HbA1c net FS*

Order Information

Cat. No.	Kit size	Instrument	Σ
1 3348 99 10 972	R1 3 x 18.5 mL	BX-3010	300 (3 x 100)
	R2 3 x 8.5 mL	BX-3010	300 (3 x 100)

Intended Use

Diagnostic reagent for quantitative in vitro determination of hemoglobin A1c in human whole blood, collected with EDTA, on automated Sysmex BX-3010.

Summary

Hemoglobin A1c (HbA1c) is a glycated hemoglobin which is formed by the non-enzymatic reaction of glucose with native hemoglobin. The rate of glycation is directly proportional to the concentration of glucose in blood. HbA1c represents the average blood glucose level over the preceding 120 days [1]. Therefore, HbA1c is recommended for diagnosis and monitoring of diabetes, especially type 2 diabetes [1,2]. Clinical studies have shown that lowering of HbA1c can help to prevent or delay the incidence of late diabetic complications [1,3]. As the amount of HbA1c also depends on the total quantity of hemoglobin the reported HbA1c value is indicated as a percentage of the total hemoglobin concentration [1,3].

Method

Hemoglobin: Photometric test
HbA1c: Colorimetric, enzymatic method

The concentrations of HbA1c and hemoglobin are determined separately and are used to calculate the HbA1c ratio from total hemoglobin exclusively.

Hemoglobin measurement

Whole blood samples are lysed with hemolyzing solution. Hemoglobin is released from the erythrocytes. The absorbance of hemoglobin is measured at 570 nm after addition of reagent R1 and is proportional to the total hemoglobin concentration in the sample.

HbA1c measurement [4]

After addition of R2, fructosylated dipeptides from the N-terminal part of the hemoglobin β-chain are released by a protease. Hydrogen peroxide (H_2O_2) is produced by oxidative cleavage of fructosylated dipeptides by FPOX (fructosyl peptide oxidase). The H_2O_2 generated is determined colorimetrically by reaction with a chromogen in presence of peroxidase at 660 nm. The absorbance increase is proportional to the HbA1c concentration.

Standardization

The assay is standardized according to the approved IFCC reference method [5].

NGSP and IFCC values show a linear relationship and, therefore, can be calculated from each other using the following equation:

HbA1c *(IFCC[a])* = (HbA1c *(NGSP[b])* – 2.15)/0.0915

HbA1c *(NGSP[b])* = 0.0915 x HbA1c *(IFCC[a])* + 2.15

a: IFCC values in mmol/mol
b: NGSP values in %

IFCC: International Federation of Clinical Chemistry [5-7]
DCCT: Diabetes Control and Complications Trial [8]
NGSP: National Glycohemoglobin Standardization Program [9]

HbA1c and Average Glucose Concentrations

Due to a linear correlation between hemoglobin A1c and average glucose concentrations HbA1c values can be converted in estimated average glucose values by means of the following equations:

Standardization according to IFCC [10]:

Average glucose conc. [mg/dL] = 2.63 x HbA1c[a] + 15.01
Average glucose conc. [mmol/L] = 0.146 x HbA1c[a] + 0.829

a: HbA1c values in mmol/mol IFCC

Standardization according to NGSP:

Average glucose conc. [mg/dL] = 28.7 x HbA1c[b] – 46.7
Average glucose conc. [mmol/L] = 1.59 x HbA1c[b] – 2.59

b: HbA1c values in % NGSP

No significant differences in the regression equation were observed for variations in individuals tested, including sex, presence or absence of diabetes, type of diabetes, age, race, and ethnicity. Although this equation can be used for the majority of individuals, each laboratory has to reassure itself if the regression equations mentioned are applicable for the patient group to be examined.

