



CYANVision Application sheet



For a <u>clear</u> and <u>precise</u> diagnose



DIRECTIONS FOR USE

AUTOMATION

CYANVision

CLINICAL CHEMISTRY





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Application sheet

α-Amylase

REF	HBE03
VOL	20 x 2 mL
Standard	-

CNPG3. Colorimetric. Kinetic

REAGENT PREPARATION AND STABILITY

The Amylase reagent is ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

After opening, the reagent is stable for 60 days when properly capped immediately after each opening and stored at 2-8 °C. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 405 nm ≥ 0,40, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with the control vials. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

- Serum or plasma, remove from cells as soon as possible. It is recommended to use heparin as anticoagulant.
- Stability: 1 month at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank ^{Note 1}	1,0 mL Reagent
For Sample/(Calibrator) ^{Note 2,4}	20 μL Sample/(Calibrator) + 1,0 mL Reagent

Prepare, mix and measure one sample at a time. Aspirate the mixture in the instrument, immediately after addition of the working solution to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample.

PROGRAM SETUP

Prog. Name:	AAMY		Linearity Max:	2200	U/L	STD variable:	No ^{Note 2}	
Prog. ID:	1		Fit:	95		Standard Conc.:	0,0000 ^{Note 2}	
Prog. Version:	1		Direction:	Up		Calibration repeats:	0	
Method ID:	1		Working reagent:	No		CAL CV%:	0	
Method Name:	A-Amylase		Blank Type:	Reagent ^{Note 1}		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	405	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	28	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	90	U/L
Decimals:	0		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	28	U/L
Aspiration Volume:	0800	μL	Blank High:	0,400 ^{Note 1}		Normal High - Female	90	U/L
Delay Time:	120	S	Blank Mandatory:	No		Normal Low - Child	28	U/L
Test Time:	090	S	Factor:	3954 ^{Note 2}		Normal High - Child	90	U/L
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	0,2439	U/L	Num of STD:	O ^{Note 2}				

MEASURING RANGE

This method is linear from 0,2439 U/L (detection limit) to 2200 U/L (linearity limit). If the obtained results are greater than 2200 U/L, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Albumin

REF **HB0010** HB0010M VOL 2 x 125 mL 8 x 30 mL Standard 1 x 5 mL

Bromocresol Green. Colorimetric

REAGENT PREPARATION AND STABILITY

Reagent and standard are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 25 °C.

Once open, the standard is stable up to 3 months.

Do not exceed the temperature of 25 °C during storage. The reagent should be a clear, yellow-green solution. If turbidity or precipitation has occurred or if blank absorbance at 620 nm ≥ 0,40, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma, free of hemolysis. Stability 1 month at 2 - 8 °C or 1 week at 15 - 25 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1 mL Reagent		
For Standard Note 2	5 μL Standard + 1 mL Reagent		
For Sample	5 μL Sample + 1 mL Reagent		

You can prepare several samples simultaneously. Mix and incubate for 10 minutes at room temperature. After the incubation time, aspirate and measure the samples within 1 hour after preparation.

PROGRAM SETUP

Prog. Name:	ALB		Linearity Max:	5,8	g/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	2		Fit:	0		Standard Conc.:	value: see	vial ^{Note 2}
Prog. Version:	1		Direction:	Not applical	ole	Calibration repeats:	0	
Method ID:	2		Working reagent:	No		CAL CV%:	0	
Method Name:	Albumin		Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	620	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	3,5	g/dL
Prog. Unit:	g/dL		Blank CV%:	0		Normal High - Male	5	g/dL
Decimals:	1		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	3,5	g/dL
Aspiration Volume:	0800	μL	Blank High:	0,400 ^{Note 1}		Normal High - Female	5	g/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	3,5	g/dL
Test Time:	003	S	Factor:	0		Normal High - Child	5	g/dL
Dilution factor:	1		Calib. By factor:	No		Method order:	0	
Linearity Min:	0,038	g/dL	Num of STD:	1				

MEASURING RANGE

This method is linear from 0,038 g/dL (detection limit) to 5,8 g/dL (linearity limit). If the obtained results are greater than 5,8 g/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

Alkaline Phosphatase

IFCC. Colorimetric. Kinetic

REF	HBE12
VOL	60 + 15 mL
Standard	-

REAGENT PREPARATION AND STABILITY

Mix 4 volumes of R1 (buffer) with 1 volume of R2 (substrate). The stability of working reagent is 21 days at 2-8 °C or 5 days at room temperature (15-25 °C).

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C. Do not freeze the reagents.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 405 nm > 1,50, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. **Use Biochemistry Normal and Pathological Controls (HBC01, HBC02)**. Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with the control vials. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum or heparinized plasma. Use non-hemolyzed serum, separated from the cloth as soon as possible. Stability: 3 days at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature.

Then, pipette into a test tube:

For Blank	1,00 mL Working reagent (R1 + R2)
For Sample/(Calibrator)Note 2	20 µL Sample/(Calibrator) + 1,00 mL Working reagent (R1 + R2)

Prepare, mix and measure **one sample at a time**. Aspirate the mixture in the instrument, **immediately** after addition of the working solution to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample.

PROGRAM SETUP

Prog. Name:	ALP		Linearity Max:	1400	U/L	STD variable:	No ^{Note 2}	
Prog. ID:	3		Fit:	95		Standard Conc.:	0,0000 ^{Note 2}	
Prog. Version:	1		Direction:	Up		Calibration repeats:	0	
Method ID:	3		Working reagent:	Yes		CAL CV%:	0	
Method Name:	ALPhosphat(IFCC)		Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	405	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	26	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	117	U/L
Decimals:	0		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	26	U/L
Aspiration Volume:	0800	μL	Blank High:	1,500 ^{Note 1}		Normal High - Female	117	U/L
Delay Time:	060	S	Blank Mandatory:	No		Normal Low - Child	26	U/L
Test Time:	090	S	Factor:	2764 ^{Note 2}		Normal High - Child	117	U/L
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	1,307	U/L	Num of STD:	O ^{Note 2}				

MEASURING RANGE

This method is linear from 1,307 U/L (detection limit) to 1400 U/L (linearity limit). If the obtained results are greater than 1400 U/L, dilute the sample 1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Bilirubin Direct

DMSO. Colorimetric

REF HB0260 HB0020 HB0020A VOL 2 x 125 mL 1 x 125 mL 4 x 125 mL

REAGENT PREPARATION AND STABILITY

All reagents are ready for use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-25 °C. The reagent should be a clear solution. If turbidity or precipitation has occurred or if color development has occurred in reagent N, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Preprogrammed factors can only be used when quality controls are within the defined ranges. Otherwise, use the Biochemistry Calibrator (**HBC03**) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control values are found outside the defined range, check the instrument, reagents and calibration for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma, free of hemolysis. Protect samples from direct light. Bilirubin is stable up to 4 days at 2-8 °C and 2 months at -20 °C.

PROCEDURENote 4

Make sure the reagents and samples are at room temperature. Protect samples from direct sunlight. Then, pipette into a test tube:

For Reagent Blank	750 μL Reagent D			
For Reagent	μL Reagent N + 750 μL Reagent D			
For Sample/Cal Blank	100 μL Sample/Calibrator + 750 μL Reagent D			
For Sample/Cal	100 µL Sample/Calibrator + 25 µL Reagent N + 750 µL Reagent D			

Thus, for every sample, you need to prepare 2 test tubes: one for measuring the sample blank (background coloration) and one for measuring the real sample coloration. Add Reagent N only to the second tube. Add Reagent D last, mix and incubate for exactly 5 minutes at room temperature. Aspirate the mixture in the instrument, exactly 5 minutes after addition of the Reagent D.

Use the illustrations on the next page for guidance to perform this test in a time-efficient way. Watch our Bilirubin video: https://diagnostics.be/product/hb0260

PROGRAM SETUP

Prog. Name:	BILD		Linearity Max:	20	mg/dL	STD variable:	No ^{Note 2}	
Prog. ID:	4		Fit:	0		Standard Conc.:	0,0000 ^{Note 2}	
Prog. Version:	2		Direction:	Not applicable		Calibration repeats:	3	
Method ID:	4		Working reagent:	No		CAL CV%:	10	
Method Name:	Bilirubin di	rect	Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	Yes ^{Note 4}		Calib. Mandatory:	No	
Main Filter:	546	nm	VCF:	0,97		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	0,06	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	0,25	mg/dL
Decimals:	2		Blank Low:	-0,100 ^{Note 1}		Normal Low - Female	0,06	mg/dL
Aspiration Volume:	0700	μL	Blank High:	0,100 ^{Note 1}		Normal High - Female	0,25	mg/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	0,06	mg/dL
Test Time:	003	S	Factor:	19 ^{Note 2}		Normal High - Child	0,25	mg/dL
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	0,06	mg/dL	Num of STD:	0				

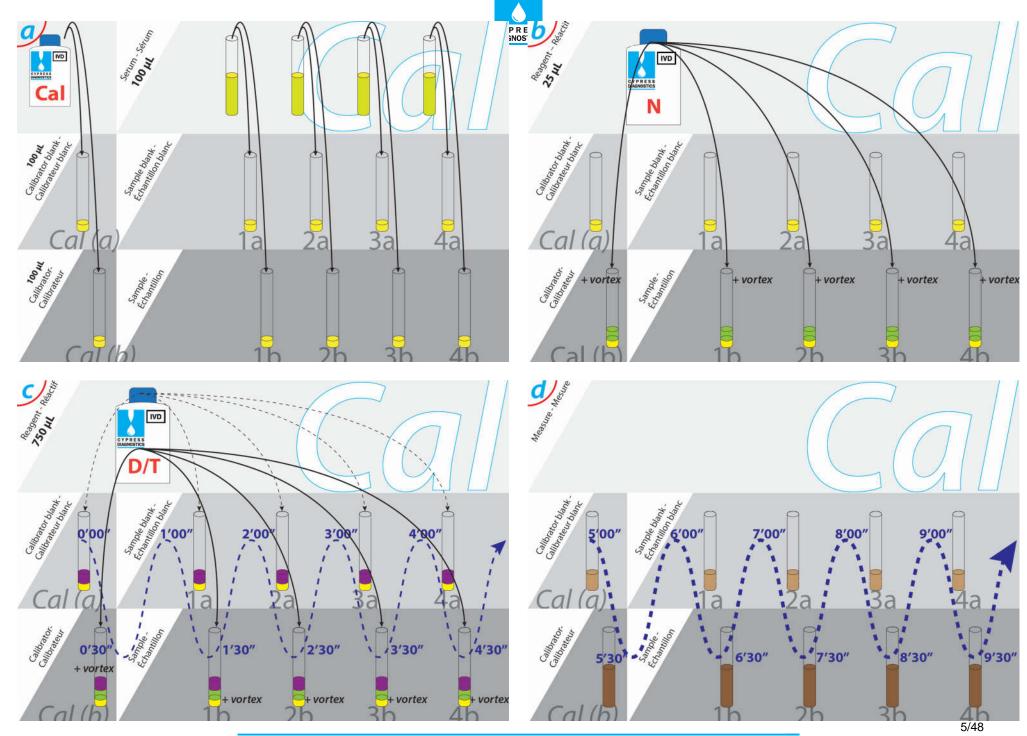
MEASURING RANGE

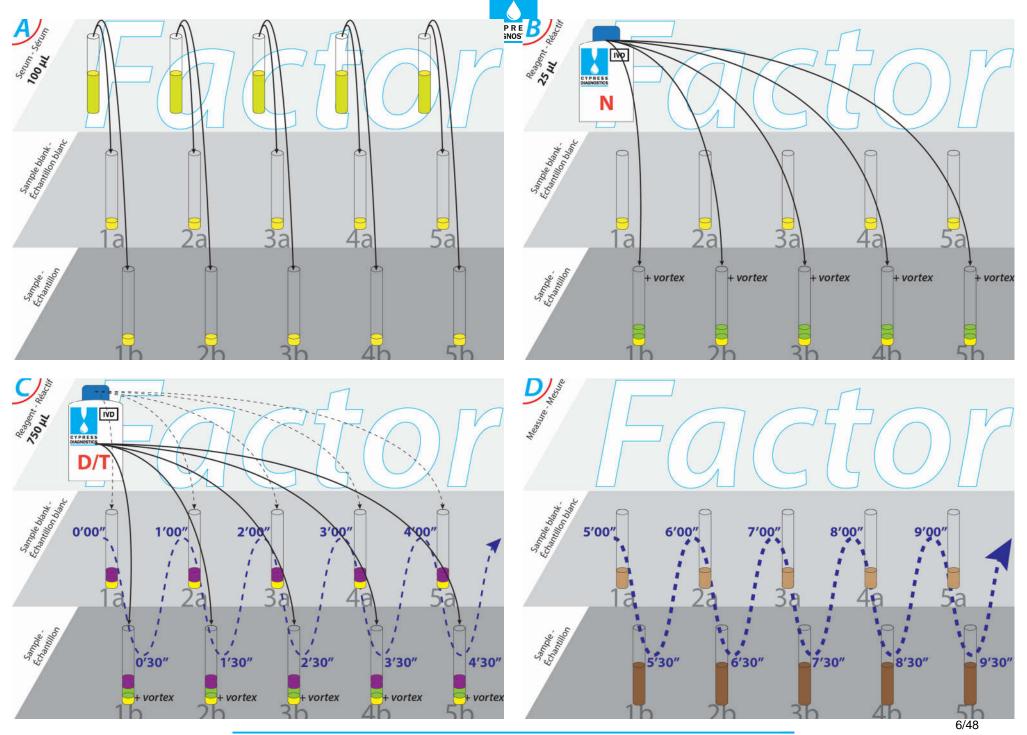
This method is linear from 0,06 mg/dL (detection limit) to 20 mg/dL (linearity limit). If the obtained results are greater than 20 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.
- 4. This program requires a Sample Blank! Pay attention, this determines the calculation of the results, not the blank aspiration!
 - Aspirate distilled water to adjust the instrument to zero (AD value)
 - In the Blank menu,
 - a. First: Aspirate "Reagent Blank"
 - b. Secondly: Aspirate "Reagent"
 - Reagent blank is required for each new reagent lot.
 - In the Standard/Sample menu,
 - $a. \quad \mbox{First: Aspirate Standard/Calibrator/Sample blank}$
 - b. Secondly: Aspirate Standard/Calibrator/Sample
- 5. Carefully aspirate the sample in the tube. In case of air bubbles, a flag will be shown and a rerun should be performed.









