Operating Manual

Vario Photometer plus
DP 550
Version 5.16 / 5.16 SI

Edition 2026-01

Diaglobal GmbH

CONTENT

1. GENERAL INFORMATION ABOUT THE PHOTOMETER

Device name: Vario Photometer plus

Model: DP 550

Basic UDI-DI: 426015249DP550VG

Manufacturer:
Diaglobal GmbH
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The Vario Photometer plus DP 550 is a device capable of detecting and quantifying light attenuation caused by a liquid.

The photometer is a portable, manual, clinical chemistry analyser for the quantitative determination of clinical chemistry analytes in blood, human serum and plasma from patients of all ages and genders.

The device is used in combination with reagents designed for manual procedures for use by qualified laboratory technicians.

Quality control is performed using clinical chemistry standards and controls available from Diaglobal GmbH and other manufacturers.

SYMBOLS

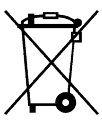
The symbols and abbreviations listed below may appear on the packaging material, the device type plate and in the instructions for use.

Manufacturer

This product complies with the requirements of Regulation (EU) 2017/746 on in vitro diagnostic (IVD) medical devices

In vitro diagnostic (IVD) medical device

Observe the instructions for use



Symbol for labelling electrical and electronic equipment in accordance with Section 7 of the German Electrical and Electronic Equipment Act (ElektroG)

Order number

Serial number

Basic UDI-DI number

STANDARDS AND GUIDELINES

The Vario Photometer plus (DP 550) meets the requirements of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVD).
In addition, the DP 550 photometer is manufactured in accordance with the special safety requirements of the EN 61010 standard for IVD medical devices; see Section 13, General Guidelines and Standards.

SAFETY INSTRUCTIONS

User qualification

The Vario Photometer plus device may be operated only by adequately trained personnel.

Environmental conditions

The Vario Photometer plus is approved for use both indoors and outdoors.

Patient environment

The Vario Photometer plus may be used in patient environments.

Electrical safety

This device has been checked and left the factory in technically perfect condition. To ensure safe and fault-free operation, follow the instructions and recommendations in this Operating Manual.
Repairs to the device, including replacement of the lithium battery, may be carried out only by authorised specialists. Improper repairs will invalidate the warranty.

Built-in lithium battery

According to the manufacturer, the battery is hermetically sealed. Therefore, the contents do not pose a hazard unless the battery is damaged or dismantled. If contents are released due to improper handling, a spontaneously flammable gas mixture may form under certain circumstances.

Caution: Improper handling of batteries may result in burns or explosion. Batteries must not be heated above 85 °C or incinerated. The contents of the battery must not come into contact with water. If the negative electrode comes into contact with water or moisture, hydrogen gas is produced, which can ignite spontaneously.

Electromagnetic waves

The photometer complies with the requirements for interference emission and immunity described in the IEC 61326 series of standards.
Do not use this device near sources of strong electromagnetic radiation, as this may interfere with its proper operation. A distance of at least 1 m should be maintained between a mobile phone that is ready for operation (switched on) and the photometer during measurement.

Reagents

With regard to the reagents used, follow the manufacturer's safety and usage instructions.
Observe the currently valid Hazardous Substances Ordinance (GefStoffV).

Biological safety

Liquid waste may pose a biological hazard. Always wear gloves when handling such materials. Do not touch any parts of the device except those intended for use. Consult the laboratory protocol for information on handling biohazardous materials. Observe the currently valid Biological Agents Ordinance (BioStoffV).
When handling potentially infectious materials (patient samples), personal protective equipment (gloves, gowns) must be worn.

Splashes and cleaning

If splashes from a sample get onto the device, wipe them off immediately and apply disinfectant; see Section 8.3, Cleaning.

Waste

When handling liquid waste, observe the legal regulations regarding water pollution, drainage and waste disposal.

Reporting requirement

Note to the user: All serious incidents related to the product must be reported to the manufacturer, the competent authority and EUDAMED.

MANUFACTURER'S WARRANTY

Diaglobal GmbH warrants that the Vario Photometer plus is free from material and manufacturing defects.
Further information is available from your sales agent.

DISPOSAL INFORMATION

At the end of its service life or useful life, the device and its accessories can be returned to the manufacturer (see address below) free of charge for environmentally friendly disposal.
Prior professional decontamination must be verified by means of a certificate.

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QUALITY MANAGEMENT SYSTEM

Diaglobal GmbH maintains a quality management system in accordance with DIN EN ISO 13485.

2. INTENDED USE AND PROPER USE

The intended purpose of the photometer is the measurement of clinical chemistry parameters in blood, human serum and plasma from human samples in conjunction with a specific reagent kit from Diaglobal by clinical personnel.

The Vario Photometer plus was developed specifically for point-of-care diagnostics using single-use reagents.

The respective diagnostic significance of the clinical chemistry parameters listed in the table below is described in the medical device documentation for the corresponding kit.

It is a closed system that is operated manually. The measurement results are recorded quantitatively and are suitable for patients of any age and gender. There is no specific target population.

The photometer is used by healthcare professionals as a diagnostic aid to determine the appropriate measures to be taken for a patient with regard to medical intervention, for example in terms of medication.

The photometer is suitable for use outside of a laboratory environment.

The photometer is not intended for self-use.

It is not an in vitro diagnostic device used to accompany therapy.

Parameters and diagnostic significance

No.	Parameter	Diagnostic significance
1	Bilirubin	Hyperbilirubinaemia (newborn diagnostics)
2	Creatine Kinase	Heart and skeletal muscle diseases, emergency diagnostics (myocardial infarction)
3	Erythrocytes	Anaemia, bone marrow disorders, vitamin deficiency
4	Glucose	Diabetes (pregnancy care, endocrinology)
5	Haemoglobin	Anaemia, iron deficiency (pregnancy care, emergency diagnostics)
6	Haematocrit	Anaemia, vitamin deficiency
7	Urea	Kidney function (urology)
8	Creatinine	Kidney function (urology)
9	Lactate	Emergency diagnostics (anaphylactic shock), training management (high-performance sport)

Test principle and operating principle

The Vario Photometer plus, item no. DP 550, is a manual, pre-programmed photometer for in vitro diagnostics for use by trained laboratory personnel.

It is operated using buttons.

Several programmed methods are available for measuring procedures to determine various parameters.

A total of 9 different parameters can be measured.

The device is capable of serial measurement for some parameters. Up to 20 samples can be measured in parallel.

The DP 550 photometer can be operated only with round cuvettes of a defined diameter, which are available as pre-filled disposable glass cuvettes together with the corresponding test kit.

The DP 550 photometer is equipped with three optical filters with wavelengths of 365 nm, 546 nm and 520 nm as standard.

A thermal printer can be connected to the device.

The measurement data are not stored or managed in the photometer.

A function test when switching on indicates that the device is ready for operation.

Test principle and compliance with legal requirements

The test principle is the documented principle or methodology on which the performance and measurement accuracy of the photometer are based and which are disclosed in its "*Technical Documentation according to IVDR 2017*" in order to demonstrate compliance with the legal requirements.

It is related to the General Safety and Performance Requirements (GSPR) in accordance with IVDR Annex I and is an essential part of the "*Technical Documentation*". The test principle is part of this evidence and is documented in the performance evaluation in accordance with Annex XIII of the IVDR.

The "*Technical Documentation*" describes the principles and methods used to determine and verify the performance and safety of the device. The test principle thus also provides the basis for the controls and reagents intended for use with the photometer and ensures that the results can be interpreted correctly.

3. INSTALLATION

3.1 Delivery scope

Check the device and the contents of the accompanying box for visible transport damage and completeness:

- Operating Manual
- Power supply unit
- Test certificate with date of commencement of warranty

The point of sale must be informed immediately of any transport damage. The original packaging should be retained in case of a possible return shipment.

3.2 Preparation for installation

The following environmental conditions must be met to ensure trouble-free operation of the device:

- Ambient temperature: 0 °C to 40 °C
- No direct exposure to sunlight or similar sources of radiant heat
- Free from excessive dust
- Free from vibrations
- Free from interference from electromagnetic waves
- Operation on a horizontal surface

3.3 Commissioning

Power supply

The Vario Photometer plus can be operated either with a power supply unit, a battery (9V block) or a rechargeable battery (type 6F22 or PP3).
Insert the rechargeable battery or battery if the device is to be operated independently of the mains supply or connect the photometer to the power supply unit.

Mains power operation

The photometer is supplied with a power supply unit for operation on a mains voltage in the range of 100 V ... 240 V AC. The mains plug is marked with a Diaglobal logo (sticker).
The connector plug of the power supply unit is connected to the power supply socket on the back of the device.

Mains-independent operation

To insert the rechargeable battery or the normal battery:
Unscrew the knurled screws on the bottom of the device and remove the battery compartment cover. Connect the battery to the push-button contact and insert it into the device. Replace the battery compartment cover and screw in the knurled screws.

Notes:

- The Vario Photometer plus can be operated using a power supply without the need to remove the rechargeable battery or the normal battery.
- The rechargeable battery cannot be charged while it is installed. A separate battery charger is required for this purpose.
- If the photometer is operated with a rechargeable battery, we recommend fully charging it before use and carrying a charged spare battery with you.

Pressing the **<ON/ENTER>** button (Fig. 4) triggers the internal device check, which the device performs automatically; see Fig. 1.

Fig. 1: Display during device check

The device indicates that it is ready for operation by displaying “Device Check OK”, see Fig. 2.

Fig. 2: Display after successful device check

The device type and version designation are then displayed, see Fig. 3.
If the printer is activated, the device type and version are printed out.
The device is now ready for measurements.

Fig. 3: Display showing device type and version designation

4. OPERATING ELEMENTS

4.1 Device description

The DP 550's controls consist of a cuvette slot for round cuvettes, a display and three control buttons; see Fig. 4.

The cuvette shaft is integrated into an optical block inside the device.

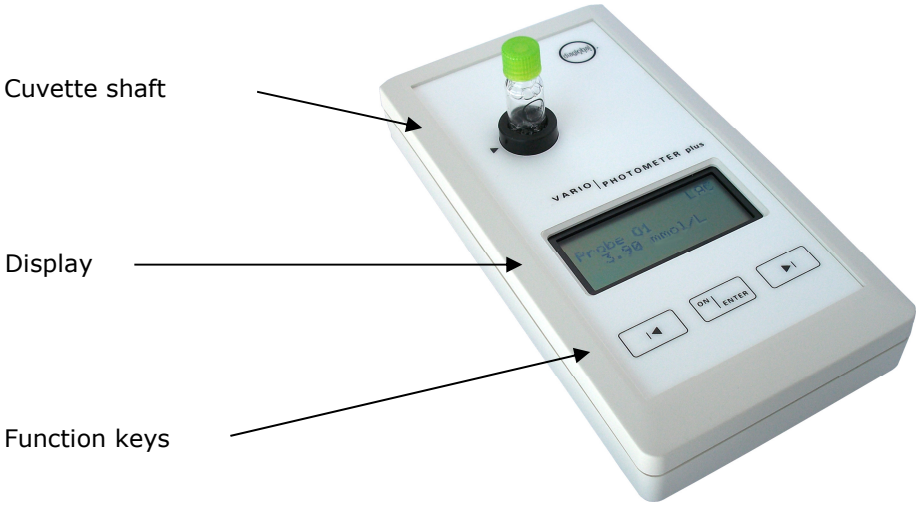


Fig. 4: Operating elements of the DP 550

4.2 Measuring system

The measuring system consists of an optical block in which three LEDs and three interference filters are integrated. The optical block is shown in Fig. 5.