Reagents

Components and Concentrations

R1:	Buffer	100 mmol/L
	FPOX	≥ 0.5 kU/L
	Ethlyene glycol derivative	< 10%
R2:	Buffer	20 mmol/L
	Protease	≥ 500 kU/L
	Chromogen	≥ 0.05 mmol/L
	Ethlyene glycol derivative	< 10%

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.
The in-use stability of the reagent is 12 months.

Warnings and Precautions

1. The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
2. Hemoglobin and HbA1c values in g/dL determined with DiaSys HbA1c net FS are used to calculate the HbA1c ratio from total hemoglobin exclusively. Individual results for hemoglobin and HbA1c must not be used for diagnostic purposes.
3. Measurement of HbA1c is not appropriate for diagnosis of gestational diabetes [11].
4. Falsely low values (low HbA1c despite high blood glucose) may occur in people with conditions such as shortened red blood cell survival (e.g. hemolytic diseases) or significant recent blood loss during the weeks before (higher fraction of young erythrocytes). Falsely high values (high HbA1c despite normal blood glucose) have been reported in iron deficiency anemia (high proportion of old erythrocytes). These circumstances have to be considered in clinical interpretation of HbA1c values [1].
5. As HbA1c represents the stable coupling of glucose at the N-terminal end of the hemoglobin A1 β-chain, glycosylated Hb variants without β-chains cannot be determined with this test. Determination of total hemoglobin includes all Hb variants; therefore, samples with high concentrations of Hb variants without β-chains may show falsely low HbA1 concentrations.
6. In very rare cases, samples of patients with gammopathy might give falsified results [12].
7. N-acetylcysteine (NAC), acetaminophen and metamizole medication leads to falsely low results in patient samples.
8. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
9. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
10. Please refer to the safety data sheets (SDS) 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.

11. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagents are ready to use.

Bring HbA1c net Hemolyzing Solution to room temperature and homogenize by repeated inversion. Due to composition of the hemolyzing solution an opalescent and slightly turbid appearance remains. Avoid foaming! Do not shake!

Materials Required

General laboratory equipment

Specimen

Human whole blood collected with EDTA

Please collect whole blood by standard venipuncture and fill the blood collection tube according to manufacturer specifications.

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Whole blood collection tubes must not be higher than 75 mm; otherwise contamination of the device may occur!

Stability [13]:

Whole blood	1 week	at	2 – 8°C
Hemolysate	1 hour	at	15 – 25°C

Discard contaminated specimens.

Sample Preparation

For sample preparation the DiaSys HbA1c net Hemolyzing Solution Cat. No. 1 4590 99 10 113 is required.

Calibrators, controls and samples have to be hemolyzed before use. Hemolysates have to be processed within 1 hour after production. Processing in batch mode is recommended. Please refer to subsequent pipetting scheme for manual hemolysis:

	Preparation			
	Calibrator Level 1	Calibrator Level 2	Control	Sample
TruCal HbA1c net Level 1	16 µL	-	-	-
TruCal HbA1c net Level 2	-	50 µL	-	-
TruLab HbA1c net Level 1 and Level 2 /Sample	-	-	50 µL	50 µL
Add				
HbA1c net Hemolyzing solution	1000 µL	1000 µL	1000 µL	1000 µL
Mix and allow standing for 1 minute. Hemolysis is completed after 1 minute. A slight turbidity remains due to the composition of the hemolyzing solution.				

Calibration

The concentrations of HbA1c and hemoglobin in unknown samples are derived from linear calibration curves. Each calibration curve is obtained with 2 calibrators at different levels without a zero value.

Calculation

After entering the calculation formula into the instrument, the calculation of HbA1c ratio from total hemoglobin is done by the instrument automatically. Please refer to the instrument manual.

