

## DIACAL AUTO

*Lyophilized calibration serum for the use in tests for the quantitative in vitro determination of various analytes in human samples on photometric systems.*

REF	Content
D98485	5 x 3 mL kit
D98485SV	1 x 3 mL single vial

**For professional in vitro diagnostic use only.**

### GENERAL INFORMATION

Shelf life	24 months
Storage	2 - 8 °C

### INTENDED USE

Lyophilized calibration serum for the use in tests for the quantitative in vitro determination of various analytes in human samples on photometric systems.

### REAGENT COMPOSITION

Diacal Auto is a lyophilized calibrator based on human serum with chemical additives and biological material of specified origin.

Analyte	Origin
Albumin	Bovine plasma
Alkaline phosphatase	Placenta (human, recombinant)
ALAT / GPT	Porcine (heart)
alpha-Amylase	Porcine (pancreas)
Pancreatic amylase	Porcine (pancreas)
ASAT / GOT	Human recombinant
Cholesterol	Bovine plasma
Cholinesterase	Human serum
Creatine kinase (CK)	Rabbit muscle
Gamma-GT	Human recombinant
GLDH	Bacterium, recombinant
LDH	Porcine heart
Lipase	Pancreas (human recombinant)
Triglycerides	Chicken egg yolk

The concentration of the biological material does not exceed the maximum, lot specific value concentration of the analyte.

### MATERIAL REQUIRED BUT NOT PROVIDED

- Clinical chemistry analyser.

### REAGENT PREPARATION

- Open the vial very carefully, avoiding any loss of the lyophilized material.
- Add exactly 3 ml of distilled water (inaccurate reconstitution of the calibrator can cause erroneous results).
- Close the vial carefully and let it stand for 30 minutes, swirling occasionally.
- Dissolve contents completely by swirling gently, avoiding the formation of foam. Do not shake!

Transfer corresponding quantity needed for calibration into a clean sample cup and treat it the same way as patient samples.

Defrost reconstituted, frozen aliquots of the reconstituted Diacal Auto protected from light at room temperature (18 – 25 °C) until they are completely thawed. After thawing, gently swirl for complete homogenization and use for calibration immediately afterwards. use.

### STORAGE AND STABILITY

Storage:	at 2 – 8 °C		
Stability:	until indicated date of expiration		
Stability after reconstitution:			
	-20 °C	+4 °C	+ 25 °C
Bilirubin (in the dark)	14 days	8 hours	3 hours
Other analytes	30 days	2 days	8 hours

Once reconstituted, Diacal Auto calibrator can be used within the period reported in the table above if stored tightly closed at the indicated temperature and bacterial contamination is avoided.

Freeze only once!

Criterion for the stability stated is a recovery within ± 5 % of the initial value.

### WARNINGS AND PRECAUTIONS

- Each individual blood donation used for production of Diacal Auto was found to be non-reactive when tested with FDA-approved methods or CE-accepted methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle Diacal Auto with the same precautions used for patient specimens.
- Diacal Auto contains biological material of specified origin. The calibrators should be handled as potentially infectious and with the same precautions used for patient specimens.
- Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
- For professional use only!

### TEST PROCEDURE

Please refer to the reagent package inserts for instructions for use.

### LOT SPECIFIC CALIBRATOR VALUES

The concentrations of the calibrator analytes are lot-specific and stated in the value sheet of the corresponding lot. Please refer to enclosed table with lot specific calibrator values.

Determinations were performed under standardized protocols using Diablab reagents and Diacal Auto master calibrator or reference materials.

### TRACEABILITY

The enclosed value sheet contains information about the traceability.

### WASTE MANAGEMENT

Please refer to local legal requirements.

### LITERATURE

- State Dati F. Reference materials and guidelines for standardization of methods in laboratory medicine. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Book Verlagsgesellschaft; 1998. p. 1404-26
- Moss DW, Henderson AR. Enzymes. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia: WB Saunders Company; 1994 p. 735-896.
- Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).