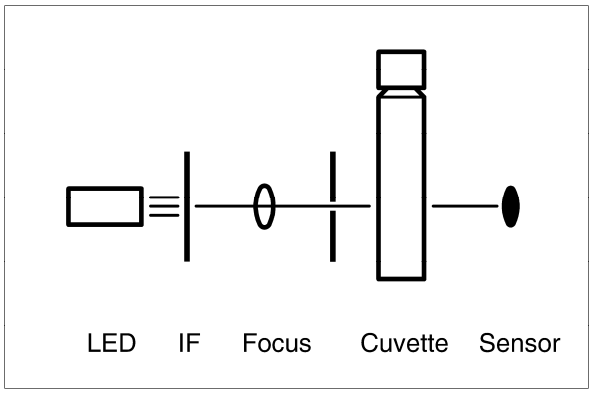


Fig. 5: Optical block, beam path and measuring principle

The light emitted by an LED is first selected into its wavelength ranges (365 nm / 520 nm / 546 nm) by an interference filter IF (FWHM ~ 5 nm) and then directed in a concentrated beam onto the cuvette in the shaft.
After passing through the cuvette, a broadband photosensor converts the light falling on its sensor surface into a current proportional to the intensity.

The measuring principle is based on Lambert-Beer's law, which describes the mathematical relationship between the attenuation of radiation intensity in relation to its initial intensity when passing through a medium containing an absorbing substance, depending on the concentration of the absorbing substance and the layer thickness.

5. PROGRAMME SELECTION

5.1 Switching the device on and off

The device is switched on by pressing the **<ON/ENTER>** button.
The device is switched off by pressing both arrow buttons simultaneously.

5.2 Self-test when switching on

When the device is switched on, a self-test of the digital and analogue circuitry is performed. The device function check runs automatically after switching on. It takes approx. 5 seconds, after which the device is ready for measuring.

Note:

If, during the test, it becomes apparent that one of the device functions does not correspond to the required settings, the message <SERVICE> will appear. In this case, the device can only be switched off. Please call Diaglobal GmbH's service department (tel. +49 30 6576 2597) or contact your specialist dealer.

5.3 Test selection

Press the **<ON/ENTER>** button.

The desired test is selected from the menu using the right or left arrow key:

LAC - CK 321 - HCT - UREA - GLU - HB-SLS - ERY - LAC-rapid - CK 121 - HB - BIL - BIL N - CRE - ABS365 - ABS520 - ABS546

Pressing the right button activates the next test, while pressing the left button returns to the previous test. The selected test is shown in the top right corner of the display.

Confirm test selection by pressing the **<ON/ENTER>** button.

5.4 Integrated device function tests

Self-test when switching on

The device automatically checks its digital and analogue circuits when it is switched on.
Refer to Section 5.2, Self-test when switching on.

Differential measurements

All measurements are based on differential measurements. This means that after selecting the desired test, the device prompts you to perform a zero measurement using a blank value cuvette. This establishes a reference basis for the measured value so that minor deviations can be compensated.

Measuring range controls

The measuring ranges of all measurement results shown on the display are checked by an integrated measuring range control. If the measuring range is exceeded, an error message is displayed.

The measuring ranges specified separately for each parameter are documented in the respective package inserts and in this Operating Manual; see Section 12, Technical Data.

Plausibility controls

For multi-point measurements, the first measured absorbance value forms the reference basis. The programme checks the individual measured values for plausibility. If certain specifications (e.g. A2 > A1 for ascending reactions) are not met, an error message is displayed.

6. METHODOLOGICAL PROCEDURES AND CALCULATION METHODS

Description of the algorithm for data evaluation

6.1 Endpoint measurement

The absorbance value is measured after reaching the endpoint.
The measurement is taken against the reagent blank value.

Parameters: Haemoglobin (HB), Haemoglobin SLS (HB SLS), Erythrocytes (ERY), Haematocrit (HCT)
Calculation: Concentration = ΔA x factor

The erythrocyte and haematocrit values are determined using internally stored reference curves.

6.2 Endpoint measurement with consideration of the sample blank value and pre-programmed measuring time

After measuring the sample blank value, the colour reaction in the cuvette is started and the endpoint absorbance is measured after a specified time has elapsed.

Parameters: Bilirubin (BIL), Neonatal bilirubin (BIL N), Creatinine (CRE)
Calculation: Concentration = ΔA x factor
Measuring time: 2 minutes

The samples are measured in succession:
Sample 01: Measurement 1 (sample blank value)
Sample 01: Measurement 2 (result)
Sample 02: Measurement 1 (sample blank value)
Sample 02: Measurement 2 (result)
etc.

Parameter: UREA
Calculation: Concentration = ΔA x factor
Measuring time: 10 minutes

Blank values of the samples are measured one after the other, up to 20 samples parallel in series:
Sample 01: Measurement 1 (sample blank value)
Sample 02: Measurement 1 (sample blank value)
Sample 03: Measurement 1 (sample blank value)
etc.

After the 10-minute measurement period has elapsed, the samples are measured in the same order as the blank values, one after the other:
Sample 01: Measurement 2 (result)
Sample 02: Measurement 2 (result)
Sample 03: Measurement 2 (result)
etc.

6.3 Multipoint measurement with consideration of the sample blank value and recognition of the endpoint

After measuring the sample blank value (= measurement 1) the colour reaction in the cuvette is started. The reaction process is monitored by the device (= measurement 2). The measuring process is terminated as soon as the endpoint is reached.

The time needed to reach the endpoint depends on the temperature. It is normally 2 - 6 minutes for the lactate test. If temperatures are close to freezing point, measuring times can take up to 20 minutes, depending on the parameters.

You can choose between single and series measurements up to a maximum of 20 samples.
For single measurements, the samples are processed one after the other.
For series measurements, all A1 values are measured first.

Parameter: Lactate (LAC)
Calculation: Concentration in plasma = ΔA x factor

6.4 Multipoint measurement with consideration of the sample blank value and calculation of the endpoint

After measuring the sample blank value (= measurement 1) the colour reaction in the cuvette is started. The course of the reaction is monitored by the device. The endpoint is calculated using several absorbance values recorded at different times.

Parameter: Glucose (GLU), Lactate-rapid (LAC-rapid)
Measuring time: Glucose: 2 minutes
Lactate-rapid: 1 minute

6.5 2-point kinetics with lead time, programmed measurement time and at 37 °C

Creatine kinase from blood (CK 321)

The reaction is started in the cuvette with the start cap. The measurement begins simultaneously on the photometer by pressing a button. After a pre-run time (incubation) of 5 minutes, the first absorbance (A1) is measured. After another 10 minutes, the second absorbance (A2) is measured.

The photometer specifies a cycle time (15 seconds) for a series measurement. For series lengths n < 6, you must switch to the A2 measurement using the **<ON/ENTER>** key. For n = 6, the device switches automatically. The measured enzyme activities of the individual samples can be called up using the arrow keys.

The CK concentration is calculated from the difference in absorbances (ΔA) using a calibration factor. As the determination is made from blood, the haematocrit value must be taken into account.

Calculation: Enzyme activity (U/L) = factor x (ΔA) / (1-0.01*HCT)

Individual haematocrit values can be taken into account; these are requested before the results are output. The default setting is an HCT value of 40 %.

Note: Since control samples can only be measured from serum, 0% must be entered for the HCT value in the case of control measurements.

Creatine kinase from serum/plasma (CK 121)

The reaction is started in the cuvette by adding the sample. Simultaneously, time measurement begins on the photometer by pressing **<ON/ENTER>**. After a pre-run time (incubation) of 5 minutes, the first absorbance (A1) is measured. After another 10 minutes, the second absorbance (A2) is measured.

The photometer specifies a cycle time (15 seconds) for a series measurement. For series lengths n < 6, you must switch to the A2 measurement using the **<ON/ENTER>** key. For n = 6, the device switches automatically. The measured enzyme activities of the individual samples can be called up using the arrow keys.

The CK concentration is calculated from the difference in absorbances (ΔA) using a calibration factor.

Calculation: Enzyme activity (U/L) = factor x ΔA

Note:

For a description of the procedures and instructions on how to perform the measurements, please refer to the video tutorials on our website, www.diaglobal.de and to the illustrations in the appendix to these instructions for use.

6.6 Calculation formulas for data analysis

Parameter	Process	λ [nm]	Calculation of results	Unit	LML	UML	CF
Bilirubin	E	546	C = 20.7 x ΔA	mg/dL	0.5	25	17.104
				µmol/L	8.5	428	
Bilirubin N	E	546	C = 99.1 x ΔA	mg/dL	2.3	50	17.104
				µmol/L	39	850	
CK 321	F	365	C = 1082 x ΔA / (1 - 0.01 x HCT)	U/L	0	3000	-
CK 121	F	365	C = 2000 x ΔA	U/L	0	2500	-
Erythrocytes	A	546	C = A x ΔA^2 + B x ΔA + C	mio./µL	1.0	10	-
Glucose	S	520	A_0 < 0.075: C = 217.5 x MwA_{End} - A_0	mg/dL	20	630	0.0555
			A_0 ≥ 0.075: C = ((217.5 + 130 x A_0) x (MwA_{End} - A_0) + 40 x A_0) x 1.04	mmol/L	1.1	35	
Haemoglobin	A	546	C = 31.4 x ΔA	g/dL	0.0	50	0.6206
				mmol/L	0.0	31	
Haemoglobin-SLS	A	546	C = 32.7 x ΔA	g/dL	0.0	50	0.6206
			520nm: C = 35.1 x ΔA	mmol/L	0.0	31	
Haematocrit	A	546	C = 92 x (A x ΔA^2 + B x ΔA + C)/10	%	5.0	90	-
Urea	C	546	C = (270.3 x ΔA) – 42.89	mg/dL	5.0	200	0.1665
			520nm: C = (374.4 x ΔA) – 83.74	mmol/L	0.8	35	
Creatinine	E	520	C = 21.3 x ΔA	mg/dL	0.0	5.0	88.402
				µmol/L	0.0	440	
Lactate	C	520	A_0 < 0.075: C = 17.3 x ΔA	mmol/L	0.2	30	-
			A_0 ≥ 0.075: C = ((16.3 x ΔA / (1-0.7 x A_0)) + 1.7 x A_0				
Lactate-rapid	CE	520	A_0 < 0.075: C = 15.2 x 1.05 x (ΔA–0.011)	mmol/L	0.2	20	-
			A_0 ≥ 0.075: C = ((15.2 x 1.05 x (ΔA – 0.011)) / (1 – 0.6 x A_0)) + 1.7 x A_0				

CF = conversion factor LML = lower measurement limit UML = upper measurement limit

A_0 ≥ 0.075 = measurement from blood A_0 < 0,075 = measurement from serum/plasma or aqueous solutions

7. ANALYTICAL PERFORMANCE OF THE PHOTOMETER

7.1 Sample types

The samples intended for the instrument are bodily fluids from the field of human medicine: capillary blood / venous blood / serum / plasma.