Depending on the standardization selected, enter the following formula:

IFCC

Values in mmol/mol according to IFCC:

$$\text{HbA1c [mmol/mol]} = \left(\frac{\text{HbA1c [g/dL]}}{\text{Hb [g/dL]}} \right) \times 1000$$

DCCT/NGSP

Values in percent according to DCCT/NGSP:

$$\text{HbA1c [\%]} = \left(91.5 \times \frac{\text{HbA1c [g/dL]}}{\text{Hb [g/dL]}} \right) + 2.15$$

Calibrators and Controls

DiaSys TruCal HbA1c net calibrator is recommended for calibration. The assigned values of TruCal HbA1c net have been made traceable to the approved IFCC reference method [5]. Use DiaSys TruLab HbA1c net controls for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal HbA1c net	1 3350 99 10 044	2 x 0.3 mL
TruLab HbA1c net Level 1	5 9930 99 10 076	6 x 1 mL
TruLab HbA1c net Level 2	5 9940 99 10 076	6 x 1 mL

Performance Characteristics

Data evaluated on Sysmex BX-3010

Measuring range from 20 – 150 mmol/mol according to IFCC (4 – 16% according to DCCT/NGSP). The assay is applicable for hemoglobin concentrations in blood from 6 – 30 g/dL (3.73 – 18.6 mmol/L).	
Limit of detection**	HbA1c: 0.2 g/dL Hemoglobin: 1.5 g/dL
On-board stability	4 weeks
Calibration stability	4 weeks

Interfering substance	Interferences ≤ 10% in serum with hematocrit correction	Analyte concentration [mmol/mol]
Ascorbic acid	50 mg/dL	35.5
	50 mg/dL	67.2
Bilirubin (conjugated)	10 mg/dL	35.8
	10 mg/dL	67.1
Bilirubin (unconjugated)	10 mg/dL	33.6
	10 mg/dL	71.1
Glucose	1000 mg/dL	34.8
	1000 mg/dL	60.8
Hemoglobin (acetylated)	10 mmol/L	33.9
	10 mmol/L	70.4
Hemoglobin (carbamylated)	10 mmol/L	36.8
	10 mmol/L	71.3
Lipemia (triglycerides)	750 mg/dL	36.1
	1000 mg/dL	72.0
N-acetylcysteine (NAC)	2000 mg/L	32.8
	2000 mg/L	72.8
Urea	300 mg/dL	31.1
	300 mg/dL	70.5

Uric acid	20 mg/dL	38.9
	20 mg/dL	78.0
For further information on interfering substances, refer to the literature [1,14-16].		

Hemoglobin variants may lead to deviant HbA1c results. The tested Hemoglobin variants HbS, HbC, HbD, HbE, HbJ, HbG, HbSC, HbSE, HbEE and HbF showed no significant interference.

Hemoglobin Variant	Percentage of Hemoglobin Variant (≤)	Target Value range HbA1c [% DCCT/NGSP]	Mean Recovery HbA1c [%]
AS	40% S	5.2 – 8.8	94.7
AC	36% C	5.0 – 7.4	97.1
AD	41% D	5.6 – 7.0	93.9
AE	26% E	5.9 – 7.6	99.1
AJ	50% J	5.2 – 8.4	100
AG	20% G	6.1 – 6.6	97.4
SC	52% S, 44%C	4.5 – 7.0	91.6
SE	65% S, 27% E	7.4	95.4
EE	94% E	5.1 – 8.9	98.0
Elevated F	4.6% F	6.5 – 8.1	93.6

Precision
Values according to IFCC

Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/mol]	32.6	32.4	66.0
CV [%]	1.92	1.79	0.950
Between day (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/mol]	28.4	28.4	69.1
CV [%]	2.81	2.35	1.84

Method comparison (n=100)	
Test x	HPLC Arkray HA-8160 V7.41 (Arkray HA-8160 V7.41)
Test y	DiaSys HbA1c net FS (Sysmex BX-3010)
Slope	1.07
Intercept	-1.09 mmol/mol
Coefficient of correlation	0.990

** according to CLSI document EP17-A2, Vol. 32, No. 8

Reference Range

Suggested target values for HbA1c [8]:

	mmol/mol IFCC	% NGSP
Non-diabetics	20 – 42	4 – 6
Target of therapy	< 53	< 7
Change of therapy	> 64	> 8

HbA1c cut point value for diagnosis of diabetes mellitus [2]:

According to a recommendation of the American Diabetes Association (ADA): ≥ 6.5% (NGSP) (48 mmol/mol (IFCC))

Patients with HbA1c values in the range of 5.7 – 6.4% HbA1c (NGSP) or 39 – 46 mmol/mol HbA1c (IFCC) may be at high risk of developing diabetes.

