

# ASAT (GOT) FS\* (IFCC mod.)

## Order Information

Cat. No.	Kit size	Instrument	Σ
1 2601 99 10 972	R1 3 x 13.8 mL	BX-3010	300 (3 x 100)
		BX-4000	216 (3 x 72)
	R2 3 x 6.1 mL	BX-3010	300 (3 x 100)
		BX-4000	216 (3 x 72)

## Intended Use

Diagnostic reagent for quantitative in vitro determination of ASAT (GOT) in serum or plasma on Sysmex BX-Series.

## Summary

Alanine Aminotransferase (ALAT/ALT), formerly called Glutamic Pyruvic Transaminase (GPT) and Aspartate Aminotransferase (ASAT/AST), formerly called Glutamic Oxalacetic Transaminase (GOT) are the most important representatives of a group of enzymes, the aminotransferases or transaminases, which catalyze the conversion of α-keto acids into amino acids by transfer of amino groups. As a liver specific enzyme, ALAT is only significantly elevated in hepatobiliary diseases. Increased ASAT levels, however, can occur in connection with damages of heart or skeletal muscle as well as of liver parenchyma. Parallel measurement of ALAT and ASAT is, therefore, applied to distinguish liver from heart or skeletal muscle damages. The ASAT/ALAT ratio is used for differential diagnosis in liver diseases. While ratios < 1 indicate mild liver damage, ratios > 1 are associated with severe, often chronic liver diseases. [1,2]

## Method

Optimized UV-test according to IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) [modified]



## Reagents

### Components and Concentrations

<b>R1:</b>	TRIS	pH 7.65	110 mmol/L
	L-Aspartate		320 mmol/L
	MDH (malate dehydrogenase)		≥ 800 U/L
	LDH (lactate dehydrogenase)		≥ 1200 U/L
<b>R2:</b>	2-Oxoglutarate		85 mmol/L
	NADH		1 mmol/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. Do not freeze and protect from light.

## Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Reagent 1 contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- 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.
- For professional use only.

## Waste Management

Refer to local legal requirements.

## Reagent Preparation

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

## Materials Required

General laboratory equipment

## Specimen

Serum or heparin plasma

Stability [4]:

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

Only freeze once. Discard contaminated specimens.

## Calibrators and Controls

DiaSys TruCal U calibrator is recommended for calibration. This method has been standardized against the original IFCC formulation. Use DiaSys TruLab N and P 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

## Performance Characteristics

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

Measuring range up to 600 U/L (10 µkat/L). In case of higher activities re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	2 U/L (0.033 µkat/L)
Onboard stability	6 weeks
Calibration stability	6 weeks

Interfering substance	Interferences ≤ 10% up to	Analyte concentration
Ascorbic acid	30 mg/dL	49.4 U/L (0.825 µkat/L)
Bilirubin (conjugated)	60 mg/dL	45.0 U/L (0.751 µkat/L)
Bilirubin (unconjugated)	38 mg/dL	45.3 U/L (0.756 µkat/L)
Hemoglobin	65 mg/dL	46.6 U/L (0.777 µkat/L)
Lipemia (triglycerides)	400 mg/dL	48.0 U/L (0.800 µkat/L)

For further information on interfering substances refer to Young DS [5,6].

Precision (BX-4000)			
Within run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	48.3	78.4	207
Mean [µkat/L]	0.806	1.31	3.46
CV [%]	0.442	0.517	0.289
Between run (n=20)	Sample 1	Sample 2	Sample 3
Mean [U/L]	46.6	51.9	165
Mean [µkat/L]	0.777	0.865	2.75
CV [%]	0.882	2.01	0.739

Method comparison (n=115)	
Test x	ASAT (GOT) FS (BioMajesty 6010C)
Test y	ASAT (GOT) FS (BX-4000)
Slope	0.995
Intercept	0.659 U/L (0.011 µkat/L)
Coefficient of correlation	0.9999

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

#### Conversion Factor

ASAT [U/L] x 0.0167 = ASAT [µkat/L]

#### Reference Range [7,8]

Women	< 31 U/L	< 0.52 µkat/L
Men	< 35 U/L	< 0.58 µkat/L

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. Alanine aminotransferase (ALT), Aspartate aminotransferase (AST). In: Thomas L, editor. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 55-65.
2. Moss DW, Henderson AR. Clinical enzymology. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 617-721.
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
5. 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.
6. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinf.wiley.com/aaccweb/aacc/>, accessed on December 2020. Published by AACC Press and John Wiley and Sons, Inc.
7. Lorentz K, Röhle G, Siekmann L. Einführung der neuen Standardmethoden 1994 zur Bestimmung der katalytischen Enzymkonzentrationen bei 37 °C. DG Klinische Chemie Mitteilungen 26; 1995; Heft 4.
8. Zawta B, Klein G, Bablok W. Temperature Conversion in Clinical Enzymology? Klin. Lab. 1994; 40: 33-42.