Parameter	Sample material			
	Capillary blood	Venous blood	Serum	Plasma
CK from blood	+	+	+	+
CK from serum	-	-	+	+
Urea	+	+	+	+
Haematocrit	+	+	-	-
Lactate	+	+	-	+
Lactate-rapid	+	+	-	+
Bilirubin	-	-	+	+
Neonatal bilirubin	+	+	+	+
Glucose	+	+	+	+
Haemoglobin (SLS method)	+	+	-	-
Haemoglobin (HiCN method)	+	+	-	-
Erythrocytes	+	+	-	-
Creatinine	-	-	+	+

7.2 Precision and correctness (intra-assay / inter-assay)

Explanation of technical terms

Correctness: Measure of the agreement between the mean value of a series of measurements and the reference value. The dispersion of the individual values is not taken into account here.

Precision: Degree of agreement between individual independent measurement results in a series of measurements. It characterises the dispersion of the measurement results around the mean value and can be represented by the (relative) standard deviation.

Accuracy: The result of correctness and precision. It is a measure of the agreement between the (individual) measurement result and the reference value. High accuracy is achieved when both precision and correctness are high.

Inaccuracy: Inaccuracy refers to the numerical difference between the arithmetic mean of a series of repeated measurements and the target value. In contrast to the concept of measurement accuracy, inaccuracy is a numerical quantity. Inaccuracy increases as the systematic error increases.

Proof of precision and correctness

The precision and correctness of the instrument have been tested both inter- and intra-assay. The LS 500 reference photometer was used as the basis for the correctness of the measured values. The measured values and evaluations determined are documented internally.

The following statistical data were determined:

- Target value
- Mean value
- Standard deviation
- Coefficient of variation
- Photometric inaccuracy

In summary, the evaluation determines whether the respective test has been passed.

The following tables show a summary of the statistical measurement data determined using the ABACUS statistics programme for precision and correctness, intra-assay and inter-assay, for three wavelengths within three different absorbance ranges: low, medium and high.

7.2.1 Intra-assay: Statistical evaluation of measurement data for three wavelengths

Wavelength λ = 356 nm, n = 25

	λ = 365 nm (low)	λ = 365 nm (medium)	λ = 356 nm (high)
Target value	0.248	0.950	1.397
Mean value	0.246	0.943	1.395
Standard deviation	0.001	0.001	0.002
Coefficient of variation	0.3 %	0.1 %	0.2 %
Inaccuracy	-0.8 %	-0.7 %	-0.2 %
Test passed?	Yes	Yes	Yes

Wavelength λ = 520 nm, n = 25

	λ = 520 nm (low)	λ = 520 nm (medium)	λ = 520 nm (high)
Target value	0.133	0.813	1.475
Mean value	0.132	0.813	1.475
Standard deviation	0.001	0.001	0.001
Coefficient of variation	0.4 %	0.1 %	0.1 %
Inaccuracy	-0.5 %	-0.05 %	0.06 %
Test passed?	Yes	Yes	Yes

Wavelength λ = 546 nm, n = 25

	λ = 546 nm (low)	λ = 546 nm (medium)	λ = 546 nm (high)
Target value	0.158	0.965	1.769
Mean value	0.158	0.966	1.765
Standard deviation	0.001	0.001	0.003
Coefficient of variation	0.4 %	0.1 %	0.2 %
Inaccuracy	-0.1 %	0.1 %	-0.2 %
Test passed?	Yes	Yes	Yes

7.2.2 Inter-assay: Statistical evaluation of measurement data for three wavelengths

Wavelength λ = 356 nm, n = 25

	λ = 365 nm (low)	λ = 365 nm (medium)	λ = 356 nm (high)
Target value	0.248	0.950	1.397
Mean value	0.245	0.945	1.389
Standard deviation	0.001	0.003	0.004
Coefficient of variation	0.2 %	0.3 %	0.3 %
Inaccuracy	-1.3 %	-0.6 %	-0.6 %
Test passed?	Yes	Yes	Yes

Wavelength λ = 520 nm, n = 25

	λ = 520 nm (low)	λ = 520 nm (medium)	λ = 520 nm (high)
Target value	0.133	0.813	1.475
Mean value	0.133	0.811	1.467
Standard deviation	0.001	0.001	0.003
Coefficient of variation	0.6 %	0.2 %	-0.2 %
Inaccuracy	-0.4 %	-0.2 %	-0.5 %
Test passed?	Yes	Yes	Yes

Wavelength λ = 546 nm, n = 25

	λ = 546 nm (low)	λ = 546 nm (medium)	λ = 546 nm (high)
Target value	0.158	0.965	1.769
Mean value	0.156	0.959	1.758
Standard deviation	0.001	0.001	0.002
Coefficient of variation	0.6 %	0.1 %	0.1 %
Inaccuracy	-1.3 %	-0.6 %	-0.2 %
Test passed?	Yes	Yes	Yes

7.2.3 Correctness through interlaboratory tests

The accuracy of the instrument's absorbance measurements has been verified by the results of interlaboratory tests conducted by the Reference Institute for Bioanalytics (RfB).

The results of the interlaboratory test are available on our website under the heading *Quality Assurance*.

7.3 Linearity, analytical sensitivity, calibration verification

7.3.1 Linearity and analytical sensitivity

Linearity

The linearity of a measurement method describes the concentration range in which the measurement signal is directly proportional to the analyte concentration or the measured value is directly proportional to the target value. This proportionality ensures the accuracy and reliability of measurements across a wide range of analyte concentrations. To confirm linearity, at least five different concentrations of the analyte are measured. The mathematical relationship between the concentration and the measurement signal is then determined by linear regression.

Test solutions were used to determine linearity and analytical sensitivity until the instrument could no longer detect the target in more than 95 % of the replicates.

To confirm linearity, each measured value was compared with an expected value calculated using linear regression. The difference between the measured value and the expected value was calculated and checked for consistency. If all differences are smaller than the specified maximum error limits, linearity is considered to be confirmed.

Calibration verification and confirmation of the analytical measurement range are used to evaluate the performance of the measurement method. During calibration verification, the differences between the target values and the measured values were checked across the entire measurement range. This ensures that these differences are within the specified maximum error limits. If this is the case, the calibration is considered confirmed.

Both the confirmation of the analytical measurement range and the calibration verification were carried out in accordance with the recommendations of the CLIA (Clinical Laboratory Improvement Act) and the CAP (College of American Pathologists). These guidelines ensure that the measurement procedures in the clinical laboratory are reliable and accurate and meet quality assurance requirements.

Analytical sensitivity

The measurement range is the specified range of extinction measurements for all wavelengths implemented in the device within which it provides reliable and accurate measurements. It defines the range in which measurement deviations and error limits are acceptable.

The measuring range of the instrument depends on the wavelength. It was determined during investigations into analytical sensitivity and linearity.

The wavelength measurement ranges of the instrument are shown in the following table:

Wavelength	Absorbance $_{\text{lower measuring range}}$	Absorbance $_{\text{upper measuring range}}$
λ = 365 nm	0.000 ± 0.001	2.600 ± 0.001
λ = 520 nm	0.000 ± 0.001	2.600 ± 0.001
λ = 546 nm	0.000 ± 0.001	2.600 ± 0.001

7.3.2 Definition of test limit values (cut-off)

The cutoff value must be distinguished from the detection limit. The detection limit is the lowest concentration that a test can reliably detect, while the cutoff value determines which concentration is considered clinically relevant.

As can be seen from the measurements of *precision and correctness*, *calibration verification* and *relative short-term standard deviation*, the accuracy of the photometer's absorbance measurements after zero adjustment is: A = ± 0.001
The zero point is set for all wavelengths using a cuvette filled with water.

The accuracy remains the same across the entire measuring range of A = 0.001 – 2.600.

7.3.3 Relative short-term standard deviation / trend according to Neumann

Short-term standard deviation, trend and drift are important statistical measures when analysing data that changes over time. Standard deviation measures the dispersion of data around its mean, while trend and drift describe how the mean itself changes over time.

Short-term standard deviation:

The standard deviation indicates how widely the individual data points in a time series deviate from their local mean (often calculated over a short period of time). A high standard deviation indicates high volatility or dispersion of the data, while a low standard deviation indicates low dispersion and greater consistency of the data. In practice, the short-term standard deviation is often used to assess the short-term stability or instability of a time series.

Trend:

The trend describes the long-term direction or development of a time series. A trend can be upward, downward or sideways. The trend is often viewed as a shift in the mean value over a longer period of time. A linear trend can be determined, for example, by means of regression analysis.

Drift:

Drift is a constant component or section of an axis in a time series that represents a uniform shift in the mean value over time. It can be interpreted as the average change in the data per unit of time. Drift can be either positive (increasing) or negative (decreasing).

Similarities and differences

The short-term standard deviation is a measure of short-term variability, while the trend describes the long-term development. Drift is a specific type of trend characterised by a constant shift in the mean value. A time series can exhibit a trend, drift and short-term standard deviation simultaneously.

Trend according Neumann

The Neumann test is a statistical trend test used to check whether a time-ordered series of values shows a trend. A trend exists if the values in the series are systematically related to each other, for example if they rise or fall continuously. The test examines whether neighbouring values are more similar than more distant values in the series. The Neumann test is used to check whether there is a systematic deviation (trend) in a series of measurements, such as a gradual misalignment, and whether the values in a series change over time.

The relative short-term standard deviation was examined as a function of wavelength and is shown below for wavelengths λ = 520 nm and λ = 546 nm and for a colour solution.

Relative short-term standard deviation at the wavelength λ = 520nm

Checking with colour solutions whether there is a trend (trend according to Neumann)

Relative short-term standard deviation 520 nm colour solution 1	
STATISTIC	
n:	60
Outliers:	0
Trend according to Neumann?	No
Mean value:	0,563 (0,562 to 0,563)
Standard deviation:	0,0007
Variance:	0
Coefficient of variation:	0,1 %
Max. CV (%):	0,5 %

Relative short-term standard deviation at the wavelength λ = 546nm

Checking with colour solutions whether there is a trend (trend according to Neumann)

Relative short-term standard deviation 546 nm colour solution 1	
STATISTIC	
n:	60
Outliers:	0
Trend according to Neumann?	No
Mean value:	0,682 (0,682 to 0,683)
Standard deviation:	0,0009
Variance:	0
Coefficient of variation:	0,1 %
Max. CV (%):	0,5 %

7.3.4 Metrological traceability of calibrator and control material values

Metrological traceability

The reference of the measurement result to suitable standards, generally international or national standards. Metrological traceability describes the property whereby the measured value displayed by a measuring instrument can be compared with the national standard for the relevant measured quantity in one or more steps. These steps form an unbroken chain of comparative measurements, whereby each measuring instrument is compared with a standard whose metrological characteristics have themselves been determined by comparison with a higher-level standard.