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

Literature

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Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.

IVD CE

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* Fluid Stable

HbA1c net FS

TWIN Test – Hemoglobin Application **Sysmex BX-3010**

(Hemolysates have to be prepared by use of HbA1c net FS Hemolyzing Solution Cat. No. 1 4590 99 10 113 only!)

Product code 1 3348 …

Chemistry Parameters 1 — **Sysmex BX-3010 Chemistry Analyzer Analytical Parameters**

Method No.	61	Method Name	HbA1c Hb	Reagent Name	Reagent (µL)	Water (µL)
Print Name	Hb	MethodColor		R1 HbA1c	150	
Sample Type	RBC			R2 HbA1c	50	
Unit	g/dL			Hemolyzer	Disable	
Assay Type	End			Sample Ppt. Wash	Disable	

Measuring points

	Start		End
Hb 1	23	–	23
Hb 2	Disable	–	25
A1c 1	25	–	26
A1c 2	45	–	46

Stirring Speed R1 Middle R2 Middle
Stirring for hemolysis Fast

Wave Length

Hb Prim.	570	Hb Sec.	800
A1c Prim.	660	A1c Sec.	800

Normal Range

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

	Sample Volume (µL) Low	Normal	High	Hemolyzed Sample (µL)	Hemolyzer (µL)	Technical Range
☐ hemolysis	0.0 <	25.0 <	0.0	10	250	(Conc) 0 – 9999
Rerun (High/Prozone)						(mAbs/10) * – *
☐ hemolysis	0.0 <	25.0 <	0.0	10	250	Previous Result Comparison (%) * * %
Rerun (Low)						
☐ hemolysis	0.0 <	25.0 <	0.0	10	250	Abnormal Range (Conc) * – *

Aspirating position 30

Panic Range (Conc) –

Decimal Point 3 Profile SI Disable

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Chemistry Parameters 2 — **Sysmex BX-3010 Chemistry Analyzer Analytical Parameters**

Method No. 61 Method Name HbA1c Hb Sample RBC

Limit Checks

- ✓ Duplicate Limit 70 mAbs/10
- ✓ Sensitivity Limit 2200 mAbs/10
- Linearity Limit %
- (mAbs/10)/min
- ☐ Prozone Limit %
- Higher
- SL1-S 1 – SL1-F 2
- SL2-S 3 – SL2-F 4
- 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:
Triplicate

Reagent blank limit checks:
- ✓ Duplicate Limit 20 mAbs/10

Instrument Factor

a 1.00 b 0.00

HbA1c net FS

TWIN Test – Hemoglobin Application

Sysmex BX-3010

(Hemolysates have to be prepared by use of HbA1c net FS Hemolyzing Solution Cat. No. 1 4590 99 10 113 only!)

Product code 1 3348 …

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No.	61
Method Name	Hb
Sample Type	RBC
Replication	Duplicate
Check Interval	42
Test without calibration	Disable
Calibration Type	Linear
Reagent Lot	New / Add
Calibrator Name	TruCal HbA1c net

	Conc.	WORK	MASTER	Calibr. Lot No. ☐ All
C1	Enter conc Level I	Automatic entry	Automatic entry	*
C2	Enter conc Level II	Automatic entry	Automatic entry	*
C3	*			
C4	*			
C5	*			
C6	*			
C7	*			