DiaSys Diagnostic Systems  
GmbH  
Alte Strasse 9 65558 Holzheim  
Germany  
[www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)

\* Fluid Stable

# ASAT (GOT) FS\* (IFCC mod.)

Chemistry Code 100 10

Chemistry Parameters 1				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="ASAT"/>	Reagent Name	Reagent (μL)	Water (μL)
Print Name	<input type="text" value="AST"/>	MethodColor		R1	<input type="text" value="ASAT"/>	<input type="text" value="100"/>
Sample Type	<input type="text" value="Serum"/>			R2	<input type="text" value="ASAT"/>	<input type="text" value="25"/>
Unit	<input type="text" value="U/L"/>			Diluent	<input type="text" value="Disable"/>	
Assay Type	<input type="text" value="Rate"/>			Sample Ppt. Wash	<input type="text" value="Disable"/>	
Measuring points		Start	End	Stirring Speed R1	<input type="text" value="Middle"/>	R2 <input type="text" value="Fast"/>
		1	<input type="text" value="30"/> - <input type="text" value="46"/>			
		2	<input type="text" value="Disable"/> - <input type="text"/>			
Wave Length	Prim. <input type="text" value="340"/>	Sec. <input type="text" value="415"/>		Normal Range		
				No.	Normal Range Name	Min
				1	Male-G1	*
				2	Male-G2	*
				3	Male-G3	*
				4	Female-G1	*
Normal	Sample Volume (μL)	Diluted Sample (μL)	Diluent (μL)	Technical Range	(Conc)	<input type="text" value="2"/> - <input type="text" value="600"/>
<input type="checkbox"/> Diluent	Low <input type="text" value="0.0"/> < Normal <input type="text" value="7.5"/> < High <input type="text" value="0.0"/>			(mAbs/10)		<input type="text" value="*"/> - <input type="text" value="*"/>
<input type="checkbox"/> Rerun (High/Prozone)				Previous Result Comparison (%)	<input type="text" value="*"/>	<input type="text" value="*"/> %
<input type="checkbox"/> Diluent	Low <input type="text" value="0.0"/> < Normal <input type="text" value="7.5"/> < High <input type="text" value="0.0"/>			Abnormal Range	(Conc) <input type="text" value="*"/>	- <input type="text" value="*"/>
<input type="checkbox"/> Rerun (Low)				Panic Range	(Conc) <input type="text" value="*"/>	- <input type="text" value="*"/>
				Decimal Point	<input type="text" value="0"/>	Profile SI <input type="text" value="Disable"/>

\*Entered by user

Chemistry Parameters 2				Sysmex BX-3010 Chemistry Analyzer Analytical Parameters		
Method No.	<input type="text" value="*"/>	Method Name	<input type="text" value="ASAT"/>	Sample	<input type="text" value="Serum"/>	
Limit Checks						
<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="50"/>	mAbs/10		Blank measurement		
<input checked="" type="checkbox"/> Sensitivity Limit	<input type="text" value="250"/>	mAbs/10		Blank measurement:		
<input checked="" type="checkbox"/> Linearity Limit	<input type="text" value="10"/>	%		<input type="text" value="Disable reagent blank and C1 blank"/>		
	<input type="text" value="230"/>	(mAbs/10)/min		Measurement of Reagent Blank during Run:		
<input type="checkbox"/> Prozone Limit	<input type="text" value="Higher"/>	%		<input type="text" value="None"/>		
	<input type="text"/>			Reagent blank measurement at calibration:		
SL1-S <input type="text"/>	-	SL1-F <input type="text"/>		<input type="text" value="Reagent blank (No sample)"/>		
SL2-S <input type="text"/>	-	SL2-F <input type="text"/>		The number of measurement:		
Sensitivity <input type="text"/>	mAbs/10			<input type="text" value="Duplicate"/>		
<input checked="" type="checkbox"/> Absorbance Limit	Reagent blank limit checks:					
Abs. in reaction <input type="text" value="Decrease"/>				<input checked="" type="checkbox"/> Duplicate Limit	<input type="text" value="20"/>	mAbs/10
Limit <input type="text" value="5000"/>	mAbs/10			Instrument Factor		
				a	<input type="text" value="1.00"/>	b <input type="text" value="0.00"/>

# ASAT (GOT) FS\* (IFCC mod.)

Chemistry Code 100 10

## Calibration Registration

## Sysmex BX-3010 Chemistry Analyzer Analytical Parameters

Method No.