Metrological traceability through interlaboratory tests with the reference photometer LS 500

Metrological traceability is ensured by referencing and adjusting the extinction measurements to the laboratory's internal reference photometer LS 500 (Hach Lange GmbH), which is subject to external testing twice a year by the Reference Institute for Bioanalytics (RfB). During the daily start-up of the reference photometer, quality assurance is carried out in the form of a check using ring test reference samples from previous photometer ring tests. This means that incorrect results with the reference photometer can be practically ruled out.

Metrological traceability through the use of a certified reference standard

The reference standard cyanhaemoglobin HiCN method, in accordance with ICSH/CLSI for photometer calibration and verification, is sourced from Bioanalytik GmbH. The certified reference standard is identified by a specified measured value. It is used to calibrate the LS 500 reference photometer and to calibrate and adjust Diaglobal photometers.

7.4 Clinical performance and clinical evidence

The clinical performance demonstrates the product's performance resulting from its medical effects, ensuring that it provides clinical benefits to patients and that it is safe. The clinical evidence consists of a collection of data and results from clinical evaluations, trials and studies that demonstrate that the photometer is safe, performs as intended and has the expected clinical benefits according to the manufacturer's specifications.

All clinical chemistry procedures used on the Vario Photometer plus are classic analysis methods described in textbooks and reference works:

> L. Thomas, Laboratory and Diagnosis, Indication and Evaluation of Laboratory Findings for Medical Diagnostics, Die Medizinische Verlagsgesellschaft Marburg, 1st edition, 1978 [current edition: 20th edition]

The analytical methods described in this classic reference work are still used in clinical chemistry practice, both as manual and automated measurement methods.

The Vario Photometer plus is a medical measuring device that has proven itself on the diagnostic market for more than 25 years.

Performance evaluation and performance studies

The performance evaluation of the photometer product is conducted as an ongoing process that evaluates and analyses data to demonstrate the scientific validity, analytical performance, and clinical performance of the photometer for its intended purpose.

A performance evaluation plan serves as proof of this. It sets out the characteristics and performance of the photometer as well as the procedures and criteria used to provide the necessary clinical evidence.

Post-market performance follow-up

The planning and follow-up of performance after placing on the market is carried out in accordance with IVDR 2017, Annex XIII within post-market surveillance (PMS).

The documentation of the monitoring and review of post-market performance follow-up is carried out annually in accordance with the applicable procedural instructions. The documentation includes a performance evaluation plan and a performance evaluation report.

The clinical data and experience used to evaluate the performance of the Vario Photometer plus are based on:

- Results of interlaboratory tests
- Monitoring of retained samples
- Measurement results from ongoing production
- Device comparisons
- Evaluations of feedback statistics
- Publications and user reports
- Feedback from customer surveys

8. QUALITY ASSURANCE IN ACCORDANCE WITH RiliBÄK [1)]

The Vario Photometer plus was developed specifically for point-of-care diagnostics using single-use reagents (RiliBÄK, Part B, Chapter 2.1.5). According to the guidelines of the German Medical Association, users are therefore not required to participate in interlaboratory tests (RiliBÄK, Part B, Chapter 2.2, Paragraph (3) a)). This eliminates the need for external quality control in the form of participation in interlaboratory tests. Only internal quality assurance needs to be carried out.

Internal quality assurance takes the form of weekly accuracy checks (calibration) followed by documentation of the measured values. The corresponding report forms are available free of charge from Diaglobal.

We offer special control solutions for checking the accuracy of lactate and glucose measurements: LAC QS and GLU QS.
For checking the accuracy of bilirubin measurements, we offer the control lyophilisate BIL QS.

To check the correctness of haemoglobin, haematocrit and erythrocyte determinations, we recommend our HEM QS and ERY QS control solutions with target values in the normal concentration range.

For all other parameters, we recommend the universal control sera from Roche, www.roche.de:

PreciControl ClinChem Multi 1	Order no.: 05 947 626 190 (4 x 5 mL) Normal range
PreciControl ClinChem Multi 2	Order no.: 05 947 774 190 (4 x 5 mL) Pathological range

In accordance with the requirements of RiliBÄK, the Vario Photometer plus includes an integrated device function check (see Operating Instructions, Section 5.4), eliminating the need for daily checks using a physical standard (RiliBÄK, Part B, Section 2.1.5, Paragraph (2)).

The Vario Photometer plus is suitable for rapid detection of gestational diabetes and meets the requirements of the Maternity Guidelines[2)] and the S3 Guideline[3)]. Glucose can be measured from both whole blood and venous plasma. The measured value displayed is always based on venous plasma, in accordance with the requirements.

[1)] Guideline of the German Medical Association on quality assurance in laboratory medical examinations
Deutsches Ärzteblatt | Volume 120 | Issue 21-22 | 30 May 2023
[2)] BAnz. No. 36, S914
[3)] AWMF- Register No. 057/008

9. MAINTENANCE AND SERVICE

9.1 Adjustment and calibration

The device is adjusted and calibrated at the factory on delivery, adjustment by the customer is not necessary.
Adjustment is carried out via the interface socket on the rear panel. It can only be carried out at the factory, adjustments by the customer are not possible.
Information on calibrating the device can be found in Section 8, Quality control according to the Guideline of the German Medical Association.

9.2 Maintenance

The device is maintenance-free. Maintenance after the warranty period has expired is recommended but not essential. Due to the integrated device function check (Section 5.4) and regular checks with control material, maintenance is recommended only if one of these two check functions displays an error message.

9.3 Cleaning

To clean the surface of the device, commercially available decontaminating solutions commonly used in clinical chemistry laboratories, such as Mikrozid® AF Liquid, Bacillol® plus, 3% Kohrsolin® or similar, are recommended. Before cleaning the device with a soft cloth and the decontaminating solution, it must be switched off and the mains plug disconnected.

Ensure that no liquids enter the device. There is no protection against liquid ingress (Code IP X0).

The cuvette shaft must not be cleaned by the user of the device, as this may damage the device. If cleaning is necessary, particularly due to spilled liquids or broken glass, please contact us.

9.4 Malfunctions

If you encounter any malfunctions or problems, simply give us a call. Many questions can be answered over the phone. Non-functional devices should be sent to our address in Berlin. We will provide a loaner device for the duration of the repair.

9.5 Disposal

We will take back and dispose of any devices that are no longer needed or cannot be repaired free of charge.

10. ERROR HANDLING AND ERROR MESSAGES

10.1 Error handling

This section discusses the most common errors that can occur during sampling and sample dosing.

Errors in sampling will always lead to incorrect measurement results.

1. Before measuring, cuvettes stored in the refrigerator must be brought to room temperature. If the cuvettes are too cold, condensation will form on the outer wall due to the humidity, which will lead to incorrect measurement results.

2. Never touch the lower part of the cuvette (where the liquid is located) with your bare hands. If this happens accidentally, clean the cuvettes with a lint-free cloth before use. Cleaning with a lint-free cloth is recommended in all cases. Even if the package is still new and unopened. Fingerprints on the cuvette will lead to incorrect measurement results.

3. If blood is collected from the heel using a Microvette (neonatal bilirubin), ensure that there is sufficient blood (approx. 60 µL) in the Microvette, as 20 µL of serum/plasma is required for measurement. Close the Microvette tightly after blood collection and return it to the small sample vessel for centrifugation.

4. After centrifuging the Microvette, please ensure that the blood clot has separated completely and sharply and that the supernatant is clear and free of suspended particles. Otherwise, repeat the centrifugation. If the supernatant is not free of suspended particles or if parts of the blood clot accidentally enter the capillary, the measurement result will be distorted.

5. If blood is taken from the fingertip or earlobe, it is important to note that the first drop that forms spontaneously must be wiped away with a cotton swab. It contains a high proportion of tissue fluid, which would distort the measurement result.

6. The second drop that forms is used for blood collection. To aid blood formation, you may press gently (!). The emphasis is on gently, as otherwise too much tissue fluid will enter the sample.

7. Ensure that the blood blister that forms is large enough to fill the capillary tube with the required sample volume in one go. Repeated filling of the capillary tube will result in air bubbles that cannot be removed from the capillary tube. If air bubbles form, discard the capillary tube and start the sampling process again.

8. The capillary must be filled exactly to the black calibration mark.

   Please note: A deviation of just 1 mm from the ring mark is sufficient to produce a significantly inaccurate measurement result!

   If the sample is above the black ring mark, this will lead to false positive measurement results. Any excess blood can be carefully dabbed off with a cotton swab.
   If the sample is below the black ring mark, this will lead to false negative measurement results. In this case, correction is virtually impossible due to the air bubble that forms.

9. Before placing the capillary tube in the cuvette, carefully remove any sample residue from the lower part of the outside of the tube using a cellulose swab. Failure to do so could lead to false positive measurement results.

10. The sample is transferred completely into the cuvette using the micropipette. The sample is transferred completely by pressing the push button on the micropipette several times.

    Please note: The micropipette is used only when the capillary is filled with the sample. It is not needed to fill the capillary. The capillary is filled solely by capillary action.

11. During serial measurements, make sure that the order of the samples is not mixed up. Otherwise, the device will not be able to assign the samples correctly, which will lead to implausible measurement results.

12. When changing caps with the starter cap, ensure that the substance in the starter cap has completely dissolved. Otherwise, a non-linear kinetic reaction process will occur, resulting in an error message on the display or implausible measurement results.

10.2 Error messages

The following error messages may appear on the photometer display:

Error message	Error description	Action
"Abs 1 too high"	Absorbance of blank value is too high	Check your working method and the individual steps and compare them with the instructions for use, and if necessary also with the tutorials on our website www.diaglobal.de and the information in Section 9.1, Troubleshooting.
"Reaction too slow"	Absorbance differences are too small	
"No reaction"	Sample addition or cap replacement missing	
"Cuvette?"	Cuvette missing or not inserted correctly	
"Device defective"	Hardware error	Please contact our service department by telephone on +49 30 6576 2597 or by email at info@diaglobal.de.
"Service"	Hardware error	

11. TEST KITS, CONSUMABLES AND ACCESSORIES

11.1 Parameters of the test kits

The following parameters can be measured with the Vario Photometer plus:

Parameter	Sample material			Tests / pack	Art. No.
	Blood	Serum	Plasma		
CK from blood [1) 2) 3)]	+	+	+	20	CK 321
CK from serum [2)]	-	+	+	20	CK 121
Urea [1) 3)]	+	+	+	20	HST 321
Haematocrit	+	-	-	40	HCT 142
Lactate	+	-	+	40	LAC 142
Lactate-rapid	+	-	+	40	LAC 342
Bilirubin	-	+	+	40	BIL 142
Neonatal bilirubin [1) 3)]	+	+	+		
Glucose	+	+	+	40	GLU 142
Haemoglobin (SLS method)	+	-	-	40	HB 342
Haemoglobin (HiCN method)	+	-	-	40	HB 142
Erythrocytes	+	-	-	40	ERY 142
Creatinine [2)]	-	+	+	20	KRE 121

[1)] Mini centrifuge required (Art. No.: DZ 002)
[2)] Dry block thermostat required (Art. No.: DZ 003)
[3)] From blood, with subsequent sample preparation (centrifugation with mini centrifuge)

11.2 Control materials for test kits

Art. No.	Description	Contents
HEM QS	Haemoglobin control Haemolysate for accuracy and precision control of haemoglobin determination in blood in the normal range	5 x 1 mL
ERY QS	Erythrocytes- and Haematocrit control Control blood for accuracy and precision control of haematocrit and erythrocytes determination in blood in the normal range	5 x 1 mL
GLU QS	Glucose control, 100 mg/dL	3 x 4 mL
LAC QS	Lactate control set, 2 mmol/L ; 4 mmol/L ; 10 mmol/L	3 x 4 mL
BIL QS	Bilirubin control Lyophilisate for accuracy and precision control of bilirubin determination	20 caps

A description of the reagents and controls, as well as any restrictions on their use, their composition in terms of the type and concentration of the active ingredients, and information on other ingredients, are documented in the respective instructions for use for each product.