Application sheet

Bilirubin Total

DMSO. Colorimetric

REF HB0270 HB0020 HB0020A VOL 2 x 125 mL 1 x 125 mL 4 x 125 mL

REAGENT PREPARATION AND STABILITY

All reagents are ready for use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-25 °C. The reagent should be a clear solution. If turbidity or precipitation has occurred or if color development has occurred in reagent N, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Preprogrammed factors can only be used when quality controls are within the defined ranges. Otherwise, use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control values.

If control values are found outside the defined range, check the instrument, reagents and calibration for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma, free of hemolysis. Protect samples from direct light. Bilirubin is stable up to 4 days at 2-8 °C and 2 months at -20 °C.

PROCEDURE Note 4

Make sure the reagents and samples are at room temperature. Protect samples from direct sunlight. Then, pipette into a test tube:

For Reagent Blank	750 μL Reagent T
For Reagent	25 μL Reagent N + 750 μL Reagent T
For Sample/Cal Blank	100 μL Sample/Calibrator + 750 μL Reagent T
For Sample/Cal	100 μL Sample/Calibrator + 25 μL Reagent N + 750 μL Reagent T

Thus for every sample, you need to prepare 2 test tubes: one for measuring the sample blank (background coloration) and one for measuring the real sample coloration. Add Reagent N only to the second tube. Add Reagent T last, mix and incubate for exactly 5 minutes at room temperature. Aspirate the mixture in the instrument, exactly 5 minutes after addition of the Reagent T.

Use the illustrations on the next page for guidance to perform this test in a time-efficient way. Watch our Bilirubin video: https://diagnostics.be/product/hb0270

PROGRAM SETUP

Prog. Name:	BILT		Linearity Max:	20	mg/dL	STD variable:	No ^{Note 2}	
Prog. ID:	5		Fit:	0	-	Standard Conc.:	0,0000 ^{Note}	2
Prog. Version:	2		Direction:	Not applicable		Calibration repeats:	3	
Method ID:	5		Working reagent:	No		CAL CV%:	10	
Method Name:	Bilirubin t	otal	Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point	:	Sample Blank:	Yes ^{Note 4}		Calib. Mandatory:	No	
Main Filter:	546	nm	VCF:	0,97		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	0,2	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	1,1	mg/dL
Decimals:	1		Blank Low:	-0,100 ^{Note 1}		Normal Low - Female	0,2	mg/dL
Aspiration Volume:	0700	μL	Blank High:	0,100 ^{Note 1}		Normal High - Female	1,1	mg/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	0,2	mg/dL
Test Time:	003	S	Factor:	12 ^{Note 2}		Normal High - Child	1,1	mg/dL
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	0,1	mg/dL	Num of STD:	0				

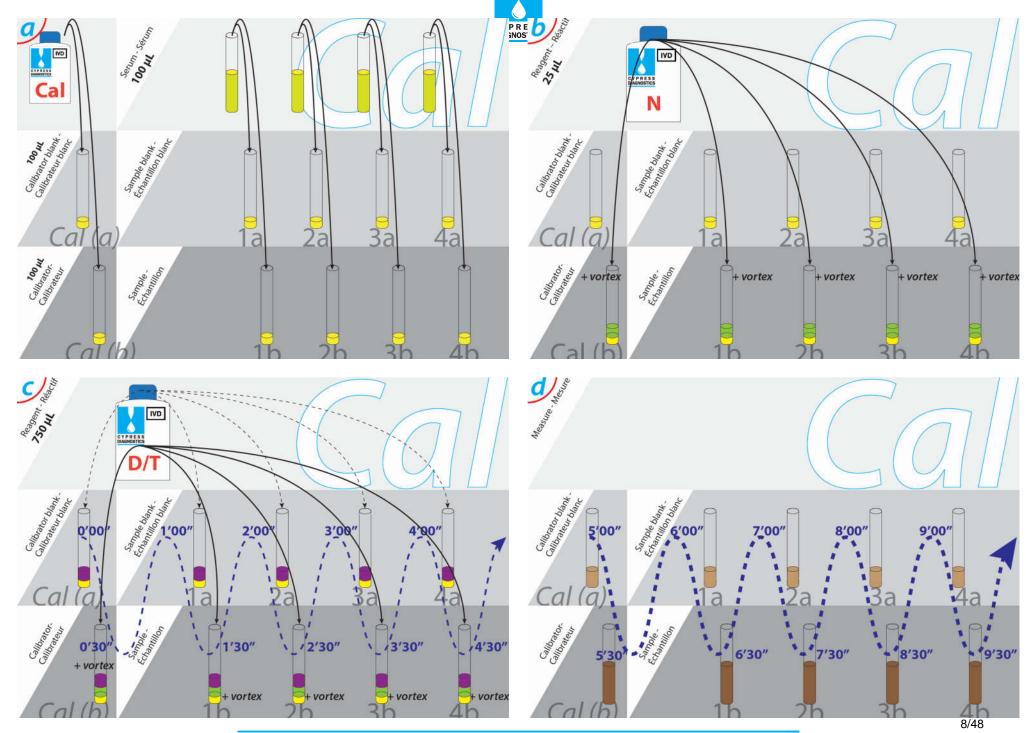
MEASURING RANGE

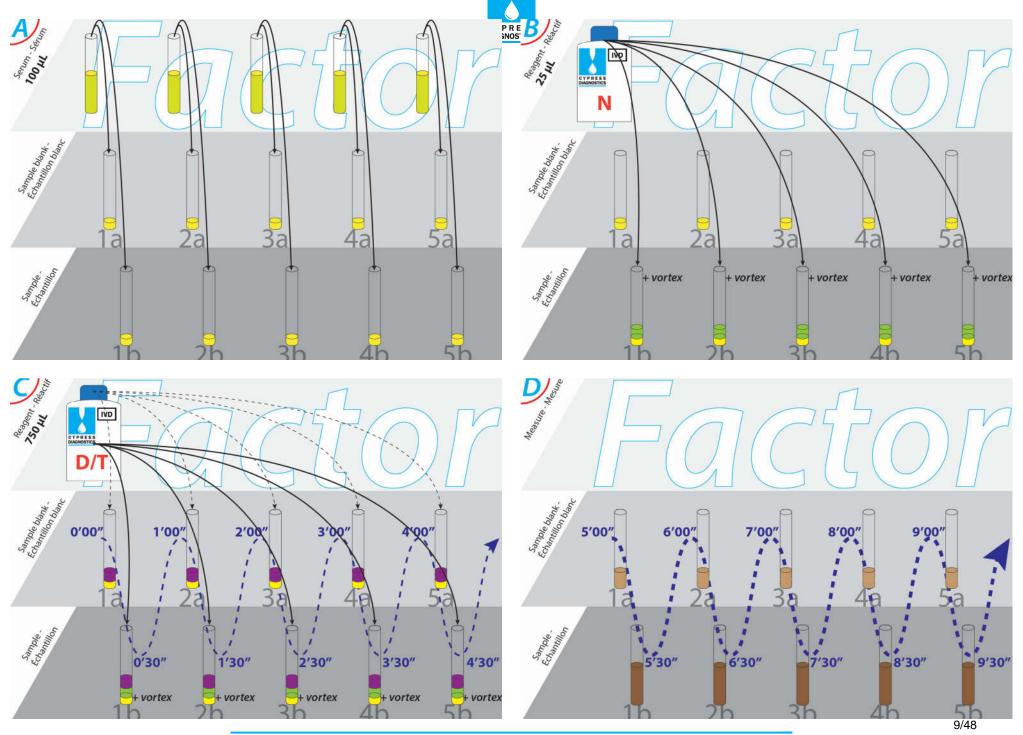
This method is linear from 0,1 mg/dL (detection limit) to 20 mg/dL (linearity limit). If the obtained results are greater than 20 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.
- 4. This program requires a Sample Blank! Pay attention, this determines the calculation of the results, not the blank aspiration!
 - Aspirate distilled water to adjust the instrument to zero (AD value)
 - In the Blank menu,
 - a. First: Aspirate "Reagent Blank"
 - b. Secondly: Aspirate "Reagent"
 - Reagent blank is required for each new reagent lot.
 - In the Standard/Sample menu,
 - a. First: Aspirate Standard/Calibrator/Sample blank
 - b. Secondly: Aspirate Standard/Calibrator/Sample
- 5. Carefully aspirate the sample in the tube. In case of air bubbles, a flag will be shown and a rerun should be performed.









Application sheet

Calcium

REF **HB0030** HB0030A **HB0030M** VOL 2 x 125 mL 8 x 125 mL 8 x 30 mL 1 x 5 mL 4 x 5 mL Standard

Arsenazo III. Colorimetric. Monoreagent

REAGENT PREPARATION AND STABILITY

The reagent and standard are ready for use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 620 nm ≥ 0,80 the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum or plasma: separated from cells as rapidly as possible. Blood anticoagulants with oxalate, citrate or EDTA are not acceptable since these chemicals will strongly chelate calcium.

Stability of the samples: Calcium is stable 10 days at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature.

Then, pipette into a test tube:

For Blank	,0 mL Reagent			
For Standard ^{Note 2}	20 μL Standard + 1,0 mL Reagent			
For Sample	20 μL Sample + 1,0 mL Reagent			

You can prepare several samples simultaneously. Mix and incubate for 2 minutes at 15 - 25 °C (room temperature). After the incubation time, aspirate and measure the samples within 1 hour after preparation.

PROGRAM SETUP

Prog. Name:	CA		Linearity Max:	20 mg/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	6		Fit:	0	Standard Conc.:	value: see via	Note 2
Prog. Version:	2		Direction:	Not applicable	Calibration repeats:	0	
Method ID:	6		Working reagent:	No	CAL CV%:	0	
Method Name:	Calcium		Blank Type:	Reagent	Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No	
Main Filter:	620	nm	VCF:	1	Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes	SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	3	Normal Low - Male	8,6	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	10	Normal High - Male	10,2	mg/dL
Decimals:	1		Blank Low:	0,000 ^{Note 1}	Normal Low - Female	8,6	mg/dL
Aspiration Volume:	0800	μL	Blank High:	0,800 ^{Note 1}	Normal High - Female	10,2	mg/dL
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	8,4	mg/dL
Test Time:	003	S	Factor:	0	Normal High - Child	11	mg/dL
Dilution factor:	1		Calib. By factor:	No	Method order:	1	
Linearity Min:	0,1629	mg/dL	Num of STD:	1 Note 2			

MEASURING RANGE

This method is linear from 0,163 mg/dL (detection limit) to 20 mg/dL (linearity limit). If the obtained results are greater than 20 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Cholesterol

REF	HBL010	HBL010A	HBL010M		
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL		
Standard	1 x 5 mL	4 x 5 mL	-		

Enzymatic. Colorimetric test CHOD-POD

REAGENT PREPARATION AND STABILITY

The reagent and standard are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 510 nm \geq 0,26, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum or plasma: stability of the sample for 7 days at 2-8 °C or 3 months at -20 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	mL Reagent			
For Standard ^{Note 2}	10 μL Standard + 1 mL Reagent			
For Sample	10 μL Sample + 1 mL Reagent			

You can prepare several samples simultaneously. Mix and incubate for 10 minutes at 37 °C or for 15 minutes at 15 - 25 °C (room temperature). After the incubation time, aspirate and measure the samples within 45 minutes after preparation.

PROGRAM SETUP

Prog. Name:	CHOL		Linearity Max:	1000	mg/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	7		Fit:	0		Standard Conc.:	value: see v	∕ial ^{Note 2}
Prog. Version:	2		Direction:	Not applicabl	e	Calibration repeats:	0	
Method ID:	8		Working reagent:	No		CAL CV%:	0	
Method Name:	Cholesterol		Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	510	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	3		Normal Low - Male	120	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	10		Normal High - Male	200	mg/dL
Decimals:	0		Blank Low:	-0,010 ^{Note 1}		Normal Low - Female	120	mg/dL
Aspiration Volume:	0800	μL	Blank High:	0,260 ^{Note 1}		Normal High - Female	200	mg/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	120	mg/dL
Test Time:	003	S	Factor:	0		Normal High - Child	170	mg/dL
Dilution factor:	1		Calib. By factor:	No ^{Note 2}		Method order:	0	
Linearity Min:	0,521	mg/dL	Num of STD:	1 Note 2				

MEASURING RANGE

This method is linear from 0,521 mg/dL (detection limit) to 1000 mg/dL (linearity limit). If the obtained results are greater than 1000 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Creatine Kinase MB

Immuno-inhibition. UV. Kinetic

REAGENT PREPARATION AND STABILITY

Working reagent: mix 4 volumes of R1 with 1 volume of R2. After mixing, allow to stand for 30 minutes prior to use. <u>The stability of the working reagent is 7 days at 2-8 °C or 12 hours at room temperature (15-25 °C).</u>

Control: dissolve the contents in 2 mL of distilled water. Cap vial and mix gently to dissolve the contents. <u>Stability: 8 hours at 15-25 °C, 5 days at 2-8 °C or 1 month at -20 °C.</u> Bring at room temperature for about 30 min before use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm \geq 1,20, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Preprogrammed factors can only be used when quality controls are within the defined ranges. Otherwise, use the Biochemistry Calibrator (**HBC03**) for calibration.