Method Name

Sample Type

Replication

Check Interval

Test without calibration

Calibration Type

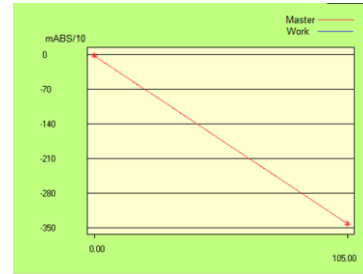
Reagent Lot

Calibrator Name

Reagent Lot No.

(R1)   
(R2)

Last



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Calibr. Lot No.	<input type="checkbox"/> All
C1	<input type="text" value="0"/>	Automatic entry	Automatic entry	*	
C2	*	Automatic entry	Automatic entry	*	
C3	*				
C4	*				
C5	*				
C6	*				
C7	*				

K   C1 Blank  
 Reagent Blank for C1

Reagent blank  mAbs/10 Last

Blank  mAbs/10 Last

Calibration Curve  Conc.

Absorbance  mAbs/10

\*Entered by user

# ASAT (GOT) FS\* (IFCC mod.)

Chemistry Code 100 10

Chemistry Parameters				Sysmex BX-4000 Chemistry Analyzer Analytical Parameters		
Method	*	Name	ASAT	Reagent Name	Reagent (µL)	Water (µL)
Print Name	AST	R1	ASAT	150		
Sample	Serum	R2	ASAT	38		
Unit	U/L	Diluent <input type="checkbox"/> Enable				
Assay Type	Rate					
Measuring points		Start	End	Decimal Points	0	
	1	44	68			
<input type="checkbox"/> Enable	2					
Wave Length	Prim. 340	Sec	<input type="checkbox"/> Disable 415	Normal Range		
				No.	Normal Range Name	Min
				1	Male-G1	*
				2	Male-G2	*
				3	Male-G3	*
				4	Female-G1	*
Normal Dilution	11.3	Sampling	Sample (µL)	Diluent (µL)	Technical Range	(Conc) 2 - 600
Rerun (High/Prozone)					(mAbs/10)	
Dilution	11.3					
Rerun (Low)						
Dilution	11.3					
SPT Wash	<input type="checkbox"/> Enable	Reagent Name				
Stirring Speed	R1 Middle	R2	High			

\*Entered by user

Chemistry Parameters				Sysmex BX-4000 Chemistry Analyzer Analytical Parameters		
Method No.	*	Name	ASAT	Sample	Serum	
Limit Checks						Blank measurement
<input checked="" type="checkbox"/> Duplicate Limit	50	mAbs/10				Blank measurement:
<input checked="" type="checkbox"/> Sensitivity Limit	250	mAbs/10				Disable reagent blank and S1 blank
<input checked="" type="checkbox"/> Linearity Limit	10	%	230	(mAbs/10)/min	Measurement of Reagent Blank during Run:	None
<input type="checkbox"/> Prozone Limit		%	Upper		Reagent blank measurement at calibration:	Reagent blank (No sample)
	SL1-S		SL1-F		The number of measurement:	Duplicate
	SL2-S		SL2-F		Reagent blank limit checks:	<input checked="" type="checkbox"/> Duplicate Limit 20 mAbs/10
Sensitivity		mAbs/10				Instrument Factor
<input checked="" type="checkbox"/> Absorbance Limit						a 1.00 b 0.00
Reaction	Decrease					
Limit	5000	mAbs/10				

# ASAT (GOT) FS\* (IFCC mod.)

Chemistry Code 100 10

## Registration Calibration

## Sysmex BX-4000 Chemistry Analyzer Analytical Parameters

Method  Name

Sample

Sampling

Check Interval  days

Auto

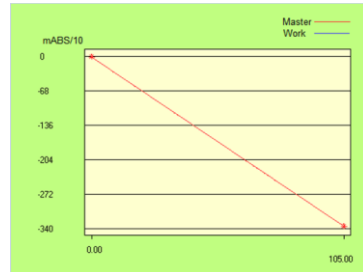
Auto Interval  hours

Type  Lot

Material Name

R Lot No. R1  Last

R2



The calibration curve is lot dependent

	Conc.	WORK	MASTER	Lot No. (S) <input type="checkbox"/> All
S1	<input type="text" value="0"/>	Automatic entry	Automatic entry	
S2	<input type="text" value="*"/>	Automatic entry	Automatic entry	
S3	<input type="text" value="*"/>			
S4	<input type="text" value="*"/>			
S5	<input type="text" value="*"/>			
S6	<input type="text" value="*"/>			
S7	<input type="text" value="*"/>			

K   S1 Blank  Reagent Blank for S1

Reagent blank  mAbs/10 Last

Blank  mAbs/10 Last

Type  Conc.

Absorbance  mAbs/10

\*Entered by user