Care must be taken to ensure that all consumables are only used within their expiry date, insofar as an expiry date is indicated.

11.3 Consumables and accessories

Art. No.	Description	Contents
LH 006	Cuvette rack	1
LH 007	Micropipetter (pipetting aid)	1
LH 017	Adapter (spare part) for micropipetter LH 007	1
LH 026	Capillaries 10 µL, with ring mark	250
LH 029	Capillaries 20 µL, with ring mark	250
LH 028	Capillaries 100 µL, with ring mark	250
LH 037	Microvettes 200 µL, Li-heparinised	100
LH 038	Capillaries 20 µL, heparinised, end-to-end	100
LH 048	Capillaries 60 µL, heparinised, end-to-end	100
LH 055	Pipette tips 50-1000 µL blue, for pipette LH 500	2 x 500
LH 500	Pipette fix 500 µL	1
DZ 001	Power supply unit for photometer	1
DZ 002	Mini centrifuge	1
DZ 003	Dry block thermostat	1
DK 002	Equipment case	1

Which of the products listed under "Consumables and accessories" are required for the measurements depends on the respective test kit.

The instructions for use of the test kits document the consumables and accessories required for this purpose.

All reagent kits, control materials and other materials are supplied by Diaglobal GmbH and can be stored and transported together with the Vario Photometer plus in a practical case.

12. TECHNICAL DATA

12.1 Brief specifications

Storage temperature:	-20 °C ... 70 °C
Operating temperature:	0 °C ... 40 °C
Dimensions:	200 x 100 x 50 mm
Weight:	450 g
Measuring principle:	Absorption measurement with single-beam photometer, pulsed operation
Projector:	LED
Spectral apparatus:	Interference filter
Measuring wavelengths:	365 nm / 520 nm / 546 nm
Spectral half-width value:	~ 5 nm
External light influence:	Negligible
Interface:	V24 (9600, 8, n, 2)
Power supply:	6 V ... 12 V DC
Current consumption:	max. 250 mA
Warm-up time:	0 min
Interference suppression:	According to DIN VDE 0871 and DIN VDE 0875
Inaccuracy:	< 0.5 % at A = 1.000
Relative photometric short-time standard deviation:	< 0.1 %

12.2 Measuring ranges and units overview

Measuring ranges:	DP 550	DP 550 SI
CK in blood / CK 321	0.0 - 3000 U/L	0.0 - 3000 U/L
CK in serum / CK 121	0.0 - 2500 U/L	0.0 - 2500 U/L
Urea	0.5 - 200 mg/dL	0.8 - 35 mmol/L
Haematocrit	5 - 90 %	5 - 90 %
Lactate	0.2 - 30 mmol/L	0.2 - 30 mmol/L
Lactate-rapid	0.2 - 20 mmol/L	0.2 - 20 mmol/L
Bilirubin	0.5 - 25 mg/dL	8.5 - 428 µmol/L
Neonatal Bilirubin	2.3 - 50 mg/dL	39 - 850 µmol/L
Glucose	20 - 630 mg/dL	1.1 - 35 mmol/L
Haemoglobin (SLS-method)	0.0 - 50 g/dL	0.0 - 31 mmol/L
Haemoglobin (HiCN-method)	0.0 - 50 g/dL	0.0 - 31 mmol/L
Erythrocytes	1.0 - 10 mio/µL	1.0 - 10 mio/µL
Creatinine	0.0 - 5 mg/dL	0.0 - 440 µmol/L
ABS 365 nm	A = 2.600	A = 2.600
ABS 520 nm	A = 2.600	A = 2.600
ABS 546 nm	A = 2.600	A = 2.600

13. GENERAL GUIDELINES AND STANDARDS

International and European directives

1. Directive 98/79 EC on in vitro diagnostic medical devices
2. EN ISO 9001: Quality management systems, model for presenting the quality management system in design/development, production, assembly and customer service
3. EN ISO 13485: Medical devices, specific requirements for the application of EN ISO 9001
4. EN ISO 14971: Medical devices, application of risk management to medical devices
5. EN 61010-1: c Safety requirements for electrical measuring, control, regulation and laboratory equipment – Part 1: General requirements
6. EN 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic medical equipment
7. EN 61326-1: Electrical measuring, control, regulation and laboratory equipment – EMC requirements – Part 1: General requirements
8. EN 61326-2-6: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements for medical in vitro diagnostic equipment
9. EN 592: Instructions for use for devices for in vitro diagnostic examinations for use by qualified personnel

National directive (Germany)

Guideline of the German Medical Association on quality assurance for quantitative laboratory medical examinations dated 30 May 2023.

14. APPENDIX: "STEP-BY-STEP" MEASUREMENT

"Step-by-step" illustrations of the measurements can be found on the following pages.

Step by step instructions

Device manual

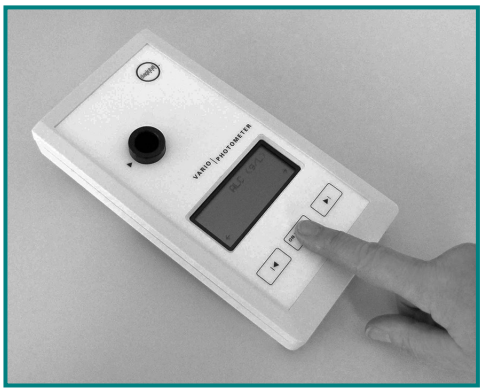
1. Switch on:

Press ON/ENTER key

Wait for device check and confirm with ON/ENTER

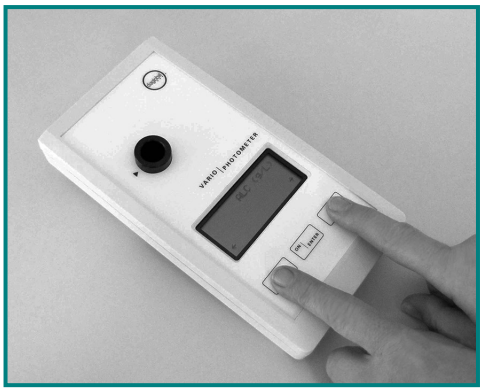
2. Select test:

Press arrow key until required test appears



3. Confirm required test:

Press ON/ENTER



4. Switch off:

Press both arrow keys at the same time

Note:
If SERVICE appears in the display after the device check, the device has a defect.

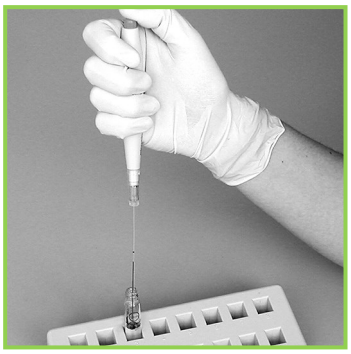
In this case, please contact our customer service at +49 (0) 30 6576 2597.

Step by step instructions

LAC 142

Single measurement

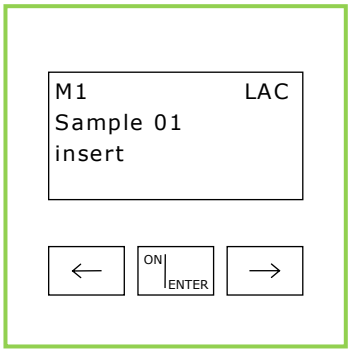
1. Insert capillary with 10 µL sample into cuvette



2. Eject sample several times with micropipetter into cuvette

3. Screw cap on

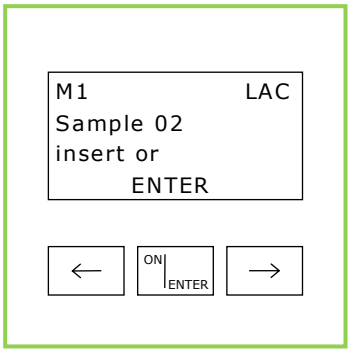
Turn cuvette upside down several times



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

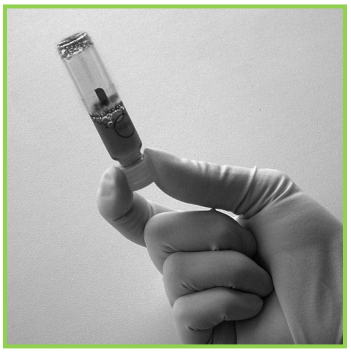
Select the required test, confirm with ON/ENTER



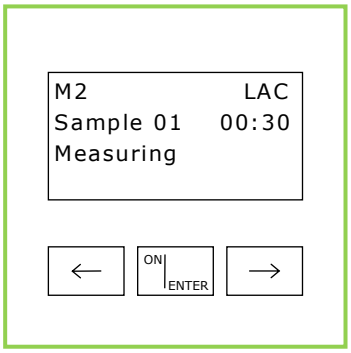
5. Zero point adjustment: Insert cuvette with sample (Fig. 3) into photometer, zero point is stored in memory

Remove cuvette after signal tone

6. Replace screw cap with starter cap



7. Turn cuvette upside down several times



8. First press ON/ENTER

Then insert cuvette into photometer

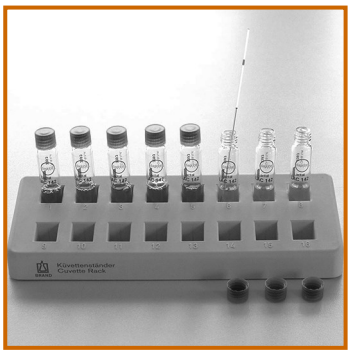
9. Time is displayed, wait for measured value

Step by step instructions

LAC 142

Series measurement

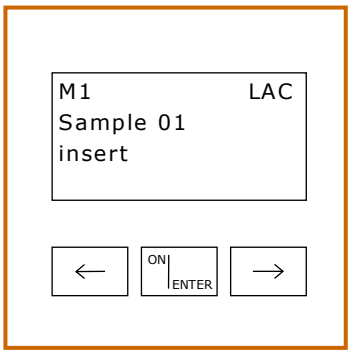
Number of samples per series: Up to 20 samples at the same time