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use the **CK (NAC&MB) control (HBC08)** included in the kit. Note 2 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the label of the control vial.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum free of hemolysis, or heparin plasma.

Stability: 7 days at 2 - 8 °C, protected from light. CK-MB activity decreases a 10% after 24 hours at 4 °C or 1 hour at 25 °C. Use fresh samples.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank ^{Note 1}	1,00 mL Working reagent (R1 + R2)
For Sample/(Calibrator)	40 μL Sample/(Calibrator) + 1,00 mL Working reagent (R1 + R2)

Mix and incubate for 10 minutes at room temperature. After the incubation time, aspirate and measure the sample.

PROGRAM SETUP

Prog. Name:	CKMB		Linearity Max:	1000	U/L	STD variable:	No	
Prog. ID:	8		Fit:	95		Standard Conc.:	0,0000	
Prog. Version:	2		Direction:	Up		Calibration repeats:	0	
Method ID:	11		Working reagent:	Yes		CAL CV%:	0	
Method Name:	Creat Kina	seMB	Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	340	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	1,9	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	24	U/L
Decimals:	2		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	1,9	U/L
Aspiration Volume:	0800	μL	Blank High:	1,200 ^{Note 1}		Normal High - Female	24	U/L
Delay Time:	10	S	Blank Mandatory:	No		Normal Low - Child	1,9	U/L
Test Time:	300	S	Factor:	8255		Normal High - Child	24	U/L
Dilution factor:	1		Calib. By factor:	Yes		Method order:	0	
Linearity Min:	1,9	U/L	Num of STD:	0				

MEASURING RANGE

This method is linear from 1,9 U/L (detection limit) to 1000 U/L (linearity limit). If the obtained results are greater than 1000 U/L, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

Creatine Kinase NAC

NAC Activated, UV. Kinetic

REF HBEL03 VOL 60 + 15 mL

REAGENT PREPARATION AND STABILITY

Mix 4 volumes of reagent 1 with 1 volume of reagent 2. The stability of the working reagent is 2 weeks a 2 - 8 °C or 48 hours at room temperature

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm ≥ 1,0 the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Preprogrammed factors can only be used when quality controls are within the defined ranges. Otherwise, use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Also a CK (NAC & MB) Control (HBC08) is available. Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Sample type: human serum free of hemolysis, or heparin plasma.

Stability: 7 days at 2 - 8 °C, protected from light. The creatinine kinase activity decreases 10% after 1 day at 2 - 5 °C or after 1 hour at 15 - 25 °C. Use fresh samples.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank ^{Note 1}	1,00 mL Working reagent (R1 + R2)
For Sample/(Calibrator)Note 2	20 μL Sample/(Calibrator) + 1,00 mL Working reagent (R1 + R2)

Prepare, mix and measure one sample at a time. Aspirate the mixture in the instrument, immediately after addition of the working solution to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks "Press PUSH Aspirate Sample".

PROGRAM SETUP

Prog. Name:	CKNAC		Linearity Max:	2000	U/L	STD variable:	No ^{Note 2}	
Prog. ID:	9		Fit:	95		Standard Conc.:	0,0000 ^{Note 2}	
Prog. Version:	1		Direction:	Up		Calibration repeats:	0	
Method ID:	12		Working reagent:	Yes		CAL CV%:	0	
Method Name:	Creat Kina	seNAC	Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	340	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	46	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	195	U/L
Decimals:	1		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	34	U/L
Aspiration Volume:	0800	μL	Blank High:	1,000 ^{Note 1}		Normal High - Female	170	U/L
Delay Time:	120	S	Blank Mandatory:	No		Normal Low - Child	34	U/L
Test Time:	090	S	Factor:	8095 ^{Note 2}		Normal High - Child	170	U/L
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	2,12	U/L	Num of STD:	0				

MEASURING RANGE

This method is linear from 2,12 U/L (detection limit) to 2000 U/L (linearity limit). If the obtained results are greater than 2000 U/L, dilute the sample 1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

Chloride

REF **HB005** VOL 2 x 125 mL 1 x 5 mL Standard

Thiocyanate. Colorimetric

REAGENT PREPARATION AND STABILITY

The reagent is ready for use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 440-500 nm \geq 0,15, the reagent should be discarded. Handle standard very carefully to prevent contamination. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

- Serum, plasma: Free of hemolysis and separated from cells as rapidly as possible. Anticoagulants such as oxalate or EDTA will interfere.
- Chloride is stable 1 week at room temperature (15-25 °C), 15 days in refrigerator (2-8 °C) and 1 month frozen (-20 °C).

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	I,00 mL Reagent 1			
For Standard ^{Note 2}	10 μL Standard + 1,00 mL Reagent 1			
For Sample	10 μL Sample + 1,00 mL Reagent 1			

You can prepare several samples simultaneously. Mix and incubate for 5 minutes at 37 °C or for 5 minutes at 15 - 25 °C (room temperature). After the incubation time, aspirate and measure the samples within 30 minutes after preparation.

PROGRAM SETUP

Prog. Name:	CL		Linearity Max:	190 mEq/L	STD variable:	Yes ^{Note 2}
Prog. ID:	10		Fit:	0	Standard Conc.:	value: see vialNote 2
Prog. Version:	2		Direction:	Not applicable	Calibration repeats:	0
Method ID:	7		Working reagent:	No	CAL CV%:	0
Method Name:	Chloride		Blank Type:	Reagent	Temp flowcell:	37 °C
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No
Main Filter:	450	nm	VCF:	1	Control Mandatory:	No
Sub Filter:	None		Blank substraction:	Yes	SampleTypeRefValue:	Serum
Bichromatic Factor:	0		Num of Blank:	1	Normal Low - Male	95 mEq/L
Prog. Unit:	mEq/L		Blank CV%:	0	Normal High - Male	115 mEq/L
Decimals:	0		Blank Low:	0,000 ^{Note 1}	Normal Low - Female	95 mEq/L
Aspiration Volume:	0800	μL	Blank High:	0,150 ^{Note 1}	Normal High - Female	115 mEq/L
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	95 mEq/L
Test Time:	003	S	Factor:	0	Normal High - Child	115 mEq/L
Dilution factor:	1		Calib. By factor:	No	Method order:	2
Linearity Min:	0,454	mEq/L	Num of STD:	1 Note 2		

MEASURING RANGE

This method is linear from 0,454 mEq/L (detection limit) to 190 mEq/L (linearity limit). If the obtained results are greater than 190 mEq/L, dilute the sample 1:2 with distilled water, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Creatinine

REF	HB0080	HB0080A	HB0080M
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL
Standard	1 x 5 ml	4 x 5 ml	_

Jaffé. Colorimetric. Kinetic without deproteinization

REAGENT PREPARATION AND STABILITY

Mix proportionally 1:1 R1 Picric Reagent and R2 Alkaline Reagent. The working reagent is stable for 10 days at 15-25 °C.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-25 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 510 nm \geq 1,80, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Use serum or heparinized plasma. Creatinine is stable 24 hours at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank ^{Note 1}	1,00 mL Working reagent
For Standard ^{Note 2}	100 μL Standard + 1,00 mL Working reagent
For Sample	100 μL Sample + 1,00 mL Working reagent

Prepare, mix and measure **one sample at a time.** Aspirate the mixture in the instrument, **immediately** after addition of the working solution to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample.

PROGRAM SETUP

I ROGRAMI SET OT								
Prog. Name:	CRE		Linearity Max:	15	mg/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	11		Fit:	0		Standard Conc.:	value: see	vial ^{Note 2}
Prog. Version:	2		Direction:	Up		Calibration repeats:	0	
Method ID:	13		Working reagent:	Yes		CAL CV%:	0	
Method Name:	Creatinine		Blank Type:	Reagent ^{Note 1}		Temp flowcell:	37	°C
Method Type:	Two Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	510	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	0,7	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	1,4	mg/dL
Decimals:	1		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	0,6	mg/dL
Aspiration Volume:	0800	μL	Blank High:	1,800 ^{Note 1}		Normal High - Female	1,1	mg/dL
Delay Time:	030	S	Blank Mandatory:	No		Normal Low - Child	0,6	mg/dL
Test Time:	060	S	Factor:	0		Normal High - Child	1,1	mg/dL
Dilution factor:	1		Calib. By factor:	No		Method order:	0	
Linearity Min:	0,115	mg/dL	Num of STD:	1 Note 2				

MEASURING RANGE

This method is linear from 0,115 mg/dL (detection limit) to 15 mg/dL (linearity limit). If the obtained results are greater than 15 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

γ-GT

REF	HBEL06	HBEL061
VOL	240 + 60 mL	60 +15 mL
Standard	1	1

Carboxy substrate. Colorimetric. Kinetic

REAGENT PREPARATION AND STABILITY

Mix 4 volumes of R1 (Buffer) with 1 volume of R2 (Substrate). The stability of this working reagent is 21 days at 2-8 °C or 5 days at room temperature (15-25 °C).

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 405 nm \geq 1,80, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum: γ -GT is stable for at least 3 days at 2-8 °C, 8 hours at 15-25 °C and 1 month at -20 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank ^{Note 1}	1,00 mL Working reagent (R1 + R2)
For Sample/(Calibrator)Note 2	100 μL Sample/(Calibrator) + 1,00 mL Working reagent (R1 + R2)

Prepare, mix and measure **one sample at a time.** Aspirate the mixture in the instrument, **immediately** after addition of the working reagent to the sample/(calibrator). Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample.

PROGRAM SETUP

Prog. Name:	GGT	·	Linearity Max:	300	U/L	STD variable:	No ^{Note 2}	·
Prog. ID:	13		Fit:	95		Standard Conc.:	0,0000 ^{Note 2}	
Prog. Version:	1		Direction:	Up		Calibration repeats:	0	
Method ID:	14		Working reagent:	Yes		CAL CV%:	0	
Method Name:	G-GT		Blank Type:	Reagent ^{Note 1}		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	405	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	11	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	50	U/L
Decimals:	0		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	7	U/L
Aspiration Volume:	0800	μL	Blank High:	1,800 ^{Note 1}		Normal High - Female	32	U/L
Delay Time:	060	S	Blank Mandatory:	No		Normal Low - Child	7	U/L
Test Time:	090	S	Factor:	1190 ^{Note 2}		Normal High - Child	32	U/L
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	2	U/L	Num of STD:	O ^{Note 2}				

MEASURING RANGE

This method is linear from 2 U/L (detection limit) to 300 U/L (linearity limit). If the obtained results are greater than 300 U/L, dilute the sample 1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Glucose

GOD-POD

Enzymatic. Colorimetric

REF	HBL04	HBL04A	HBL04M
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL
Standard	1 x 5 mL	4 x 5 mL	-

REAGENT PREPARATION AND STABILITY

Reagent and standard are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

Handle standards very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 510 nm \geq 0,32, the reagent should be discarded. Do not use the product if deterioration or contamination is suspected or beyond the expiration date. Dispose unused or deteriorated product and waste in compliance with local regulations. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Fluoride plasma, free of hemolysis. Plasma should be isolated in blood tubes containing sodium fluoride (NaF) to inhibit glycolysis. In fluoride plasma, the glucose concentration is stable for up to 3 days at room temperature. For fasting glucose determination, fasting for at least 12 hours is recommended before sample collection.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1,00 mL Reagent
For Standard ^{Note 2}	10 μL Standard + 1,00 mL Reagent
For Sample	10 μL Sample + 1,00 mL Reagent

You can prepare several samples simultaneously. Mix and incubate for 10 minutes at 37 °C or for 15 minutes at 15-25 °C (room temperature). After the incubation time, aspirate and measure the samples within 40 minutes after preparation.

PROGRAM SETUP

Prog. Name:	GLUC		Linearity Max:	420 mg/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	14		Fit:	0	Standard Conc.:	value: see vialNote 2	
Prog. Version:	2		Direction:	Not applicable	Calibration repeats:	3	
Method ID:	15		Working reagent:	No	CAL CV%:	10	
Method Name:	Glucose		Blank Type:	Reagent	Temp flowcell:	37 °C	
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No	
Main Filter:	510	nm	VCF:	1	Control Mandatory:	No	
Sub Filter:	620	nm	Blank substraction:	Yes	SampleTypeRefValue:	Plasma	
Bichromatic Factor:	0,19		Num of Blank:	1	Normal Low - Male	74 mg/d	dL
Prog. Unit:	mg/dL		Blank CV%:	0	Normal High - Male	100 mg/d	dL
Decimals:	0		Blank Low:	-0,010 ^{Note 1}	Normal Low - Female	74 mg/d	dL
Aspiration Volume:	0800	μL	Blank High:	0,320 ^{Note 1}	Normal High - Female	100 mg/d	dL
Delay Time:	001	S	Blank Mandatory:	Yes	Normal Low - Child	60 mg/d	dL
Test Time:	003	S	Factor:	0	Normal High - Child	100 mg/d	dL
Dilution factor:	1		Calib. By factor:	No	Method order:	0	
Linearity Min:	14,10	mg/dL	Num of STD:	1 Note 2			

MEASURING RANGE

This method is linear from 14,1 mg/dL (detection limit) to 420 mg/dL (linearity limit). If the obtained results are greater than 420 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

GOT (AST)

REF	HBEL010	HBEL010M
VOL	1 x 240 + 1 x 60 mL	6 x 30 + 3 x 15 mL

NADH. UV. Kinetic. According to IFCC

REAGENT PREPARATION AND STABILITY

Mix 4 volumes of R1 (buffer) with 1 volume of R2 (substrate). The stability of the working reagent is 24 hours at 15 - 25 °C or 14 days at 2 - 8 °C. All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm < 1,00, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Preprogrammed factors can only be used when quality controls are within the defined ranges. Otherwise, use the Biochemistry Calibrator (**HBC03**) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma Stability 2 days at 2 - 8 °C. Fasting of at least 12 hours is recommended before sample collection.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank ^{Note 1}	1,00 mL Working reagent (R1 + R2)
For Sample/(Calibrator)Note 2	100 μL Sample/(Calibrator) + 1,00 mL Working reagent (R1 + R2)

Prepare, mix and measure **one sample at a time.** Aspirate the mixture in the instrument, **immediately** after addition of the working reagent to the sample/(calibrator). Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample.

