name UA Sample Serum

Limit Checks

- ✓ Duplicate Limit 50 mAbs/10
- ✓ Sensitivity Limit 500 mAbs/10
- ✓ Linearity Limit %
- (mAbs/10)/min
- ☐ Prozone Limit Higher %

SL1-S – SL1-F

SL2-S – SL2-F

Sensitivity mAbs/10

✓ Absorbance Limit
Abs. in reaction Increase

Limit 25000 mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
✓ Duplicate Limit 10 mAbs/10

Instrument Factor

a 1.00 b 0.00

Uric acid FS* TOOS

Chemistry Code 100 79

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name UA

Sample Type Serum

Replication Duplicate

Check Interval 42

Test without calibration

Disable

Calibration Type Linear

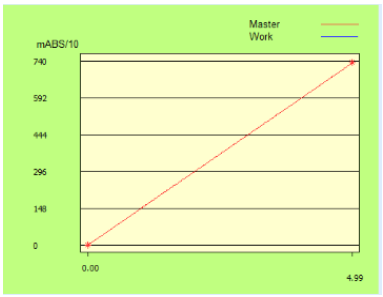
Reagent Lot New Add

Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No. ☐ All
C1	0	Automatic entry	Automatic entry	*
C2	*	Automatic entry	Automatic entry	*
C3	*			
C4	*			
C5	*			
C6	*			
C7	*			

K Automatic entry ☐ C1 Blank
☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

***Entered by user**

Uric acid FS* TOOS

Chemistry Code 100 79

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method	*	Name	UA		Reagent Name	Reagent (µL)	Water (µL)
Print Name	Uric acid			R1	UA	150	
Sample	Serum			R2 ✓ Enable	UA	38	
Unit	mg/dL						
Assay Type	End			Diluent ☐ Enable			

Measuring points

	Start	End
1	33	34
☐ Enable 2	67	68

Decimal Points: 1

Wave Length: Prim. 546 Sec ☐ Disable 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	3.0		
Rerun (High/Prozone) ☐ Dilution	3.0		
Rerun (Low) ☐ Dilution	3.0		

Technical Range
(Conc) 0.05 – 20
(mAbs/10) –

SPT Wash ☐ Enable — Reagent Name

Stirring Speed R1 Middle R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * Name UA Sample Serum

Limit Checks

✓ Duplicate Limit 50 mAbs/10

✓ Sensitivity Limit 500 mAbs/10

✓ Linearity Limit % (mAbs/10)/min

☐ Prozone Limit % Upper

SL1-S – SL1-F

SL2-S – SL2-F

Sensitivity mAbs/10

✓ Absorbance Limit

Reaction Increase

Limit 25000 mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
✓ Duplicate Limit 10 mAbs/10

Instrument Factor

a 1.00 b 0.00

Uric acid FS* TOOS

Chemistry Code 100 79

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: UA

Sample: Serum

Sampling: Duplicate

Check Interval: 42 days

Auto: Change Lot — Full Calibration

Auto Interval: hours

Type: Linear Lot: New

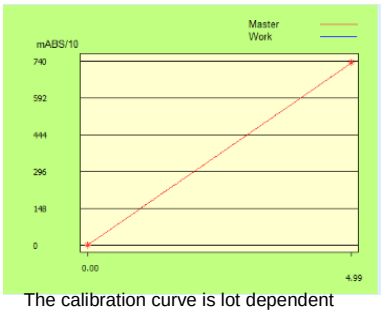
Material Name: TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * R2: * Last:



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation

Uric acid FS* TOOS

Chemistry Code 100 79

Chemistry Parameters 1

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	*	Method Name	UA U	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Uric acid	MethodColor		R1	UA	108	
Sample Type	Urine			R2	UA	27	
Unit	mg/dL			Diluent	Saline		
Assay Type	End			Sample Ppt. Wash	Disable		

Measuring points

	Start		End
1	22	–	23
2	45	–	46

Stirring Speed R1: Middle R2: Middle

Wave Length: Prim. 546 Sec. 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Normal Sample Volume (µL) Low	<	Normal	<	High	Diluted Sample (µL)	Diluent (µL)
☐ Diluent	0.0	<	2.2	<	0.0	10.0	100
Rerun (High/Prozone)							
☐ Diluent	0.0	<	2.2	<	0.0	10.0	100
Rerun (Low)							
☐ Diluent	0.0	<	2.2	<	0.0	10.0	100

Technical Range
(Conc) 1.0 – 300
(mAbs/10) * – *

Previous Result Comparison (%) * – * %

Abnormal Range (Conc) * – *

Panic Range (Conc) * –

Decimal Point 1 Profile SI Disable

***Entered by user**

Chemistry Parameters 2

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. * Method Name UA U Sample Urine

Limit Checks

- ✓ Duplicate Limit 50 mAbs/10
- ✓ Sensitivity Limit 500 mAbs/10
- ✓ Linearity Limit %
  (mAbs/10)/min
- ☐ Prozone Limit Higher %