1. Eject all samples one after the other several times with micropipetter into cuvette

2. Screw all caps on again

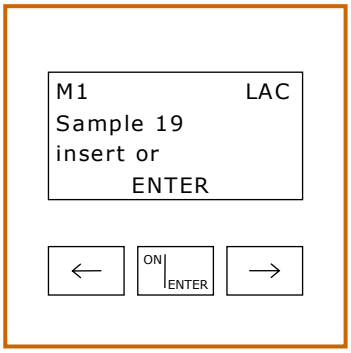
Turn cuvettes upside down several times



3. Switch photometer on with ON/ENTER key

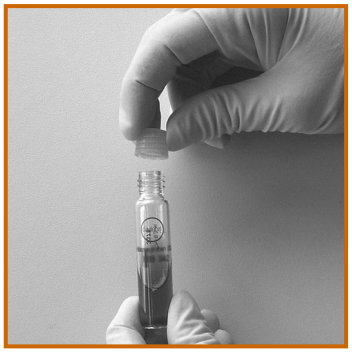
Wait for device check, confirm with ON/ENTER

Select the required test, confirm with ON/ENTER

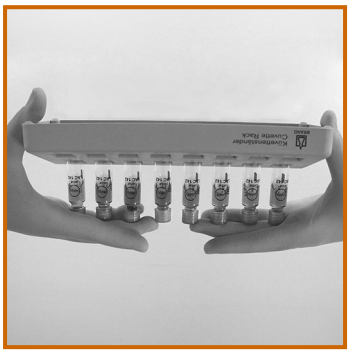


4. Zero point adjustment: Insert cuvettes with samples (Fig. 2) one after the other into photometer, all zero points are stored in memory

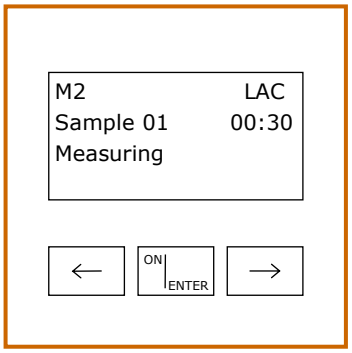
Note: Ensure the correct order of the samples!



5. After the zero point adjustment of the last cuvette replace all screw caps with starter caps



6. Turn all cuvettes **simultaneously** upside down, repeat several times



7. First press ON/ENTER key

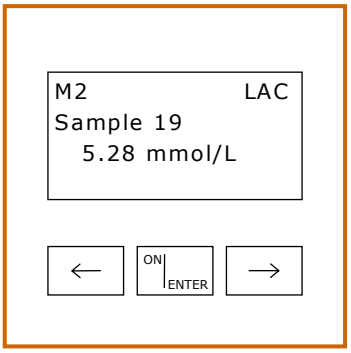
Then insert 1st cuvette into photometer

Time is displayed, wait for measured value

8. Read the measured value of the 1st cuvette, remove cuvette

Insert 2nd cuvette, read the measured value, remove cuvette,

and so on



9. Insert the last cuvette, read the measured value, remove cuvette

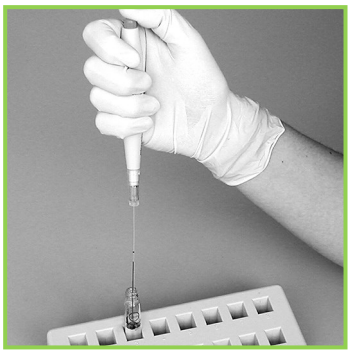
Note: Ensure the correct order of the samples!

Step by step instructions

LAC 342

Single measurement

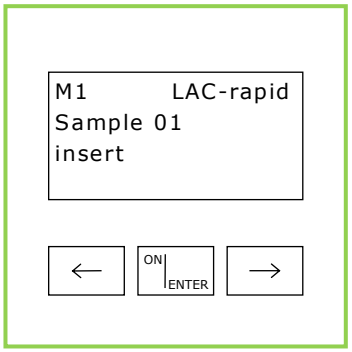
1. Insert capillary with 10 µL sample into cuvette



2. Eject sample several times with micropipetter into cuvette

3. Screw cap on

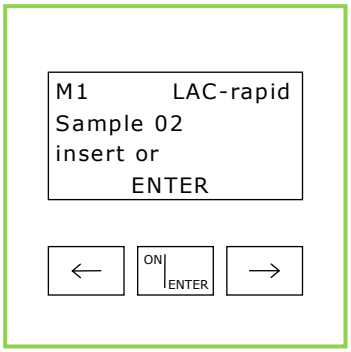
Turn cuvette upside down several times



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

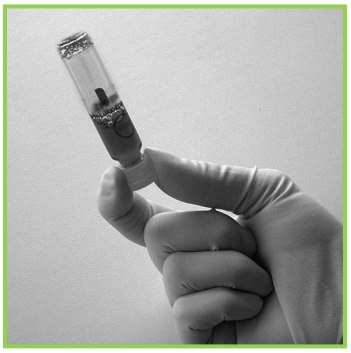
Select the required test, confirm with ON/ENTER



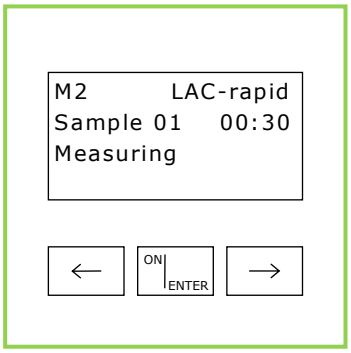
5. Zero point adjustment: Insert cuvette with sample (Fig. 3) into photometer, zero point is stored in memory

Remove cuvette after signal tone

6. Replace screw cap with starter cap



7. Turn cuvette upside down several times



8. First press ON/ENTER

Then insert cuvette into photometer

9. Time is displayed, wait for measured value

Step by step instructions

CK 321

Number of samples per series: Up to 6 samples at the same time

Additionally required: Dry block thermostat (30 minutes preheated), Mini centrifuge, Haematocrit HCT 142

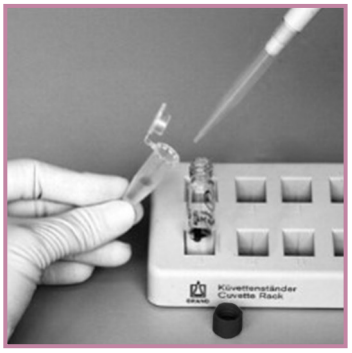
1. Transfer 60 µL of the sample with an end-to-end capillary into each reaction tube "R" and mix well

Note: The hematocrit value should be known or must have been measured previously with HCT 142

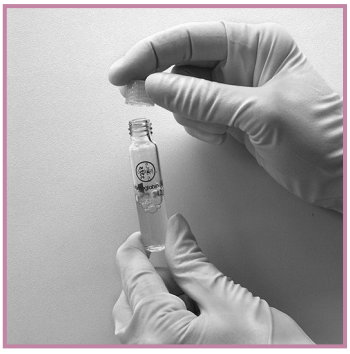
2. Insert reaction tube „R" with capillary into mini centrifuge

Centrifugate for 1 minute

Note: Ensure an even loading inside the mini centrifuge

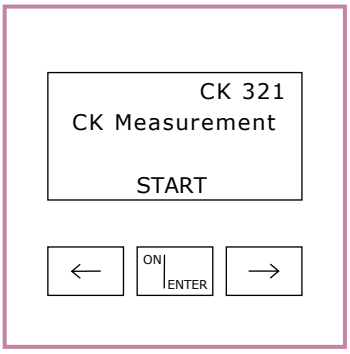


3. Pipette 500 µL supernatant from the reaction tube "R" into the cuvette



4. Screw starter cap on and mix extremely well

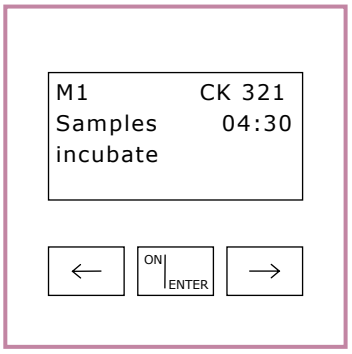
Then insert the cuvette immediately into the dry block thermostat



5. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

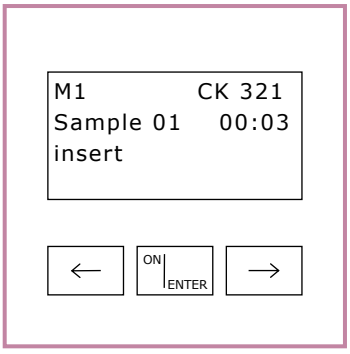
Select CK 321, confirm with ON/ENTER



6. Start measurement with ON/ENTER

Time (5 minutes) counts backwards. All cuvettes remain in the dry block thermostat during this time

Double signal tone: The **M1** measurement starts in 30 seconds!

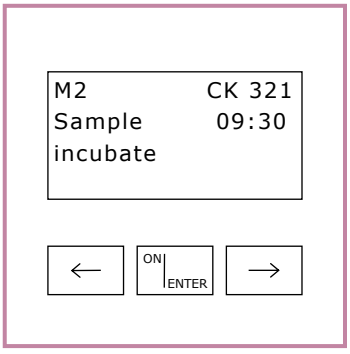


7. Follow the display, insert sample 1 into the photometer, „Measuring" is displayed, wait for 10 seconds

Then remove the cuvette and incubate it again

Proceed in the same way with all other cuvettes in the correct order

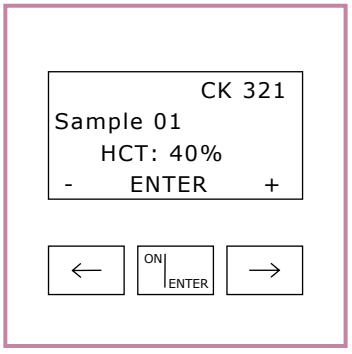
Then press ON/ENTER



8. Time (10 minutes) counts backwards. All cuvettes remain in the dry block thermostat during this time

Double signal tone: The **M2** measurement starts in 30 seconds!