PROGRAM SETUP

Prog. Name:	GOT		Linearity Max:	260	U/L	STD variable:	No	
Prog. ID:	15		Fit:	95		Standard Conc.:	0,0000	
Prog. Version:	1		Direction:	Down		Calibration repeats:	0	
Method ID:	17		Working reagent:	Yes		CAL CV%:	0	
Method Name:	GOT (ast)		Blank Type:	ReagentNote 1		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	340	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	3,1	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	38	U/L
Decimals:	1		Blank Low:	1,000 ^{Note 1}		Normal Low - Female	3,1	U/L
Aspiration Volume:	0800	μL	Blank High:	3,500 ^{Note 1}		Normal High - Female	38	U/L
Delay Time:	060	S	Blank Mandatory:	No		Normal Low - Child	3,1	U/L
Test Time:	090	S	Factor:	-1750 ^{Note 2}		Normal High - Child	31	U/L
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	3,12	U/L	Num of STD:	0				

MEASURING RANGE

This method is linear from 3,12 U/L (detection limit) to 260 U/L (linearity limit). If the obtained results are greater than 260 U/L, dilute the sample 1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

NOTES

- 1.If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

GPT (ALT)

REF HBEL020 HBEL020M VOL 1 x 240 + 1 x 60 mL 6 x 30 + 3 x 15 mL

NADH. UV. Kinetic. According to IFCC

REAGENT PREPARATION AND STABILITY

Mix 4 volumes of R1 (Buffer) with 1 volume of R2 (Substrate). The stability of the working reagent is 24 hours at 15-25 °C or 4 weeks at 2-8 °C. All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm < 1,00, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Preprogrammed factors can only be used when quality controls are within the defined ranges. Otherwise, use the Biochemistry Calibrator (**HBC03**) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma. Stability 1 day at 2-8 °C. Fasting of at least 12 hours is recommended before sample collection.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank ^{Note 1}	1,00 mL Working reagent (R1 + R2)
For Sample/(Calibrator)Note 2	100 μL Sample/(Calibrator) + 1,00 mL Working reagent (R1 + R2)

Prepare, mix and measure **one sample at a time**. Aspirate the mixture in the instrument, **immediately** after addition of the working reagent to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample.

PROGRAM SETUP

Prog. Name:	GPT		Linearity Max:	260	U/L	STD variable:	No	
Prog. ID:	16		Fit:	95		Standard Conc.:	0,0000	
Prog. Version:	1		Direction:	Down		Calibration repeats:	0	
Method ID:	18		Working reagent:	Yes		CAL CV%:	0	
Method Name:	GPT (alt)		Blank Type:	ReagentNote 1		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	340	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	3	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	40	U/L
Decimals:	0		Blank Low:	1,000 ^{Note 1}		Normal Low - Female	3	U/L
Aspiration Volume:	0800	μL	Blank High:	3,500 ^{Note 1}		Normal High - Female	32	U/L
Delay Time:	060	S	Blank Mandatory:	No		Normal Low - Child	3	U/L
Test Time:	090	S	Factor:	-1750 ^{Note 2}		Normal High - Child	32	U/L
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	3	U/L	Num of STD:	0				

MEASURING RANGE

This method is linear from 3 U/L (detection limit) to 260 U/L (linearity limit). If the obtained results are greater than 260 U/L, dilute the sample 1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

HbA1c Turbi

Turbidimetric

REF HT001 VOL 30 + 10 mL Standard

REAGENT PREPARATION AND STABILITY

Reagent 1, 2 and 3 are ready to use. Latex may sediment. Mix reagents gently before use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

Reagent 1 and 2 are stable for at least one month after opening when stored at 2 - 8 °C. Reagent deterioration: alterations in the physical appearance of the reagents or values of control materials outside of the manufacturer's acceptable range may be an indication of reagent instability.

CALIBRATION & QUALITY CONTROL

Use the **HbA1c Calibrator set (HT001S)** Program the values mentioned on the vials in the method programming. Use saline solution (9 g/L NaCl) or distilled water as STD 1, with value 0.001. Note 2

Control sera are recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. **HbA1c Control (HT001C) is available.** The control values can be found on the label of the control vial. Prepare and measure these controls the same as samples. The controls require pretreatment (hemolysate preparation) after being reconstituted. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human blood.

Special preparation of the patients is unnecessary. Fasting samples are not required. No special additives or preservatives other than anticoagulants are required. Collect venous blood with EDTA using aseptic technique. HbA_1c in whole blood collected with EDTA is stable for one week at 2 - 8 °C.

To determine HbA1c, a hemolysate must be prepared for each sample as well as for the HbA1c Calibrator (Level 1 to 4) and HbA1c Control:

- 1. Dispense 1 mL of Reagent 3 into labelled test tubes (glass or plastic). Also provide test tubes for the calibrator and control.
- 2. Add 20 µL of well mixed whole blood (sample, calibrator, control) in the appropriate labelled test tube. Mix.
- 3. Allow to stand for 5 minutes or until complete lysis is evident. Hemolysates may be stored up to 10 days at 2 8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Mix reagents gently and pipette into a test tube:

For Blank	540 μL Reagent 1				
For Calibrators/Sample	15 μL Calibrator/Sample (hemolyzed) + 540 μL Reagent 1				
Mix and incubate for exactly 5 min	Mix and incubate for exactly 5 minutes at 37 °C. Then add:				
For Blank	180 μL Reagent 2				
For Calibrators/Sample	180 μL Reagent 2				
Mix and incubate for exactly 5 minutes at 37 °C. Then aspirate to measure.					

You can prepare several samples simultaneously, as long as you respect the incubation times indicated.

PROGRAM SETUP

Prog. Name:	HbA1c		Fit:	0	Standard Conc. 2:	(=CAL1)Note 2	%
Prog. ID:	17		Direction:	Not applicable	Standard Conc. 3:	(=CAL2)Note 2	%
Prog. Version:	2		Working reagent:	No	Standard Conc. 4:	(=CAL3)Note 2	%
Method ID:	20		Blank Type:	Reagent	Standard Conc. 5:	(=CAL4)Note 2	%
Method Name:	HbA1c		Sample Blank:	No	Calibration repeats:	0	
Method Type:	End Point		VCF:	1	CAL CV%:	0	
Main Filter:	670	nm	Blank substraction:	Yes	Temp flowcell:	37	°C
Sub Filter:	None		Num of Blank:	1	Calib. Mandatory:	No	
Bichromatic Factor:	0		Blank CV%:	0	Control Mandatory:	No	
Prog. Unit:	%		Blank Low:	0,000 ^{Note 1}	SampleTypeRefValue:	Blood	
Decimals:	0		Blank High:	2,000 ^{Note 1}	Normal Low - Male	2	%
Aspiration Volume:	0500	μL	Blank Mandatory:	No	Normal High - Male	6	%
Delay Time:	001	S	Factor:	0	Normal Low - Female	2	%
Test Time:	003	S	Calib. By factor:	No	Normal High - Female	6	%
Dilution factor:	1		Num of STD:	5 ^{Note 2}	Normal Low - Child	2	%
Linearity Min:	2.0000	%	STD variable:	Yes ^{Note 2}	Normal High - Child	6	%
Linearity Max:	16,0000	%	Standard Conc. 1:	0.0010 ^{Note 2} %	Method order:	0	

MEASURING RANGE

This method is linear from 2,0 % (detection limit) to 16,0 % (linearity limit).

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Enter the concentration values shown on the calibrator vials. STD1 corresponds with a saline solution of 9 g/L or distilled water, STD 2 corresponds to calibrator 1; STD 3 to calibrator 2; STD 4 to calibrator 3 and STD 5 to calibrator 4.





Application sheet

HDL Cholesterol

Enzymatic. Colorimetric

| REF | HBL011 | 120 + 40 mL | Standard | -

REAGENT PREPARATION AND STABILITY

R1 and R2 are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C. The reagents are <u>light sensitive</u>. Do not leave bottles open. Do not freeze the reagents.

R1 and R2: once opened they are stable 60 days at 2-8 °C. The reagent should be a clear solution. If turbidity or precipitation has occurred, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Use the HDL/LDL calibrator (HBC11) for calibration. The concentration is lot specific and given on the label of the calibrator. Note 3

Control sera are recommended to monitor the performance of assay procedures. Use the **HDL/LDL Control kit** (**HBC10**). Prepare and measure these controls the same as samples. The control values can be found on the label of the control vial (**HBC10**). If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum or plasma (EDTA, citrate, Li Heparin). Fasting and non-fasting samples can be used.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Reagent Blank ^{Note 2}	10 μL Distilled water + 750 μL R1					
For Reagent ^{Note 2}	10 µL Distilled water + 750 µL R1					
For Sample/Calibrator Blank ^{Note 3}	10 μL Sample/Calibrator + 750 μL R1					
For Sample/CalibratorNote 3	10 µL Sample/Calibrator + 750 µL R1					
Mix and incubate for exactly 5 minu	Mix and incubate for exactly 5 minutes at 37 °C. Then add:					
For Reagent Blank ^{Note 2}	-					
For Reagent ^{Note 2}	250 μL R2					
For Sample/Calibrator Blank ^{Note 3}	-					
For Sample/CalibratorNote 3	250 μL R2					
Mix and incubate for exactly 5 minu	Mix and incubate for exactly 5 minutes at 37 °C. Then aspirate to measure.					

Thus, for every sample, you need to prepare 2 test tubes: one for the Calibrator/Sample Blank, to measure the background coloration caused by the sample, and one for the Calibrator/Sample to measure the coloration caused by the reaction. After mixing Calibrator/Sample and R1, incubate at 37 °C for exactly 5 minutes. Then add R2 only to the Calibrator/Sample tube, mix and incubate for another 5 minutes at 37 °C. Then aspirate the mixtures in the analyser to measure exactly 10 minutes after adding R1. You can prepare several samples simultaneously, as long as you respect the incubation times indicated. Use the illustrations on the next page for quidance to perform this test in a time-efficient way.

PROGRAM SETUP

FROGRAM SET OF								
Prog. Name:	HDL		Linearity Max:	184,8	mg/dL	STD variable:	Yes ^{Note 3}	
Prog. ID:	18		Fit:	0	_	Standard Conc.:	(value see	vial)Note 3
Prog. Version:	1		Direction:	Not applica	able	Calibration repeats:	0	
Method ID:	9		Working reagent:	No		CAL CV%:	0	
Method Name:	Cholestero	l HDL	Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	Yes ^{Note 2}		Calib. Mandatory:	No	
Main Filter:	578	nm	VCF:	0,75		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	59	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	70	mg/dL
Decimals:	0		Blank Low:	-0,010 ^{Note 1}		Normal Low - Female	59	mg/dL
Aspiration Volume:	0550	μL	Blank High:	1,000 ^{Note 1}		Normal High - Female	89	mg/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	59	mg/dL
Test Time:	003	S	Factor:	0		Normal High - Child	81	mg/dL
Dilution factor:	1		Calib. By factor:	No ^{Note 3}		Method order:	0	J
Linearity Min:	1,06	mg/dL	Num of STD:	1 Note 3				

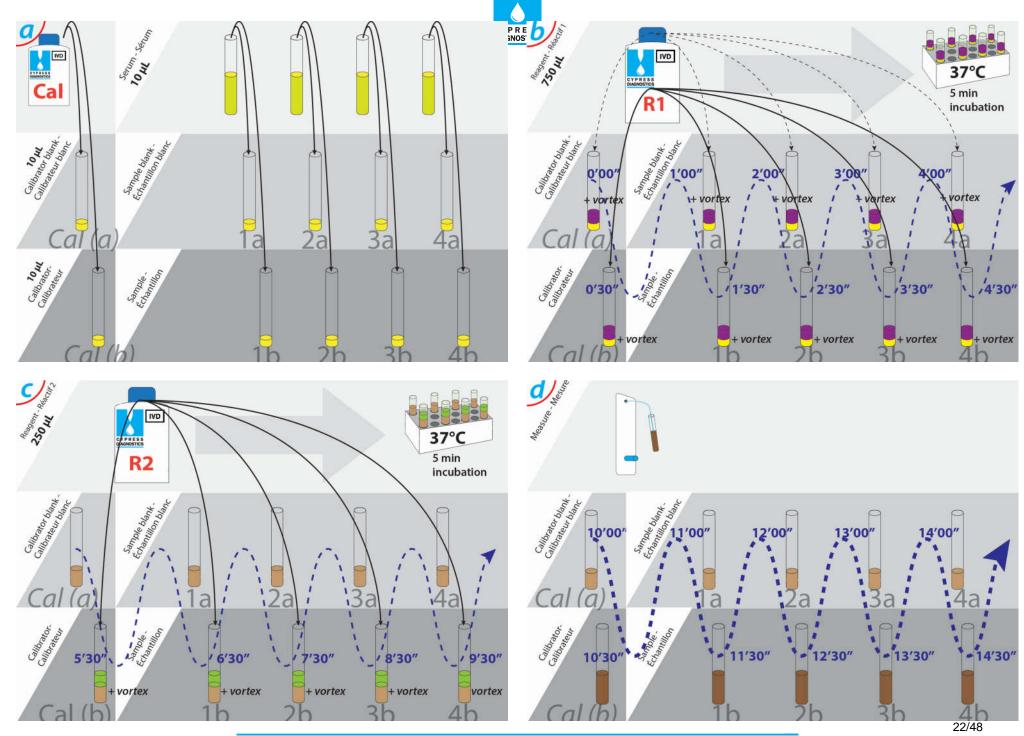
MEASURING RANGE

This method is linear from 1,06 mg/dL (detection limit) to 184,8 mg/dL (linearity limit). If the obtained results are greater than 184,8 mg/dL, dilute the sample 1:2 with NaCl 9 g/L, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. This program requires a Sample Blank! Pay attention, this determines the calculation of the results, not the blank aspiration!
 - Aspirate distilled water to adjust the instrument to zero (AD value)
 - In the Blank menu,
 - a. First: Aspirate "Reagent Blank"
 - b. Secondly: Aspirate "Reagent"
 - Reagent blank is required for each new reagent lot.
 - In the Standard/Sample menu,
 - a. First: Aspirate Standard/Calibrator/Sample blank
 - b. Secondly: Aspirate Standard/Calibrator/Sample
- 3. Use the HDL/LDL calibrator (HBC11) for calibration. Enter the concentration values shown on the calibrator vials (HBC11).