K: Automatic entry ☐ C1 Blank ☐ Reagent Blank for C1

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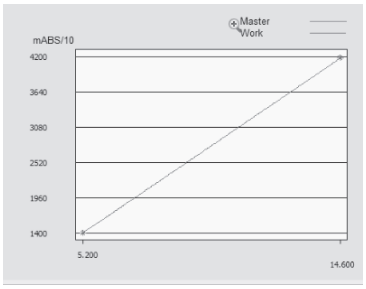
Reagent Lot No.
(R1) * Last
(R2) *



The calibration curve is lot dependent

Reagent blank		mAbs/10	Last	
Blank	Automatic entry	mAbs/10	Last	
Calibration Curve			Conc.	
Absorbance		mAbs/10	Recalculation	

HbA1c net FS

TWIN Test – HbA1c Application **Sysmex BX-3010**

(Hemolysates have to be prepared by use of HbA1c net FS Hemolyzing Solution Cat. No. 1 4590 99 10 113 only!)

Product code 1 3348 …

Chemistry Parameters 1 **Sysmex BX-3010 Chemistry Analyzer Analytical Parameters**

Method No.	60	Method Name	HbA1c A1c	Reagent Name	Reagent (µL)	Water (µL)
Print Name	A1c	MethodColor		R1 HbA1c	150	
Sample Type	RBC			R2 HbA1c	50	
Unit	g/dL			Hemolyzer	Disable	
Assay Type	End			Sample Ppt. Wash	Disable	

Measuring points — Start — End — Stirring Speed R1: Middle — R2: Middle

	Start		End
Hb 1	23	–	23
Hb 2	Disable	–	25
A1c 1	25	–	26
A1c 2	45	–	46

Normal Range

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

Wave Length

Hb Prim.	570	Hb Sec.	800
A1c Prim.	660	A1c Sec.	800

	Sample Volume (µL) Low	Normal	High	Hemolyzed Sample (µL)	Hemolyzer (µL)	Technical Range
☐ hemolysis	0.0 <	25.0 <	0.0	10	250	(Conc) 0 – 9999
						(mAbs/10) * – *
Rerun (High/Prozone) ☐ hemolysis	0.0 <	25.0 <	0.0	10	250	Previous Result Comparison (%) * * %
Rerun (Low) ☐ hemolysis	0.0 <	25.0 <	0.0	10	250	Abnormal Range (Conc) * – *
						Panic Range (Conc) –

Decimal Point 3 — Profile SI Disable

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Chemistry Parameters 2 **Sysmex BX-3010 Chemistry Analyzer Analytical Parameters**

Method No. 60 — Method Name HbA1c A1c — Sample RBC

Limit Checks

- ✓ Duplicate Limit 50 mAbs/10
- ✓ Sensitivity Limit 500 mAbs/10
- Linearity Limit %
- (mAbs/10)/min
- ☐ Prozone Limit Higher %
- SL1-S 1 – SL1-F 2
- SL2-S 3 – SL2-F 4
- 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: Triplicate
- Reagent blank limit checks:
  - ✓ Duplicate Limit 20 mAbs/10

Instrument Factor

a 1.00 b 0.00

HbA1c net FS

TWIN Test – HbA1c Application **Sysmex BX-3010**

(Hemolysates have to be prepared by use of HbA1c net FS Hemolyzing Solution Cat. No. 1 4590 99 10 113 only!)