For the **M2** measurement follow the display in the same way as discribed in Fig. 7



9. After inserting the last cuvette, the request to enter the HCT values for each sample is displayed

Enter the known or previously measured HCT values with the right or left arrow key and confirm with ON/ENTER

After entering the last HCT value, read all measured values one after the other by pressing the right arrow key

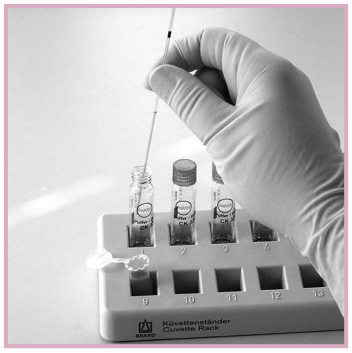
Step by step instructions

CK 121

Number of samples per series: Up to 6 samples at the same time

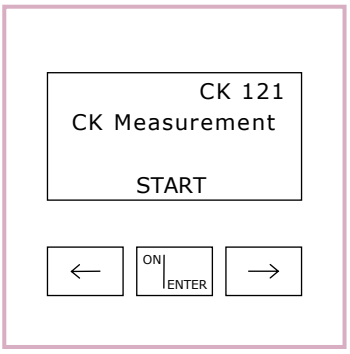
Additionally required: Dry block thermostat (30 minutes preheated)

1. Pipette 500 mL enzyme-substrate solution in each cuvette



2. Transfer 20 µL of the sample (serum/plasma) with a ringmark capillary into each cuvette

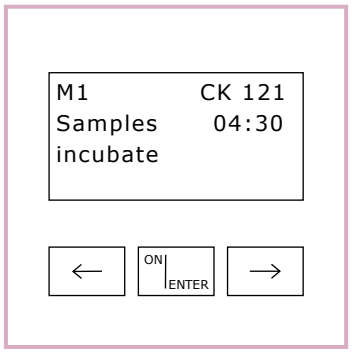
3. Close cuvettes, mix and insert them immediately into the dry block thermostat



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

Select CK 121, confirm with ON/ENTER

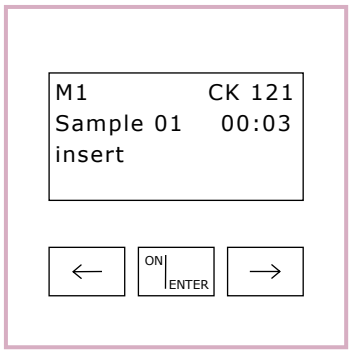


5. Start measurement with ON/ENTER

Time (5 minutes) counts backwards

All cuvettes remain in the dry block thermostat during this time

Double signal tone: The **M1** measurement starts in 30 seconds!



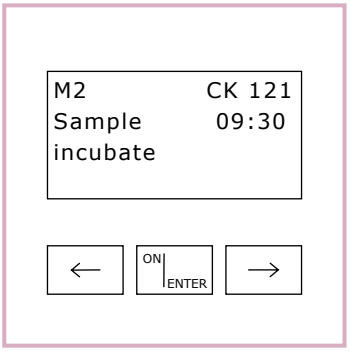
6. Follow the display, insert sample 1 into the photometer

„Measuring" is displayed, wait for 10 seconds

Then remove the cuvette and incubate it again

Proceed in the same way with all other cuvettes in the correct order

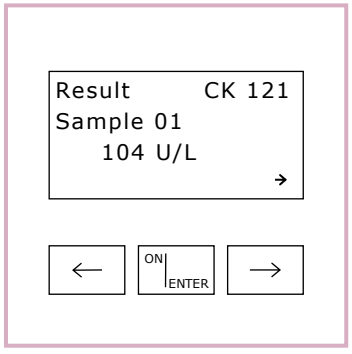
Then press ON/ENTER



7. Time (10 minutes) counts backwards. All cuvettes remain in the dry block thermostat during this time

Double signal tone: The **M2** measurement starts in 30 seconds!

For the **M2** measurement follow the display in the same way as discribed in Fig. 6

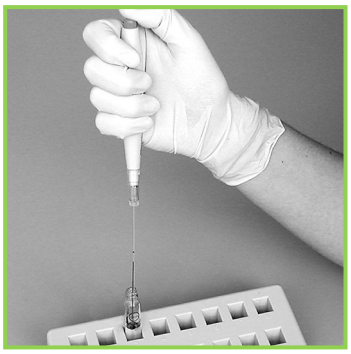


8. All measured values can now be displayed one after the other by pressing the right arrow key

Step by step instructions

GLU 142

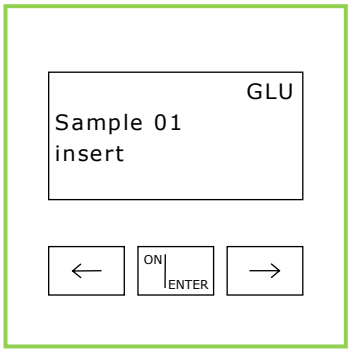
1. Insert capillary with 10 µL sample into cuvette



2. Eject sample several times with micropipetter into cuvette

3. Screw cap on

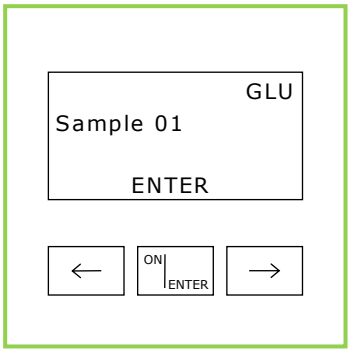
Turn cuvette upside down several times



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

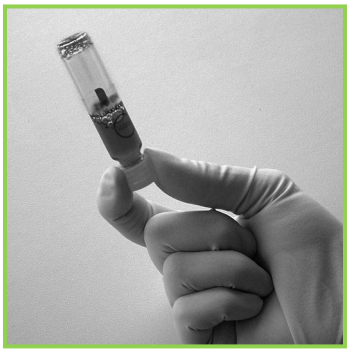
Select the required test, confirm with ON/ENTER



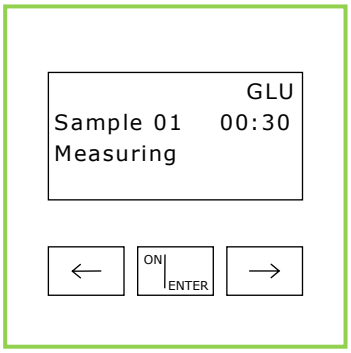
5. Zero point adjustment: Insert cuvette with sample (Fig. 3) into photometer, zero point is stored in memory

Remove cuvette after signal tone

6. Replace screw cap with starter cap



7. Turn cuvette upside down several times



8. First press ON/ENTER

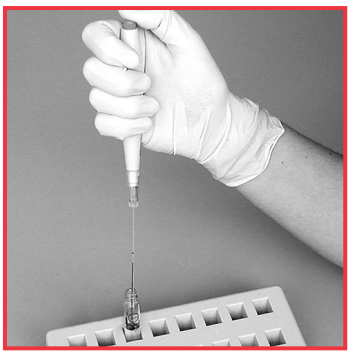
Then insert cuvette into photometer

9. Time is displayed, wait for measured value

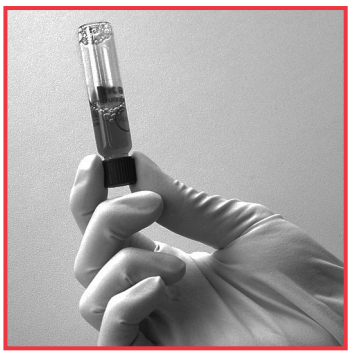
Step by step instructions

HB 142 / HB 342 / ERY 142 / HCT 142

1. Insert capillary with 10 µL blood sample into cuvette



2. Eject blood several times with micropipetter into cuvette

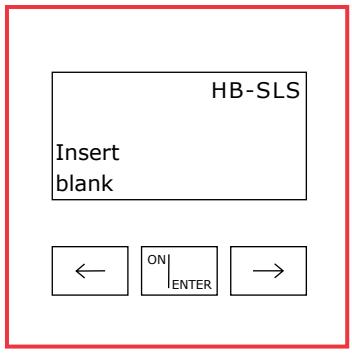


3. Screw cap on

Turn cuvette upside down several times

Wait 3 minutes

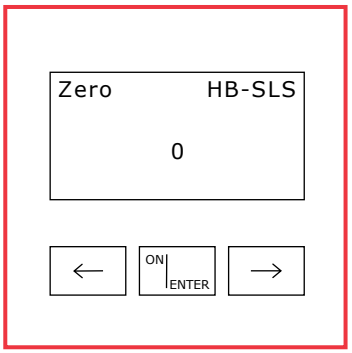
HB 342: wait 30 seconds



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

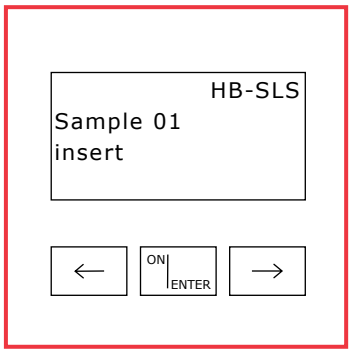
Select the required test, confirm with ON/ENTER



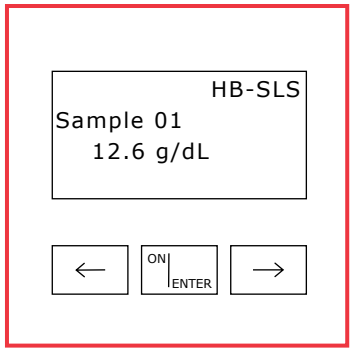
5. Zero point adjustment:

Insert an unprocessed cuvette from package into photometer

Zero point is stored in memory



6. Remove cuvette after signal tone



7. Insert cuvette with blood sample (Fig. 3) into photometer

Read measured value

In regard to series measurement:

After zero point setting any number of additional samples can be measured

Step by step instructions

HST 321

Number of samples per series: Up to 20 samples at the same time

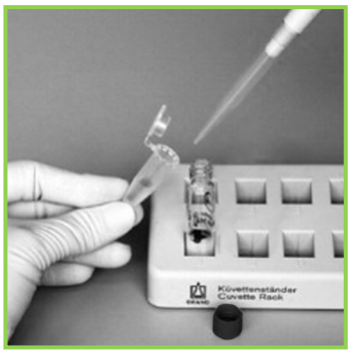
Additionally required: Mini centrifuge

1. Insert 20 µL sample with an end-to-end capillary into the reaction tube "R" and mix well

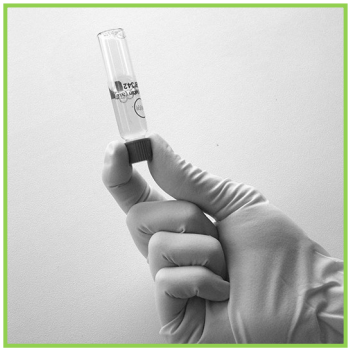
2. Insert reaction tube „R" with capillary into mini centrifuge

Centrifugate for 1 minute

Note: Ensure an even loading inside the mini centrifuge

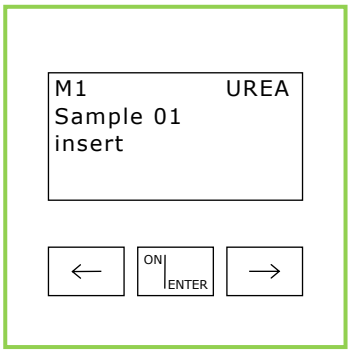


3. Pipette 500 µL supernatant from the reaction tube "R" into the cuvette



4. Screw cap on

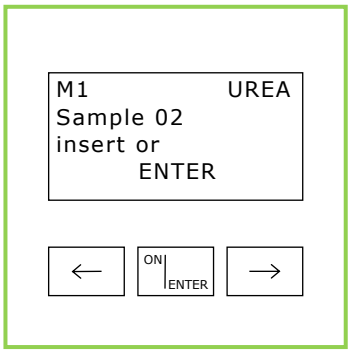
Turn cuvette upside down several times



5. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

Select UREA,
confirm with ON/ENTER

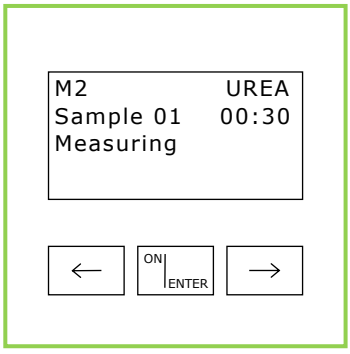


6. Zero point adjustment: Insert cuvette with sample (Fig. 4) into photometer, zero point is stored in memory

Remove cuvette after signal tone

7. Replace screw cap with starter cap

Turn cuvette upside down several times



8. First press ON/ENTER

Then insert cuvette into photometer

Time is displayed

9. Wait for measured value (10 minutes)

Note: Series measurement of Urea up to 20 samples is the same procedure as the serial measurement of LAC 142