Application sheet

Hemoglobin

Drabkin. Colorimetric.

REAGENT PREPARATION AND STABILITY

Working reagent:

- 4,9 mL distilled water + 2 drops of reagent and mix.

Or:

- 245 mL distilled water + 5 mL of reagent and mix.

The diluted reagent (working reagent) is stable 2 months at 2-8 °C, protected from sunlight.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 540 nm \geq 0,01, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Use the Hemoglobin Calibrator (HBS02). Note 2

Hemoglobin Calibrator (**HBS02**) is ready to use. Hemoglobin Calibrator (**HBS02**) is stable at 2-8 °C up to the date of expiration as specified, when stored tightly closed, protected from light and contaminations, prevented during its use.

Control sera are recommended to monitor the performance of assay procedures. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Capillary or venous blood. Use anticoagulants like EDTA, heparin or oxalate. Stability 7 days at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	2,5 mL Working Reagent
For Calibrator	10 μL Calibrator + 2,5 mL Working Reagent
For Sample	10 μL Sample + 2,5 mL Working Reagent

Mix and incubate for 3 minutes at 15-25 °C. Then aspirate to measure. You can prepare several samples simultaneously, as long as you respect the incubation times indicated.

PROGRAM SETUP

Prog. Name:	HGB		Linearity Max:	20	g/dL	STD variable:	No ^{Note 2}	
Prog. ID:	19		Fit:	0		Standard Conc.:	15,0000 ^{Note 2}	
Prog. Version:	1		Direction:	Not applicab	le	Calibration repeats:	0	
Method ID:	19		Working reagent:	Yes		CAL CV%:	0	
Method Name:	Haemoglobin		Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	546	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes		SampleTypeRefValue:	Blood	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	14	g/dL
Prog. Unit:	g/dL		Blank CV%:	0		Normal High - Male	18	g/dL
Decimals:	0		Blank Low:	-0,010 ^{Note 1}		Normal Low - Female	12	g/dL
Aspiration Volume:	0800	μL	Blank High:	0,010 ^{Note 1}		Normal High - Female	16	g/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	12	g/dL
Test Time:	003	S	Factor:	0		Normal High - Child	16	g/dL
Dilution factor:	1		Calib. By factor:	No ^{Note 2}		Method order:	0	
Linearity Min:	0,1	g/dL	Num of STD:	1 Note 2				

MEASURING RANGE

This method is linear from 0,1 g/dL (detection limit) to 20 g/dL (linearity limit). If the obtained results are greater than 20 g/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Use the Hemoglobin Calibrator (HBS02). Enter the concentration value shown on the calibrator vial.





Application sheet

ron

 REF
 HB012

 VOL
 4 x 50 mL

 Standard
 1 x 10 mL

Ferrozine. Colorimetric

REAGENT PREPARATION AND STABILITY

R3 is ready to use.

Add the contents of one tube R2 reductant to the contents of one bottle R1 buffer. Cap and mix gently to dissolve content. This working reagent is stable for 3 months at 2-8 °C or 1 month at room temperature (15-25 °C). All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C. Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if the reagent blanc absorbance at 530-590 nm \geq 0,02, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator Specific (**HBC03-S**) for calibration. Note 3 Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls Specific (**HBC01-S**, **HBC02-S**). Prepare and measure these controls the same as samples. The control values can be found on the control sheets, delivered together with the control vials. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum or heparinized plasma. Hemolysis interferes with the test. Separate from the cells as rapidly as possible. The iron is stable up to 7 days stored at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Reagent Blank ^{Note 2}	200 μL Distilled water + 1 mL Working reagent
For Reagent ^{Note 2}	200 μL Distilled water + 1 mL Working reagent + 1 drop R3
For Standard Blank ^{Note 3}	200 μL Standard + 1 mL Working reagent
For Sample Blank ^{Note 2}	200 μL Sample + 1 mL Working reagent
For Standard ^{Note 3}	200 μL Standard + 1 mL Working reagent + 1 drop R3
For Sample	200 μL Sample + 1 mL Working reagent + 1 drop R3

Mix and incubate for 10 minutes at 15-25 °C. After the incubation time, aspirate and measure all the samples within 30 min after preparation.

Thus, <u>for every sample</u>, <u>you need to prepare 2 test tubes</u>: one for measuring the sample blank (background coloration) and one for measuring the real sample coloration.

PROGRAM SETUP

Prog. Name:	IRON		Linearity Max:	1000 μg/dL	STD variable:	Yes ^{Note 3}
Prog. ID:	20		Fit:	0	Standard Conc.:	value: see vialNote 3
Prog. Version:	2		Direction:	Not applicable	Calibration repeats:	0
Method ID:	21		Working reagent:	Yes	CAL CV%:	0
Method Name:	Iron		Blank Type:	Reagent ^{Note 2}	Temp flowcell:	37 °C
Method Type:	End Point		Sample Blank:	Yes ^{Note 2}	Calib. Mandatory:	No
Main Filter:	578	nm	VCF:	0,96	Control Mandatory:	No
Sub Filter:	None		Blank substraction:	No	SampleTypeRefValue:	Serum
Bichromatic Factor:	0		Num of Blank:	1	Normal Low - Male	65 μg/dL
Prog. Unit:	μg/dL		Blank CV%:	0	Normal High - Male	175 μg/dL
Decimals:	0		Blank Low:	-0,010 ^{Note 1}	Normal Low - Female	40 μg/dL
Aspiration Volume:	0800	μL	Blank High:	0,020 ^{Note 1}	Normal High - Female	150 μg/dL
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	40 μg/dL
Test Time:	003	S	Factor:	0	Normal High - Child	150 μg/dL
Dilution factor:	1		Calib. By factor:	No ^{Note 3}	Method order:	3
Linearity Min:	0,85	μg/dL	Num of STD:	1 Note 3		

MEASURING RANGE

This method is linear from $0.85 \,\mu\text{g/dL}$ (detection limit) to $1000 \,\mu\text{g/dL}$ (linearity limit). If the obtained results are greater than $1000 \,\mu\text{g/dL}$, dilute the sample $1.2 \,\text{with saline}$ solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. This program requires a Sample Blank! Pay attention, this determines the calculation of the results, not the blank aspiration!
 - Aspirate distilled water to adjust the instrument to zero (AD value)
 - In the Blank menu,
 - a. First: Aspirate "Reagent Blank"
 - b. Secondly: Aspirate "Reagent"
 - Reagent blank is required for each new reagent lot.
 - In the Standard/Sample menu,
 - a. First: Aspirate Standard/Calibrator/Sample blank
 - b. Secondly: Aspirate Standard/Calibrator/Sample
- 3. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator Specific (HBC03-S) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Lactate Dehydrogenase

Pyruvate DGKC. UV. Kinetic.

REF	HBEL04	HBEL041
VOL	240 + 60 mL	60 + 15 mL
Standard	-	-

REAGENT PREPARATION AND STABILITY

Mix 4 volumes of R1 (buffer) with 1 volume of R2 (substrate). The stability of working reagent is 15 days at 2-8 $^{\circ}$ C or 5 days at room temperature (15-25 $^{\circ}$ C).

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm < 1,00, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). The control values can be found on the control sheets, delivered together with the control vials. Prepare and measure these controls the same as samples.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum, separated from the cells as rapidly as possible. Do not use oxalates as anticoagulants since they inhibit the enzyme. Do not use hemolyzed samples. LDH in the serum is stable for 2 days at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature.

Then, pipette into a test tube:

For Blank ^{Note 2}	0,9 mL Working reagent (R1 + R2)
For Sample/(Calibrator)Note 2	15 µL Sample/(Calibrator) + 0,9 mL Working reagent (R1 + R2)

Prepare, mix and measure one sample at a time. Aspirate the mixture in the instrument, immediately after addition of the working solution to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample

PROGRAM SETUP

Prog. Name:	LDH		Linearity Max:	1600	U/L	STD variable:	No ^{Note 2}	
Prog. ID:	21		Fit:	95		Standard Conc.:	0,0000Note 2	
Prog. Version:	1		Direction:	Down		Calibration repeats:	0	
Method ID:	22		Working reagent:	No		CAL CV%:	0	
Method Name:	LDH		Blank Type:	Reagent ^{Note 1}		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	340	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	230	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	460	U/L
Decimals:	0		Blank Low:	1,000 ^{Note 1}		Normal Low - Female	230	U/L
Aspiration Volume:	0700	μL	Blank High:	3,500 ^{Note 1}		Normal High - Female	460	U/L
Delay Time:	060	S	Blank Mandatory:	No		Normal Low - Child	230	U/L
Test Time:	090	S	Factor:	-9690 ^{Note 2}		Normal High - Child	460	U/L
Dilution factor:	1		Calib. By factor:	Yes ^{Note 2}		Method order:	0	
Linearity Min:	3,42	U/L	Num of STD:	O ^{Note 2}				

MEASURING RANGE

This method is linear from 3,42 U/L (detection limit) to 1600 U/L (linearity limit). If the obtained results are greater than 1600 U/L, dilute the sample 1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. Calibration by means of a Factor. Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

LDL Cholesterol

Enzymatic. Colorimetric.

| REF | HBL012 | 120 + 40 mL | Standard | -

REAGENT PREPARATION AND STABILITY

R1 and R2 are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, **protected from light** and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C. The reagents are <u>light sensitive</u>. Do not leave bottles open. Do not freeze the reagents.

R1 and R2: once opened they are stable for 60 days at 2-8 °C. The reagents should be a clear solution. If turbidity or precipitation has occurred, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

Use the HDL/LDL calibrator (HBC11) for calibration. The concentration is lot specific and given on the label of the calibrator. Note 3

Control sera are recommended to monitor the performance of assay procedures. **Use the HDL/LDL Control kit (HBC10).** Prepare and measure these controls the same as samples. The control values can be found on the label of the HDL/LDL Direct control set vials (**HBC10**). If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum or plasma (EDTA, citrate). Fasting and non-fasting samples can be used. Do not use plasma containing heparin as anticoagulant.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Reagent Blank ^{Note 2}	10 μL Distilled water + 750 μL R1			
For Reagent ^{Note 2}	10 µL Distilled water + 750 µL R1			
For Sample/Calibrator Blank ^{Note 3}	10 µL Sample/Calibrator + 750 µL R1			
For Sample/Calibrator ^{Note 3}	10 µL Sample/Calibrator + 750 µL R1			
Mix and incubate for exactly 5 minutes at 37 °C. Then add:				
For Reagent Blank ^{Note 2}	-			
For Reagent ^{Note 2}	250 μL R2			
For Sample/Calibrator Blank ^{Note 3}	-			
For Sample/CalibratorNote 3	250 μL R2			
Mix and incubate for exactly 5 minu	tes at 37 °C. Then aspirate to measure.			

Thus for every sample, you need to prepare 2 test tubes: one for the Calibrator/Sample Blank, to measure the background coloration caused by the sample, and one for the Calibrator/Sample to measure the coloration caused by the reaction. After mixing Calibrator/Sample and R1, incubate at 37 °C for exactly 5 minutes. Then add R2 only to the Calibrator/Sample tube, mix and incubate for another 5 minutes at 37 °C. Then aspirate the mixtures in the analyser to measure exactly 10 minutes after adding R1. You can prepare several samples simultaneously as long as you respect the times mentioned.

Use the illustrations on the next page for guidance to perform this test in a time-efficient way.