Product code 1 3348 …

Calibration Registration

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Method No. 60

Method Name HbA1c

Sample Type RBC

Replication Duplicate

Check Interval 42

Test without calibration: Disable

Calibration Type Linear

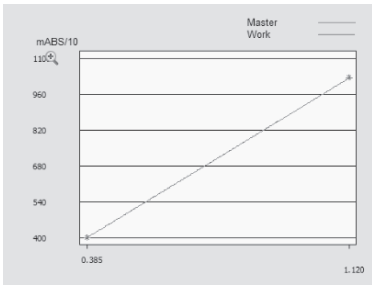
Reagent Lot New Add

Calibrator Name TruCal HbA1c net

	Conc.	WORK	MASTER	Calibr. Lot No.	☐ All
C1	Enter conc Level I	Automatic entry	Automatic entry	*	
C2	Enter conc Level II	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

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HbA1c net FS TWIN Test – HbA1c Calculation

Calculated Test

Sysmex BX-3010 Chemistry Analyzer
Analytical Parameters

Calculated test No. 3003

Calculated Test Name HbA1c2

Print Name HbA1c net

Sample Type Hemolysate/Hemolysate

Unit mmol/mol

Decimal Point 2

Expression

{60}/{61}*1000

Normal Range

No.	Range Name	Min	Max
1	Male-G1	0.00	0.00
2	Male-G2	0.00	0.00
3	Male-G3	0.00	0.00
4	Female-G1	0.00	0.00
5	Female-G2	0.00	0.00
6	Female-G3	0.00	0.00

[+] [-] [*] [/] [( ] [ )]

16	FE	17	GLUHK	18	HDL-C
19	LDL-C	20	LDH	21	MG
22	PO3	23	TRIG	24	TP
25	UREA	26	UA	27	IIBC
28	FerrFD	29	HDLpj	30	HCG
31	LPS	32	CL	33	NA
34	K	35	Glyc	36	CRP
37	CRPU	38	CRPhs	39	PAMY
40	IgG	41	ASO	42	TRF
43	A1cHig	44	Lp(a)	45	MALBs
46	RF				
		53	16µL	54	8µL
55	2µL	56	Olin	57	SPTS
58	RPTS	59	RPT2S	60	HbA1c
61	Hb				
1001	ISE-Na	1002	ISE-K	1003	ISE-Cl
1005	ISE(U)-Na	1005	ISE(U)-K	1007	ISE(U)-Cl
2001	SI-H	2002	SI-L	2003	SI-I

HbA1c net FS

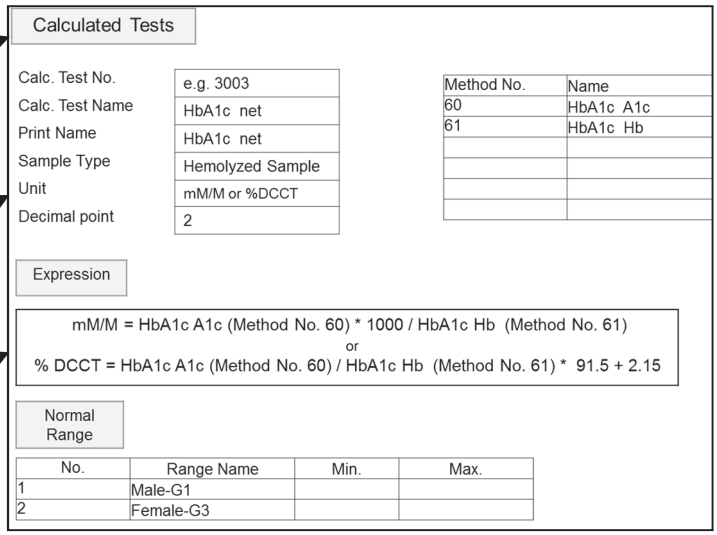
Instruction for Entering Calculation Formula into Sysmex BX-3010:

Window A:

2. Choose „Calculated Tests“ in „Calculator“

1. Choose preferred unit mM/M (IFCC) or % (NGSP).

3. Enter calculation formula for preferred unit mM/M (IFCC) or % (NGSP).



Please note: Hemoglobin and HbA1c values determined with DiaSys HbA1c net FS are used for calculation of the HbA1c ratio from total hemoglobin exclusively. The individual results for hemoglobin (HbA1c Hb) and HbA1c (HbA1c A1c) must not be used for diagnostic