Step by step instructions

KRE 121

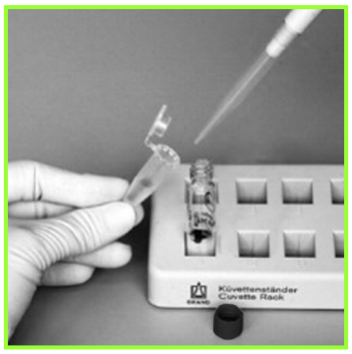
Single measurement

Additionally required: Dry block thermostat (30 minutes preheated)

1. Pipette 1 mL buffer solution into each cuvette, then close cuvettes

Note: The example shows 6 samples. They can only be processed one after the other, serial measurement is not possible

2. Incubate cuvettes in the preheated dry block thermostat for 7 minutes

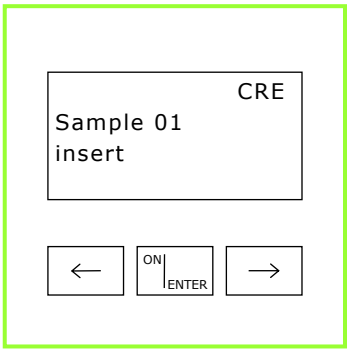


3. Transfer 500 µL of the sample (serum/plasma) into the cuvette

Then insert the cuvette **immediately** into the dry block thermostat

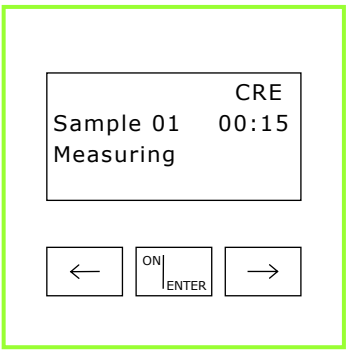
4. Incubate the cuvette with the sample for exactly 1 minute

Already during the incubation time, switch the photometer on with ON/ENTER



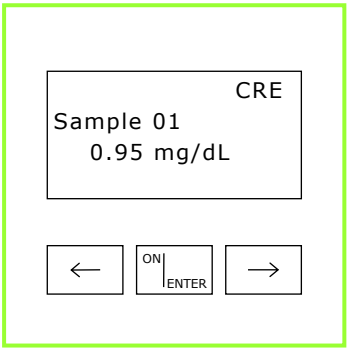
5. After switching the photometer on, wait for device check and confirm with ON/ENTER

Select CRE, confirm with ON/ENTER



6. Insert cuvette into photometer

Time is displayed



7. Wait for measured value (2 minutes)

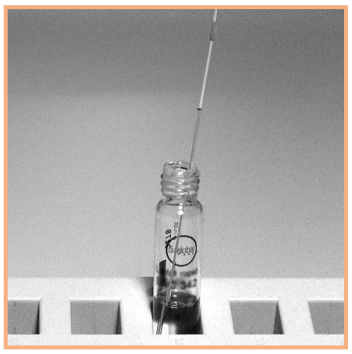
8. Read the measured value, remove the cuvette and repeat the same process with all other cuvettes, starting from Fig. 3

Step by step instructions

BIL / BIL N (BIL 142)

Neonatal bilirubin: Blood collection and sample preparation see page 2

Additionally required: Mini centrifuge, Microvette

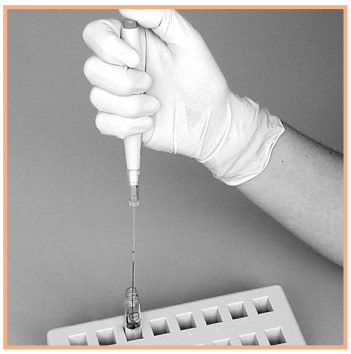


1. Insert capillary with sample (serum/plasma) into cuvette

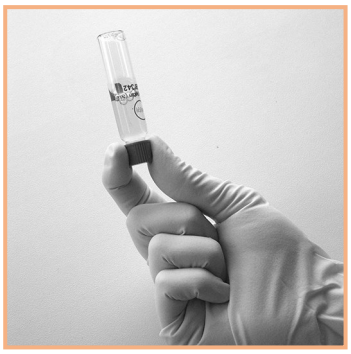
BIL: 100 µL (adults)

BIL N: 20 µL (newborns)

Sampling of BIL N see next page

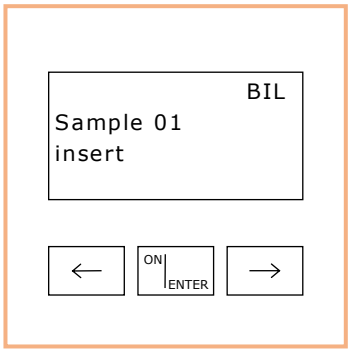


2. Eject sample several times with micropipetter into cuvette



3. Screw cap on

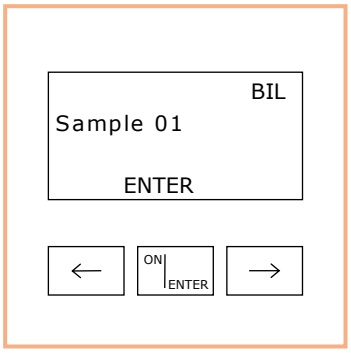
Turn cuvette upside down several times



4. Switch photometer on with ON/ENTER key

Wait for device check, confirm with ON/ENTER

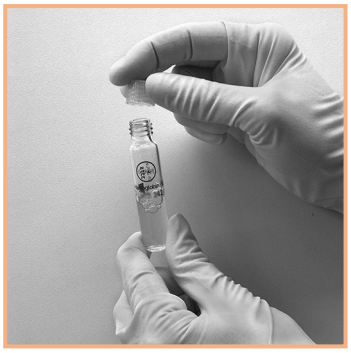
Select the required test, confirm with ON/ENTER



5. Zero point adjustment:

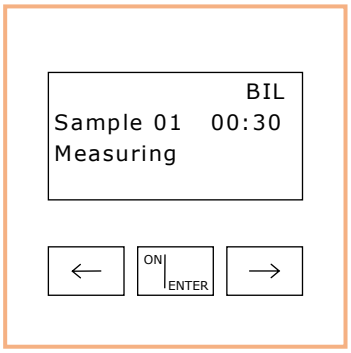
Insert cuvette with sample (Fig. 3) into photometer, zero point is stored in memory

Remove cuvette after signal tone



6. Replace screw cap with starter cap

7. Turn cuvette upside down several times



8. First press ON/ENTER

Then insert cuvette into photometer

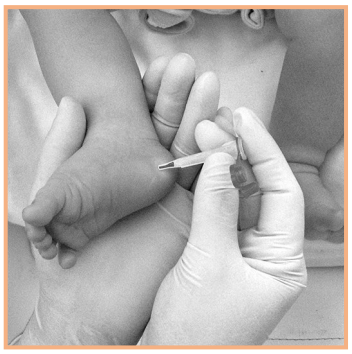
9. Time is displayed, wait for measured value

Step by step instructions

BIL / BIL N (BIL 142)

Neonatal bilirubin: Blood collection and sample preparation

Additionally required: Mini centrifuge, Microvette



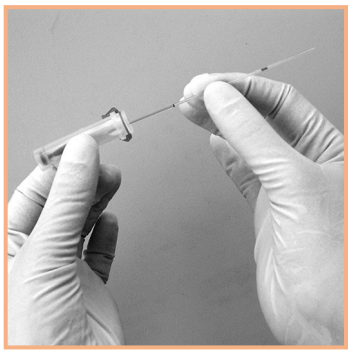
1. After pricking with the lancet, take about 60 µL of blood (approx. 1 drop) from the heel with the microvette

Note: Close the microvette carefully before placing it into the mini centrifuge

2. Insert microvette into mini centrifuge

Centrifugate for 3-5 minutes

Note: Ensure an even loading inside the mini centrifuge



3. Take 20 µL plasma from the microvette

Continue with Fig. 1 on the previous page

Mini centrifuge

Art. No. DZ 002

Microvette

Art. No. LH 037
(100 pieces per package)

Step by step instructions

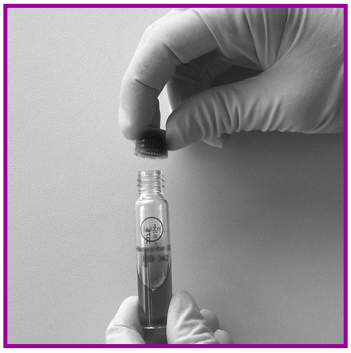
BIL QS

Quality assurance

Photometer testing with control caps

1. 20 control caps with lyophilized control serum

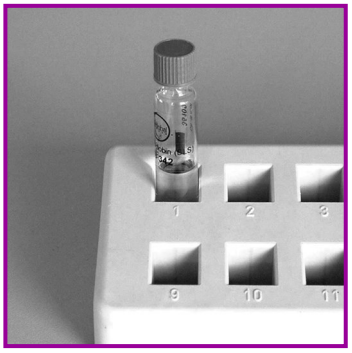
BIL QS: Bilirubin (adults), Bilirubin N (newborns)



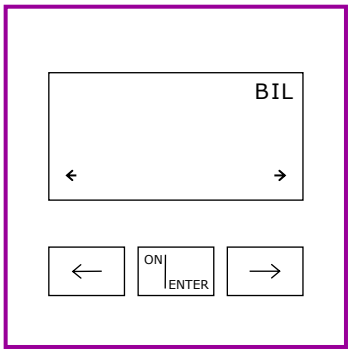
2. Screw the control cap onto a cuvette of the test you want to check

Mix well

Now the cuvette contains a sample with a known concentration



3. Leave the cuvette for 1 minute



4. Switch photometer on with ON/ENTER key

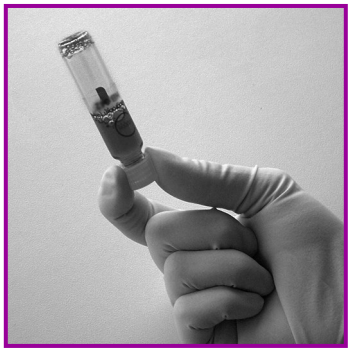
Wait for device check, confirm with ON/ENTER

Select the required test, confirm with ON/ENTER

5. Zero point adjustment: Insert cuvette with sample (Fig. 3) into photometer, zero point is stored in memory

Remove cuvette after signal tone

6. Replace control cap with starter cap



7. Turn cuvette upside down several times

8. First press ON/ENTER, then insert cuvette into photometer

Wait for measured value

Compare the measured value with the target value on the package insert