PROGRAM SETUP

Prog. Name:	LDL		Linearity Max:	250	mg/dL	STD variable:	Yes ^{Note 3}	
Prog. ID:	22		Fit:	0	3	Standard Conc.:	value: see	vial ^{Note 3}
Prog. Version:	1		Direction:	Not applic	able	Calibration repeats:	0	
Method ID:	10		Working reagent:	No		CAL CV%:	0	
Method Name:	Cholestero	l LDL	Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	Yes ^{Note 2}		Calib. Mandatory:	No	
Main Filter:	578	nm	VCF:	0,75		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	50	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	100	mg/dL
Decimals:	0		Blank Low:	-0,010 ^{Note 1}		Normal Low - Female	62	mg/dL
Aspiration Volume:	0550	μL	Blank High:	1,000 ^{Note 1}		Normal High - Female	100	mg/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	46	mg/dL
Test Time:	003	S	Factor:	0		Normal High - Child	100	mg/dL
Dilution factor:	1		Calib. By factor:	No ^{Note 3}		Method order:	0	
Linearity Min:	1,64	mg/dL	Num of STD:	1 Note 3				

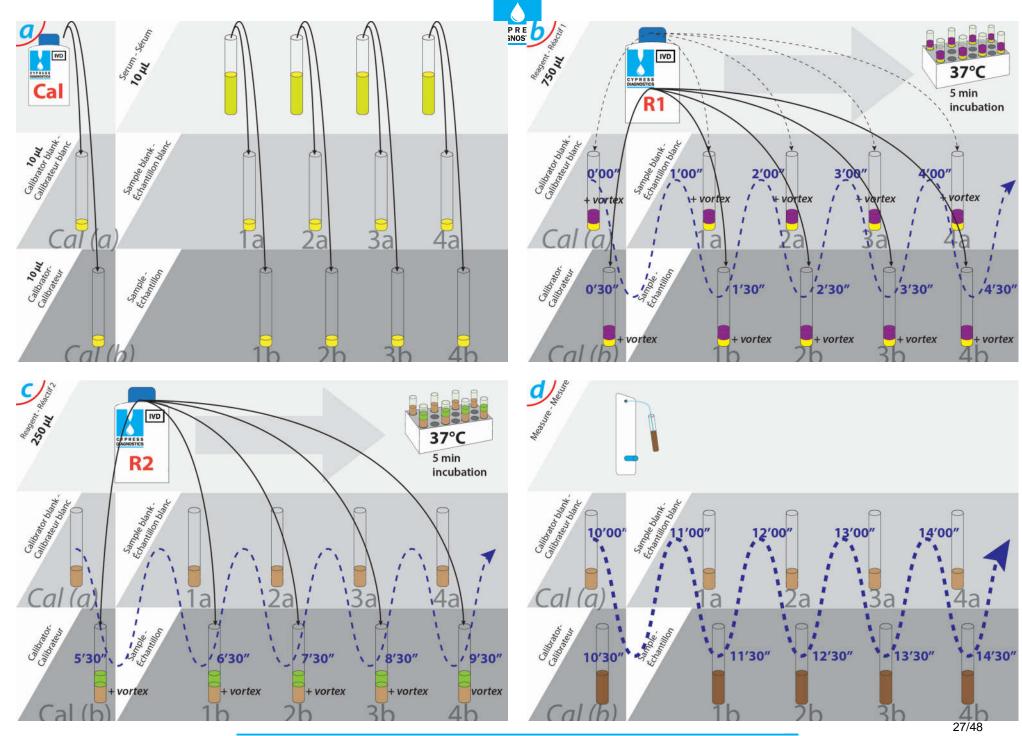
MEASURING RANGE

This method is linear from 1,64 mg/dL (detection limit) to 250 mg/dL (linearity limit). If the obtained results are greater than 250 mg/dL, dilute the sample 1:2 with NaCl 9 g/L, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. This program requires a Sample Blank! Pay attention, this determines the calculation of the results, not the blank aspiration!
 - Aspirate distilled water to adjust the instrument to zero (AD value)
 - In the Blank menu,
 - a. First: Aspirate "Reagent Blank"
 - b. Secondly: Aspirate "Reagent"
 - Reagent blank is required for each new reagent lot.
 - In the Standard/Sample menu,
 - a. First: Aspirate Standard/Calibrator/Sample blank
 - b. Secondly: Aspirate Standard/Calibrator/Sample
- 3. Use the HDL/LDL calibrator (HBC11) for calibration. Enter the concentration values shown on the calibrator vials (HBC11).







Application sheet

Lipase

REF	HBE09
VOL	4 x 10 mL
Calibrator	1 x Lyoph 1 mL

Enzymatic. Colorimetric. Kinetic

REAGENT PREPARATION AND STABILITY

R1 and R2: ready to use. Stability after opening 90 days at 2-8 °C.

R2: mix gently before use. Note 1

Calibrator: reconstitute the contents of one vial with 1 mL of distilled water. Mix gently until complete solution. Stability: 7 days at 2-8 °C. Divide calibrator solution into small volumes and freeze. Stability: 3 months at -20 °C.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 580 nm \geq 1,4, the reagent should be discarded. R2 is a turbid orange-colored micro-emulsion, discard if turning to red. Note 2

CALIBRATION & QUALITY CONTROL

Use the calibrator included in the kit. Note 3

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Note 4 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma. Plasma: with sodium citrate, EDTA or heparin. Stability: 2 days at 2 - 8 $^{\circ}$ C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Reagent Blank ^{Note 2}	10 μL Distilled water + 1 mL Reagent 1 + 200 μL Reagent 2
For Calibrator ^{Note 3}	10 μL Calibrator + 1 mL Reagent 1 + 200 μL Reagent 2
For Sample	10 μL Sample + 1 mL Reagent 1 + 200 μL Reagent 2

Prepare, mix and measure **one sample at a time.** Aspirate the mixture in the instrument, **immediately** after addition of the working reagent to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample.

PROGRAM SETUP

Prog. Name:	LIPASE		Linearity Max:	250	U/L	STD variable:	Yes ^{Note 3}	
Prog. ID:	23		Fit:	95		Standard Conc.:	value: see	vial ^{Note 3}
Prog. Version:	1		Direction:	Up		Calibration repeats:	3	
Method ID:	23		Working reagent:	No		CAL CV%:	10	
Method Name:	Lipase		Blank Type:	ReagentNote 1		Temp flowcell:	37	°C
Method Type:	Kinetic		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	578	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	5	U/L
Prog. Unit:	U/L		Blank CV%:	0		Normal High - Male	38	U/L
Decimals:	0		Blank Low:	0,000 ^{Note 2}		Normal Low - Female	5	U/L
Aspiration Volume:	0800	μL	Blank High:	1,400 ^{Note 2}		Normal High - Female	38	U/L
Delay Time:	060	S	Blank Mandatory:	No		Normal Low - Child	5	U/L
Test Time:	090	S	Factor:	0		Normal High - Child	38	U/L
Dilution factor:	1		Calib. By factor:	No ^{Note 3}		Method order:	0	
Linearity Min:	5	U/L	Num of STD:	1 Note 3				

MEASURING RANGE

This method is linear from 5 U/L (detection limit) to 250 U/L (linearity limit). If the obtained results are greater than 250 U/L, dilute the sample 1:10 with saline solution, repeat the determination, and multiply the result by factor 10.

NOTES

- 1. In some storage conditions (lower than the one indicated) a precipitate may appear in the vial that will not influence the reagent performance. However, it is recommended to re-suspend the product with a slight rotation.
- 2. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 3. Use the calibrator included in the kit. Enter the concentration values shown on the calibrator vials. Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 4. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

Magnesium

Xylidyl Blue - EGTA. Colorimetric

REF HB0320 HB0320M VOL 2 x 125 mL 8 x 30 mL Standard 1 x 5 mL

REAGENT PREPARATION AND STABILITY

The reagent and standard are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 25 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear blue solution. If turbidity or precipitation has occurred, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or heparinized plasma, free of hemolysis and separated from cells as rapidly as possible. Do not use oxalates, citrate or EDTA as anticoagulant. Stability: 5 days at 4 - 8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1 mL Reagent
For Standard ^{Note 2}	10 μL Standard + 1 mL Reagent
For Sample	10 μL Sample + 1 mL Reagent

You can prepare several samples simultaneously. Mix and incubate for 3 minutes at 37 °C or for 5 minutes at 15-25 °C (room temperature). After the incubation time, aspirate and measure the samples within 45 minutes after preparation.

PROGRAM SETUP

Prog. Name:	MG		Linearity Max:	6,6 mg/dL	STD variable:	Yes ^{Note 2}
Prog. ID:	24		Fit:	0	Standard Conc.:	value: see vialNote 2
Prog. Version:	2		Direction:	Not applicable	Calibration repeats:	3
Method ID:	24		Working reagent:	No	CAL CV%:	10
Method Name:	Magnesium		Blank Type:	Reagent	Temp flowcell:	37 °C
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No
Main Filter:	510	nm	VCF:	1	Control Mandatory:	No
Sub Filter:	None		Blank substraction:	Yes	SampleTypeRefValue:	Serum
Bichromatic Factor:	0		Num of Blank:	3	Normal Low - Male	1,6 mg/dL
Prog. Unit:	mg/dL		Blank CV%:	10	Normal High - Male	2,5 mg/dL
Decimals:	1		Blank Low:	0,000 ^{Note 1}	Normal Low - Female	1,6 mg/dL
Aspiration Volume:	0800	μL	Blank High:	1,500 ^{Note 1}	Normal High - Female	2,5 mg/dL
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	1,6 mg/dL
Test Time:	003	S	Factor:	0	Normal High - Child	2,5 mg/dL
Dilution factor:	1		Calib. By factor:	No	Method order:	4
Linearity Min:	0,05	mg/dL	Num of STD:	1		

MEASURING RANGE

This method is linear from 0,05 mg/dL (detection limit) to 6,6 mg/dL (linearity limit). If the obtained results are greater than 6,6 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

Phosphorus

Phosphomolybdate. UV.

REF **HB014** 2 x 125 mL VOL 1 x 5 mL Standard

REAGENT PREPARATION AND STABILITY

Reagent and standard are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm ≥ 0,54, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma, free of hemolysis and separated from cells as rapidly as possible. Stability: 7 days at 2 - 8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1 mL Reagent
For Standard ^{Note 2}	10 μL Standard + 1 mL Reagent
For Sample	10 μL Sample + 1 mL Reagent

Mix and incubate for 5 minutes at 37 °C. Then aspirate to measure. You can prepare several samples simultaneously, as long as you respect the incubation times indicated.

PROGRAM SETUP

Prog. Name:	PHOSPH		Linearity Max:	35	mg/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	25		Fit:	0		Standard Conc.:	value: see	vial ^{Note 2}
Prog. Version:	2		Direction:	Not applicab	ole	Calibration repeats:	3	
Method ID:	25		Working reagent:	No		CAL CV%:	10	
Method Name:	Phosphorus		Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	340	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	2,5	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	5	mg/dL
Decimals:	1		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	2,5	mg/dL
Aspiration Volume:	0800	μL	Blank High:	0,540 ^{Note 1}		Normal High - Female	5	mg/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	4	mg/dL
Test Time:	003	S	Factor:	O ^{Note 2}		Normal High - Child	7	mg/dL
Dilution factor:	1		Calib. By factor:	No		Method order:	5	
Linearity Min:	0	mg/dL	Num of STD:	1				

MEASURING RANGE

This method is linear from 0 mg/dL (detection limit) to 35 mg/dL (linearity limit). If the obtained results are greater than 35 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

Potassium Prec

REF HB015 VOL 3 x 50 mL Standard 1 x 3 mL

NaTPB. Colorimetric. Precipitation

REAGENT PREPARATION AND STABILITY

Working reagent: Shake R2 (NaOH) before use. Mix proportionally 1:1 Reagent 1 and Reagent 2. After mixing, allow to stand for 30 minutes prior to use. Before each use, **the working reagent must be shaken. The working reagent is stable for 7 days at 15-25 °C and 30 days at 2-8 °C.** All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C. Handle standard very carefully to prevent contamination. Do not freeze or expose to elevated temperatures. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator Specific (**HBC03-S**) for calibration. Note 2 Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls Specific (**HBC01-S**, **HBC02-S**). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: non hemolytic serum or heparin plasma.

PROCEDURE

Make sure the reagents and samples are at room temperature.

Then, pipette into a test tube:

PRECIPITATION STEP:					
For Sample	50 μL Sample + 500 μL Reagent 3				
Mix carefully. Centrifuge at high speed (± 5000 rpm) for 5-10 minutes. Separate the clear supernatant in a new test tube.					
TEST STEP: pipette into a cuvette:					
For Blank 1,0 mL Working reagent (R1 + R2)					
For Standard ^{Note 2} 100 μL Standard + 1,0 mL Working reagent (R1 + R2)					
For Sample 100 μL Supernatant + 1,0 mL Working reagent (R1 + R2)					

You can prepare several samples simultaneously. To produce a homogeneous turbidity, the standard or the clear supernatant must be added to the surface of the working reagent in the test tube. Mix each test tube carefully before proceeding to the next sample. Mix and allow to stand for 5 min. After the incubation time, aspirate and measure all the samples within 30 min after addition of the working solution.