SL1-S – SL1-F

SL2-S – SL2-F

Sensitivity mAbs/10

- ✓ Absorbance Limit
  Abs. in reaction Increase
  Limit 25000 mAbs/10

Blank measurement

Blank measurement:
Disable reagent blank and C1 blank

Measurement of Reagent Blank during Run:
None

Reagent blank measurement at calibration:
Reagent blank (No sample)

The number of measurement:
Duplicate

Reagent blank limit checks:
- ✓ Duplicate Limit 10 mAbs/10

Instrument Factor

a 1.00 b 0.00

Uric acid FS* TOOS

Chemistry Code 100 79

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. *

Method Name UA U

Sample Type Urine

Replication Duplicate

Check Interval 42

Test without calibration

Disable

Calibration Type Linear

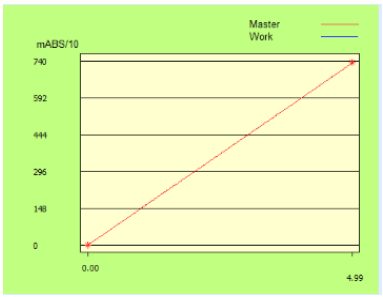
Reagent Lot New Add

Calibrator Name TruCal U

	Conc.	WORK	MASTER	Calibr. Lot No. ☐ All
C1	0	Automatic entry	Automatic entry	*
C2	*	Automatic entry	Automatic entry	*
C3	*			
C4	*			
C5	*			
C6	*			
C7	*			

K Automatic entry ☐ C1 Blank
☐ Reagent Blank for C1

Reagent Lot No.
(R1) *
(R2) *
Last



The calibration curve is lot dependent

Reagent blank mAbs/10 Last

Blank Automatic entry mAbs/10 Last

Calibration Curve Conc.

Absorbance mAbs/10 Recalculation

***Entered by user**

Uric acid FS* TOOS

Chemistry Code 100 79

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * | Name: UA U

Print Name: Uric acid

Sample: Urine

Unit: mg/dL

Assay Type: End

	Reagent Name	Reagent (µL)	Water (µL)
R1	UA	150	
R2 ✓ Enable	UA	38	
Diluent ✓ Enable	NaCl		

Measuring points

	Start	End
1	33	34
☐ Enable 2	67	68

Decimal Points: 1

Wave Length: Prim. 546 | Sec | ☐ Disable 700

Normal Range

No.	Normal Range Name	Min	Max
1	Male-G1	*	*
2	Male-G2	*	*
3	Male-G3	*	*
4	Female-G1	*	*

	Sampling	Sample (µL)	Diluent (µL)
Normal ☐ Dilution	3.0	10.0	100
Rerun (High/Prozone) ☐ Dilution	3.0	10.0	100
Rerun (Low) ☐ Dilution	3.0	10.0	100

Technical Range

(Conc)	1.0	–	300
(mAbs/10)		–	

SPT Wash ☐ Enable — Reagent Name:

Stirring Speed: R1 Middle | R2 Middle

***Entered by user**

Chemistry Parameters

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method No. * | Name: UA U | Sample: Urine

Limit Checks

✓ Duplicate Limit: 50 mAbs/10

✓ Sensitivity Limit: 500 mAbs/10

✓ Linearity Limit: % (mAbs/10)/min

☐ Prozone Limit: % Upper

SL1-S – SL1-F

SL2-S – SL2-F

Sensitivity: mAbs/10

✓ Absorbance Limit

Reaction: Increase

Limit: 25000 mAbs/10

Blank measurement

Blank measurement: Disable reagent blank and S1 blank

Measurement of Reagent Blank during Run: None

Reagent blank measurement at calibration: Reagent blank (No sample)

The number of measurement: Duplicate

Reagent blank limit checks:
✓ Duplicate Limit: 10 mAbs/10

Instrument Factor

a: 1.00 b: 0.00

Uric acid FS* TOOS

Chemistry Code 100 79

Registration Calibration

Sysmex BX-4000 Chemistry Analyzer
Analytical Parameters

Method: * Name: UA U

Sample: Urine

Sampling: Duplicate

Check Interval: 42 days

Auto: Change Lot | Full Calibration

Auto Interval: hours

Type: Linear Lot: New

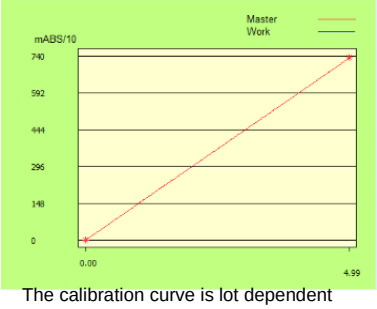
Material Name: TruCal U

	Conc.	WORK	MASTER	Lot No. (S) ☐ All
S1	0	Automatic entry	Automatic entry	
S2	*	Automatic entry	Automatic entry	
S3	*			
S4	*			
S5	*			
S6	*			
S7	*			

K: Automatic entry ☐ S1 Blank ☐ Reagent Blank for S1

***Entered by user**

R Lot No. R1: * R2: * Last:



The calibration curve is lot dependent

Reagent blank: mAbs/10 Last:

Blank: Automatic entry mAbs/10 Last:

Type: Conc.:

Absorbance: mAbs/10 Recalculation