PROGRAM SETUP

I HOGHAM SETOL								
Prog. Name:	POT		Linearity Max:	10	mEq/L	STD variable:	Yes ^{Note 2}	
Prog. ID:	26		Fit:	0		Standard Conc.:	value: see v	vial ^{Note 2}
Prog. Version:	2		Direction:	Not applicab	le	Calibration repeats:	0	
Method ID:	26		Working reagent:	Yes		CAL CV%:	0	
Method Name:	Potassium		Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	578	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	3,6 ^{Note 4}	mEq/L
Prog. Unit:	mEq/L		Blank CV%:	0		Normal High - Male	5,5 ^{Note 4}	mEq/L
Decimals:	1		Blank Low:	0,000 ^{Note 1}		Normal Low - Female	3,6 ^{Note 4}	mEq/L
Aspiration Volume:	0800	μL	Blank High:	3,500 ^{Note 1}		Normal High - Female	5,5 ^{Note 4}	mEq/L
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	3,6 ^{Note 4}	mEq/L
Test Time:	003	S	Factor:	0		Normal High - Child	5,5 ^{Note 4}	mEq/L
Dilution factor:	1		Calib. By factor:	No		Method order:	6	
Linearity Min:	2	mEq/L	Num of STD:	1				

MEASURING RANGE

This method is linear from 2,0 mEq/L (detection limit) to 10,0 mEq/L (linearity limit). If the obtained results are greater than 10,0 mEq/L, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator Specific (**HBC03-S**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.
- 4. These values are for serum samples. For plasma, please check the insert for the values.





Application sheet

Sodium Prec

 REF
 HB016

 VOL
 2 x 60 mL

 Standard
 1 x 2 mL

Mg-Uranylacetate. Colorimetric. Precipitation

REAGENT PREPARATION AND STABILITY

Reagents are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C. Handle standard very carefully to prevent contamination. Precipitating solution becomes discolored when exposed to the light. Store protected from light. A slight turbidity does not affect the determination. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator Specific (**HBC03-S**) for calibration. Note 2 Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls Specific (**HBC01-S**, **HBC02-S**). Note 3 Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: serum or ammonium or lithium heparin plasma

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

PRECIPITATION STEP:					
For Blank					
For Standard ^{Note 2}	20 μL Standard + 1,0 mL Reagent 2				
For Sample	20 μL Sample + 1,0 mL Reagent 2				
Mix well. Incubate for 5 min. Th	en shake intensively for at least 30 sec. Then incubate for 30 min.				
Centrifuge for 5-10 min at 5000 rpm. Collect the supernatant in a new test tube					
TEST STEP: pipette into a cuvette:					
For Blank	20 μL Reagent 2 + 1,0 mL Reagent 1				
For Standard	20 μL Supernatant + 1,0 mL Reagent 1				
For Sample	20 μL Supernatant + 1,0 mL Reagent 1				

You can prepare several samples simultaneously. Mix and incubate for 5 minutes at 15-25 °C (room temperature). After the incubation time, aspirate and measure the samples within 30 minutes after preparation.

PROGRAM SETUP

PROGRAM 3ETOP							
Prog. Name:	SOD		Linearity Max:	300 mEq/L	STD variable:	Yes ^{Note 2}	
Prog. ID:	27		Fit:	0	Standard Conc.:	value: see vialNote 2	
Prog. Version:	3		Direction:	Not applicable	Calibration repeats:	0	
Method ID:	27		Working reagent:	No	CAL CV%:	0	
Method Name:	Sodium		Blank Type:	Reagent	Temp flowcell:	37 °C	
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No	
Main Filter:	405	nm	VCF:	1	Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes	SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1	Normal Low - Male	135 mE	Eq/L
Prog. Unit:	mEq/L		Blank CV%:	0	Normal High - Male	155 mE	Eq/L
Decimals:	0		Blank Low:	0,000 ^{Note 1}	Normal Low - Female	135 mE	Eq/L
Aspiration Volume:	0800	μL	Blank High:	3,500 ^{Note 1}	Normal High - Female	155 mE	Eq/L
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	135 mE	Eq/L
Test Time:	003	S	Factor:	0	Normal High - Child	155 mE	Eq/L
Dilution factor:	1		Calib. By factor:	No ^{Note 2}	Method order:	7	
Linearity Min:	49	mEq/L	Num of STD:	1			

MEASURING RANGE

This method is linear from 49 mEq/L (detection limit) to 300 mEq/L (linearity limit). If the obtained results are greater than 300 mEq/L, dilute the sample 1:2 with distilled water, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator Specific (**HBC03-S**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.





Application sheet

Total Protein

Biuret. Colorimetric

REF	HB0190	HB0190A HB019		
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL	
Standard	1 x 5 mL	4 x 5 mL	-	

REAGENT PREPARATION AND STABILITY

The reagent and standard are ready for use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 546 nm \geq 0,22, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Control sera are recommended to monitor the performance of assay procedures. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). The control values can be found on the control sheets, delivered together with the control vials. Prepare and measure these controls the same as samples.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Serum or heparinized plasma: stability: 1 month at 2-8 °C

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1 mL R1 Biuret
For Standard ^{Note 2}	25 μL Standard + 1 mL R1 Biuret
For Sample	25 μL Sample + 1 mL R1 Biuret

You can prepare several samples simultaneously. Mix and incubate for 5 minutes at 37 °C or for 10 minutes at 15-25 °C (room temperature). After the incubation time, aspirate and measure the samples within 1 hour after preparation.

PROGRAM SETUP

Prog. Name:	TP		Linearity Max:	15 g/dL	STD variable:	Yes ^{Note 2}
Prog. ID:	28		Fit:	0	Standard Conc.:	value: see vialNote 2
Prog. Version:	1		Direction:	Not applicable	Calibration repeats:	0
Method ID:	29		Working reagent:	No	CAL CV%:	0
Method Name:	Tot Prot (Bio	r)	Blank Type:	Reagent	Temp flowcell:	37 °C
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No
Main Filter:	546	nm	VCF:	1	Control Mandatory:	No
Sub Filter:	None		Blank substraction:	Yes	SampleTypeRefValue:	Serum
Bichromatic Factor:	0		Num of Blank:	1	Normal Low - Male	6,6 g/dL
Prog. Unit:	g/dL		Blank CV%:	0	Normal High - Male	8,3 g/dL
Decimals:	1		Blank Low:	0,000 ^{Note 1}	Normal Low - Female	6,6 g/dL
Aspiration Volume:	0800	μL	Blank High:	0,220 ^{Note 1}	Normal High - Female	8,3 g/dL
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	6,6 g/dL
Test Time:	003	S	Factor:	0	Normal High - Child	8,3 g/dL
Dilution factor:	1		Calib. By factor:	No	Method order:	5
Linearity Min:	0,008	g/dL	Num of STD:	1 Note 2		

MEASURING RANGE

This method is linear from 0,008 g/dL (detection limit) to 15 g/dL (linearity limit). If the obtained results are greater than 15 g/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.





Application sheet

Urine Total Protein

Pyrogallol-Red. Colorimetric.

REF HB020 VOL 2 x 125 mL Standard 1 x 5 mL

REAGENT PREPARATION AND STABILITY

The reagents are ready for use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if the reagent blanc absorbance is out of range, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. $^{\text{Note}\,2}$

Control sera are recommended to monitor the performance of assay procedures. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Urine 24h: Stability 8 days at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1 mL Reagent 1
For Standard ^{Note 2}	20 μL Standard + 1 mL Reagent 1
For Sample	20 μL Sample + 1 mL Reagent 1

You can prepare several samples simultaneously. Mix and incubate for 5 minutes at 37 °C or for 10 minutes at 15-25 °C (room temperature). After the incubation time, aspirate and measure the samples within 30 minutes after preparation.

PROGRAM SETUP

Prog. Name:	TPU		Linearity Max:	400 mg/dL	STD variable:	Yes	
Prog. ID:	29		Fit:	0	Standard Conc.:	value: see v	∕ial ^{Note 2}
Prog. Version:	2		Direction:	Not applicable	Calibration repeats:	0	
Method ID:	28		Working reagent:	No	CAL CV%:	0	
Method Name:	Tot Prot (Py	/r)	Blank Type:	Reagent	Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No	
Main Filter:	578	nm	VCF:	1	Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes	SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	3	Normal Low - Male	0	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	10	Normal High - Male	10	mg/dL
Decimals:	0		Blank Low:	0,000 ^{Note 1}	Normal Low - Female	0	mg/dL
Aspiration Volume:	0800	μL	Blank High:	0,700 ^{Note 1}	Normal High - Female	10	mg/dL
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	0	mg/dL
Test Time:	003	S	Factor:	0	Normal High - Child	10	mg/dL
Dilution factor:	1		Calib. By factor:	No	Method order:	6	
Linearity Min:	0,944	mg/dL	Num of STD:	1			

MEASURING RANGE

This method is linear from 0,944 mg/dL (detection limit) to 400 mg/dL (linearity limit). If the obtained results are greater than 400 mg/dL, dilute the sample 1:2 with NaCl 9 g/L, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial).

2021-09 (2.0) - Replaces all previous versions





Application sheet

Triglycerides

Enzymatic. Colorimetric. GPO-POD

REF **HBL060** HBL060M VOL 2 x 125 mL 8 x 30 mL 1 x 5 mL Standard

REAGENT PREPARATION AND STABILITY

The reagent and standard are ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 510 nm ≥ 0,23, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. Note 2

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Prepare and measure these controls the same as samples. Measure at least one replicate per control. The control values can be found on the control sheets, delivered together with the control vials.

If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma. The stability of the sample: 5 days at 2-8 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1 mL Reagent
For Standard ^{Note 2}	10 μL Standard + 1 mL Reagent
For Sample	10 μL Sample + 1 mL Reagent

You can prepare several samples simultaneously. Mix and incubate for 5 minutes at 37 °C or for 10 minutes at 15-25 °C (room temperature). After the incubation time, aspirate and measure the samples within 30 minutes after preparation.

PROGRAM SETUP

Prog. Name:	TRIG		Linearity Max:	1000	mg/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	30		Fit:	0		Standard Conc.:	value: see	∕ial ^{Note 2}
Prog. Version:	2		Direction:	Not applicab	ole	Calibration repeats:	0	
Method ID:	30		Working reagent:	No		CAL CV%:	0	
Method Name:	Triglycerides		Blank Type:	Reagent		Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	510	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	Yes		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	40	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	160	mg/dL
Decimals:	0		Blank Low:	-0,010 ^{Note 1}		Normal Low - Female	35	mg/dL
Aspiration Volume:	0800	μL	Blank High:	0,230 ^{Note 1}		Normal High - Female	135	mg/dL
Delay Time:	001	S	Blank Mandatory:	No		Normal Low - Child	35	mg/dL
Test Time:	003	S	Factor:	0		Normal High - Child	135	mg/dL
Dilution factor:	1		Calib. By factor:	No		Method order:	0	
Linearity Min:	1,01	mg/dL	Num of STD:	1				

MEASURING RANGE

This method is linear from 1,01 mg/dL (detection limit) to 1000 mg/dL (linearity limit). If the obtained results are greater than 1000 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.

2023-06 (3.0) - Replaces all previous versions





Application sheet Uric Acid

Enzymatic. Colorimetric. URICASE-POD

REF	HBL020	HBL020M	
VOL	2 x 125 mL	8 x 30 mL	
Standard	1 x 5 mL	-	

REAGENT PREPARATION AND STABILITY

Mix equal volumes of R1 (Buffer) and R2 (Enzymes). This working reagent is stable for 2 months at 2-8 °C or 2 weeks at room temperature (15-25 °C).

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2-8 °C.

Handle standard very carefully to prevent contamination. The reagents should be clear solutions. If turbidity or precipitation has occurred or if blank absorbance of the working reagent at 510 nm \geq 0,12, the reagents should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. Note 2 Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal

Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). Note 3 The control values can be found on the control sheets, delivered together with the control vials. Note 4 Prepare and measure these controls the same as samples. Measure at least one replicate per control. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: **serum or plasma:** stability 3-5 days at 2-8 °C or 6 months at -20 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1 mL Working reagent (R1 + R2)
For Standard ^{Note 2}	25 μL Standard + 1 mL Working reagent (R1 + R2)
For Sample	25 μL Sample + 1 mL Working reagent (R1 + R2)

You can prepare several samples simultaneously. Mix and incubate for 5 minutes at 37 °C or for 10 minutes at 15-25 °C (room temperature). After the incubation time, aspirate and measure the samples within 45 minutes after preparation.

PROGRAM SETUP

Prog. Name:	UA		Linearity Max:	25 mg/	dL STD variable:	Yes ^{Note 2}	
Prog. ID:	31		Fit:	0	Standard Conc.:	value: see v	/ial ^{Note 2}
Prog. Version:	4		Direction:	Not applicable	Calibration repeats:	0	
Method ID:	32		Working reagent:	Yes	CAL CV%:	0	
Method Name:	Uric Acid		Blank Type:	Reagent	Temp flowcell:	37	°C
Method Type:	End Point		Sample Blank:	No	Calib. Mandatory:	No	
Main Filter:	510	nm	VCF:	1	Control Mandatory:	No	
Sub Filter:	None	nm	Blank substraction:	Yes	SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1	Normal Low - Male	3,6	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0	Normal High - Male	7,7	mg/dL
Decimals:	2		Blank Low:	-0,010 ^{Note 1}	Normal Low - Female	2,5	mg/dL
Aspiration Volume:	0800	μL	Blank High:	0,02 ^{Note 1}	Normal High - Female	6,8	mg/dL
Delay Time:	001	S	Blank Mandatory:	No	Normal Low - Child	2,5	mg/dL
Test Time:	003	S	Factor:	0	Normal High - Child	6,8	mg/dL
Dilution factor:	1		Calib. By factor:	No	Method order:	0	
Linearity Min:	0,15	mg/dL	Num of STD:	1			

MEASURING RANGE

This method is linear from 0,15 mg/dL (detection limit) to 25 mg/dL (linearity limit). If the obtained results are greater than 25 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. In case the Reagent Blank is too high, see CYANVision User manual § 8 for troubleshooting ("Blank is out of range").
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. Fill the values for monochromatic methods. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.
- 4. Fill the values for semi-automates (monochromatic).

2023-06 (5.0) - Replaces all previous versions





Application sheet

REF	HBL030	HBL030M
VOL	240 + 60 mL	6 x 30 + 3 x 15 mL
Standard	1 x 5 mL	-

Urea

Urease-GLDH. UV. Kinetic

REAGENT PREPARATION AND STABILITY

Working reagent: Mix 4 volumes of R1 (Buffer) with 1 volume of R2 (Substrate). After mixing, allow to stand for 30 minutes prior to use. The working reagent can be stored at 2-8 °C or at room temperature (15 – 25 °C) and can be used as long as the blank absorbance is < 0,90 AU. The stability of the working reagent is at least 24h at 15 - 25 °C. The standard is ready to use.

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 8 °C.

Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 340 nm \leq 0,90 AU, the reagent should be discarded. Note 1

CALIBRATION & QUALITY CONTROL

For calibration, use the standard included in the kit. Alternatively, you can use the Biochemistry Calibrator (**HBC03**) for calibration. Note 2 Quality Control is recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration. Use Biochemistry Normal and Pathological Controls (**HBC01**, **HBC02**). Note 3 The control values can be found on the control sheets, delivered together with the control vials. Prepare and measure these controls the same as samples. Measure at least one replicate per control. If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

SAMPLES

Sample type: human serum or plasma: do not use ammonium salts or fluoride as anticoagulants. Stability of samples: 7 days at 4 - 25 °C.

PROCEDURE

Make sure the reagents and samples are at room temperature. Then, pipette into a test tube:

For Blank	1,00 mL Working reagent (R1 + R2)
For Standard ^{Note 2}	10 μL Standard + 1,00 mL Working reagent (R1 + R2)
For Sample	10 μL Sample + 1,00 mL Working reagent (R1 + R2)

Prepare, mix and measure **one sample at a time. Aspirate** the mixture in the instrument, **immediately** after addition of the working solution to the sample/calibrator. Wait with the preparation of the next sample until the instrument is finished with measuring the previous one. At this time, the instrument asks to aspirate the sample. Note 4

PROGRAM SETUP

Prog. Name:	UREAn		Linearity Max:	206	mg/dL	STD variable:	Yes ^{Note 2}	
Prog. ID:	33		Fit:	0		Standard Conc.:	value: see	vial ^{Note 2}
Prog. Version:	2		Direction:	Down		Calibration repeats:	3	
Method ID:	31		Working reagent:	Yes		CAL CV%:	10	
Method Name:	Urease - Gl	LDH	Blank Type:	Reagent ^{Note 1}		Temp flowcell:	37	°C
Method Type:	Two Point		Sample Blank:	No		Calib. Mandatory:	No	
Main Filter:	340	nm	VCF:	1		Control Mandatory:	No	
Sub Filter:	None		Blank substraction:	No		SampleTypeRefValue:	Serum	
Bichromatic Factor:	0		Num of Blank:	1		Normal Low - Male	15	mg/dL
Prog. Unit:	mg/dL		Blank CV%:	0		Normal High - Male	45	mg/dL
Decimals:	0		Blank Low:	0,9 ^{Note 1}		Normal Low - Female	15	mg/dL
Aspiration Volume:	0800	μL	Blank High:	2,5000 ^{Note 1}		Normal High - Female	45	mg/dL
Delay Time:	030	S	Blank Mandatory:	Yes		Normal Low - Child	15	mg/dL
Test Time:	060	S	Factor:	0		Normal High - Child	45	mg/dL
Dilution factor:	1		Calib. By factor:	No		Method order:	0	
Linearity Min:	3,16	mg/dL	Num of STD:	1				

MEASURING RANGE

This method is linear from 3,16 mg/dL (detection limit) to 206 mg/dL (linearity limit). If the obtained results are greater than 206 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

NOTES

- 1. If the blank absorbance is out of range, the instrument will give you a flag. Programming reagent as blank gives you the advantage that deterioration of the reagent can be easily detected.
- 2. Program the value of the standard (see vial). Alternatively, you can use the Biochemistry Calibrator (HBC03) for calibration. See CYANVision user manual for instructions to calibrate a test with a calibrator.
- 3. If other controls (not manufactured by Cypress Diagnostics) are used, they have to be validated by the user as they can vary.
- 4. Carry-over by pathological samples is possible. To prevent this, we recommend to follow a sample with concentration >50 mg/dL by aspiration of 0,8 mL Reagent Blank (working solution) before proceeding with the next sample.

2023-06 (2.0) - Replaces all previous versions









DRIFT

PROGRAM SETUP

Prog. Name:	DRIFT		Num of Blank:	0	
Prog. ID:	92		Blank CV%:	0	
Prog. Version:	2		Blank Low:	-0,01	
Method ID:	92		Blank High:	0,1	
Method Name:	DRIFT		Blank Mandatory:	No	
Method Type:	End Point		Factor:	1000	
Main Filter:	340	nm	Calib. By factor:	Yes	
Sub Filter:	None		Num of STD:	0	
Bichromatic Factor:	0		STD variable:	No	
Prog. Unit:	mA		Standard Conc.:	0,0000	
Decimals:	4		Calibration repeats:	0	
Aspiration Volume:	0800	μL	CAL CV%:	0	
Delay Time:	3	S	Temp flowcell:	37	°C
Test Time:	3	S	Calib. Mandatory:	No	
Dilution factor:	1		Control Mandatory:	No	
Linearity Min:	0	mA	SampleTypeRefValue:	Serum	
Linearity Max:	3500	mA	Normal Low - Male	Not applicable	mA
Fit:	0		Normal High - Male	Not applicable	mA
Direction:	Not applicable		Normal Low - Female	Not applicable	mA
Working reagent:	No		Normal High - Female	Not applicable	mA
Blank Type:	Water		Normal Low - Child	Not applicable	mA
Sample Blank:	No		Normal High - Child	Not applicable	mA
VCF:	1		Method order:	999	
Blank substraction:	Yes				

2021-02 (1.0) - Replaces all previous versions





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After installing your analyzer, our experts will advise you and help you get the most out of your equipment. In the event of a problem, we help you immediately through our local partners.



A supported implementation

Our certified distributors take care of the smallest details for each new project. Your analyzer will be installed, and your team trained.

CYANVision

Our semi-automated biochemistry analyzer

What do our customers say about the CYANVision?

- "Structured manipulation similar to working on an automate"
- "Stable and trustworthy results"
- "Compact and robust analyzer"
- "No more stress for reporting biochemistry results"
- "Convenience in the patient follow-up"

The external screen and its advantages

Did you know that an integrated 7-inch touch screen of reasonable quality and resolution with associated electronics costs as much if not more than a 23-inch computer screen? This is the reason why we opted to work with an external computer screen.

Without the heat emitted by the built-in display, there is no need for a fan for cooling.

Without a fan, there is no dust aspiration and therefore no dirt deposit on the optical filters with these harmful consequences.

Working with an external computer screen offers you many advantages::

- A larger screen
- · More value for the same budget
- · More convenience of use
- Increased durability of the optical system
- · Less power consumption
- · Fewer technical interventions

Clever, right?





The incubator is optional

Cypress Diagnostics biochemistry kits do not require external incubation. There is therefore no need nor advantage to include an incubator in the analyzer.

If you wish, we can offer you the CL017 dry incubator.

The hydraulic system is ultra-short and directly accessible

By design, we simplified the CYANVision to be more robust. Small tricks like an ultra-short and directly accessible hydraulic system, increase the detectability of complications and reduce cross-contamination.

Here's how to kill two birds with one stone!

Light-emitting diodes (LEDs) as a light source

The CYANVision works with light-emitting diodes (LEDs), not with a conventional halogen lamp!

This design choice offers many advantages.

LEDs are more energy efficient and reach their maximum intensity instantly. This property allows the LEDs to be turned on just before the test and turned off immediately after. The consumption of LEDs must therefore be expressed in tests.

The CYANVision can perform 100 000 tests without the costs for lamp replacement.

Software

Software is at the heart of our value proposition.

Unique, intuitive, clear and informative, it is a real element of differentiation from the competition.

The functionality of the CYANVision software must be compared with that of a good biochemistry analyzer.

The software allows to

- Structure the information (worklist, test sequencing suggestions, prioritize emergencies...)
- Standardize the testing process in accordance with the accreditation requirements. For example, the CYANVision will ask to do or redo the auto-zero, blank or calibration when reaching certain predefined thresholds.
- Guide the user during the tests. The CYANVision suggests and encourages steps beneficial to accuracy and precision. On the other hand, the CYANVision detects and reports deviations with alerts, graphs, and measurement ranges. This process increases the scientific validity of your work.

Savings

The CYANVision is designed to provide an operational life of over 100 000 tests. As such, the impact of CYANVision is expressed in cents per test.

The simplicity of the required maintenance allows the user to carry out most of the tasks. The CYANVision has a unique washing solution, available at a reasonable price.

The CYANVision produces better financial results. Investment is limited. It is approximately equivalent to your

Investment is limited. It is approximately equivalent to your billing for 1500 glucose tests to your patients. The CYANVision makes a very positive contribution to your institution.



Discover the CYANVision



Technical specifications, frequently asked questions, videos,







Our offer

	Basic	Plus	Extra
CYANVision	~	~	~
23 inch screen		~	~
Keyboard			~
Mouse			✓
CL017 Dry incubator			~
Order code	CY014	CY014+	CY014++

Contact:

E-mail: cypress@diagnostics.be Tel: + 32 (0)15 67 67 68 Nijverheidsstraat 8 2235 Hulshout Belgium

URL: www.diagnostics.be

Your distributor

CYANVision EN Release date 2022-07-19

Disclaimer: this information is indicative and subject to change without prior notice. Use the documentation included with the products. If in doubt, contact cypress@diagnostics.be

ISO 13485:2016

Key figures

Distinctive features

- Test counter
- LIS Connectivity
- Reference detector
- External HDMI display
- ✓ Light emitting diodes (LEDs)
- Multiple reference ranges
- Patient report
- ✓ Scanning of control values and calibration
- ✓ Memory for 100 000 results

Methods

- 31 from Cypress Diagnostics
- ✓ 100 free choice

Hydraulic system

- ✓ Ultra-short
- 1 peristaltic pump
- ✓ Fully visible
- ✓ Minimum volume of 500 μL per test

Optical system

- ✓ 100 000 tests without lamp replacement
- 8 LEDs on board
- Wavelengths: 340, 405, 450, 510, 546, 578, 620 & 670 nm



Test platform



Code	Name	Pack Cond.	Test per kit
HB0010	Albumin	2 x 125 mL	250
HB0010M	Albumin	8 x 30 mL	240
HB0020	Bilirubin Total & Direct	2 x 125 mL	2 x 166
HB0030	Calcium	2 x 125 mL	250
HB0030M	Calcium	8 x 30 mL	240
HB005	Chloride	2 x 125 mL	250
HB0080	Creatinine	2 x 125 mL	250
HB0080M	Creatinine	8 x 30 mL	240
HB011	Hemoglobin	4 x 5 mL	400
HB012	Iron	4 x 50 mL	200
HB014	Phosphorus	2 x 125 mL	250
HB015	Potassium - Prec	2 x 50 mL	100
HB016	Sodium - Prec	60 mL	60
HB0190	Total Protein	2 x 125 mL	250
HB0190M	Total Protein	8 x 30 mL	240
HB020	Urine Total Protein	2 x 125 mL	250
HB0260	Bilirubin Direct	2 x 125 mL	333
HB0270	Bilirubin Total	2 x 125 mL	333
HB0320	Magnesium	2 x 125 mL	250
HB0320M	Magnesium	8 x 30 mL	240
HBE01	Acid Phosphatase	18 x 2 mL	36
HBE03	α-Amylase	20 x 2 mL	40
HBE09	Lipase	4 x 10 mL	40
HBE12	Alkaline Phosphatase	60 + 15 mL	75

Code	Name	Pack Cond.	Test per kit
HBEL010	GOT (AST)	240 + 60 mL	300
HBEL010M	GOT (AST)	6 x 30 + 3 x 15 mL	225
HBEL020	GPT (ALT)	240 + 60 mL	300
HBEL020M	GPT (ALT)	6 x 30 + 3 x 15 mL	225
HBEL03	Creatine Kinase NAC	60 + 15 mL	75
HBEL04	Lactate Dehydrogenase	240 + 60 mL	160
HBEL041	Lactate Dehydrogenase	60 + 15 mL	83
HBEL05	Creatine Kinase MB	60 + 15 mL	75
HBEL06	γ-GT	240 + 60 mL	300
HBEL061	γ-GT	60 + 15 mL	75
HBL010	Cholesterol	2 x 125 mL	250
HBL010M	Cholesterol	8 x 30 mL	240
HBL011	Cholesterol HDL	120 + 40 mL	160
HBL012	Cholesterol LDL	120 + 40 mL	160
HBL020	Uric Acid	2 x 125 mL	250
HBL020M	Uric Acid	8 x 30 mL	240
HBL030	Urea	240 + 60 mL	200
HBL04	Glucose	2 x 125 mL	250
HBL04M	Glucose	8 x 30 mL	240
HBL060	Triglycerides	2 x 125 mL	250
HBL060M	Triglycerides	8 x 30 mL	240
HT001	HbA1c Turbi	30 + 10 mL	69



An attractive solution

Performance

- Capacity
- Startup
- Training
- Software
- Accietance
- Emergencies

Reputation

- Accreditation
- Alerts
- Availability
- Reliability
- Clear and attractive reports
- Scientific validity

Management

- Continuity
- Contro
- Durability
- Saving
- Financing
- Planning
- Standardization
- Return on