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Sérum de calibration universel  
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<b>ALB</b> Albumin Albumine Albúmina Альбумин	bromocresol green Bromocresolgrün vert de bromocrésol verde de bromocresol Бромкрезоловый зеленый	ERM-DA 470	3,57 35,7	g/dL g/L
	DGKC (1970) 37°C	DGKC recommended formulation 37 °C Test nach DGKC Empfehlung Méthode recommand. de la DGKC Test acuerdo a la DGKC	446 7,43	U/L µkat/L
<b>ALP</b> Alkaline phosphatase Alkalische Phosphatase Phosphatase alcaline Fosfatasa alcalina Щелочная фосфатаза	IFCC 37 °C	IFCC recommended formulation 37 °C Test nach IFCC Empfehlung Méthode recommand. de la IFCC Test acuerdo a la IFCC	226 3,76	U/L µkat/L
	IFCC with pyridoxal phoshate 37°C mit Pyridoxalphosphat 37°C avec phosphate de pyridoxal 37°C con piridoxalfosfato 37°C с пиридоксальфосфатом 37°C	Original IFCC formulation 37 °C Original IFCC Formulierung formule originale de l'IFCC original fórmula IFCC	100,0 1,67	U/L µkat/L
<b>ALT/GPT</b> АЛТ Alanine Aminotransferase / Glutamic Pyruvic Transaminase Alaninaminotransferase / Glutamat-Pyruvat-Trans-aminase L'alanine-aminotransférase / glutamate-pyruvate-transaminase Alanino Aminotransferasa / Transaminasa Glutámico Pirúvica Аланинаминотрансфераза / Глута-мат-пируваттрансминазой	IFCC without pyridoxal phoshate 37°C ohne Pyridoxalphosphat 37°C sans phosphate de pyridoxal 37°C sin piridoxalfosfato 37°C без пиридоксальфосфата 37°C	modified IFCC formulation, ε NADH 37 °C modifizierte IFCC Formulierung, ε NADH modifié formule de l'IFCC, ε NADH modifica fórmula IFCC, ε NADH	103 1,71	U/L µkat/L
	IFCC with pyridoxal phoshate 37°C mit Pyridoxalphosphat 37°C avec phosphate de pyridoxal 37°C con piridoxalfosfato 37°C с пиридоксальфосфатом 37°C	Original IFCC formulation 37 °C Original IFCC Formulierung formule originale de l'IFCC original fórmula IFCC	100 1,66	U/L µkat/L
<b>AST/GOT</b> АСТ Aspartate Amino-transferase / Glutamic Oxalacetic Trans-aminase Aspartat-amino-transferase / Glutamat-Oxalacetat-Trans-aminase l'aspartate-aminotransférase / glutamate-oxaloacétate-transaminase Aspartato Aminotransferasa / Transaminasa Glutámico Oxalacética Аспаргатаминотрансфераза / Глутамат-оксалоацетаттрансминаза	IFCC without pyridoxal phoshate 37°C ohne Pyridoxalphosphat 37°C sans phosphate de pyridoxal 37°C sin piridoxalfosfato 37°C без пиридоксальфосфата 37°C	modified IFCC formulation, ε NADH 37 °C modifizierte IFCC Formulierung, ε NADH modifié formule de l'IFCC, ε NADH modifica fórmula IFCC, ε NADH	105 1,75	U/L µkat/L
	IFCC with pyridoxal phoshate 37°C mit Pyridoxalphosphat 37°C avec phosphate de pyridoxal 37°C con piridoxalfosfato 37°C с пиридоксальфосфатом 37°C	Original IFCC formulation 37 °C Original IFCC Formulierung formule originale de l'IFCC original fórmula IFCC	181 3,02	U/L µkat/L
<b>AMY</b> α-Amylase α-Amilasa α-Амилаза	EPS-G7	Original IFCC formulation 37 °C Original IFCC Formulierung formule originale de l'IFCC original fórmula IFCC	181 3,02	U/L µkat/L
	CNPG3	Dialab formulation, ε p-Nitrophenol 37 °C Dialab Formulierung, ε p-Nitrophenol formule de Dialab, ε p-Nitrophenol fórmula Dialab, ε p-nitrofenol	169 2,82	U/L µkat/L

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<b>P-AMY</b> Pancreatic $\alpha$ -Amylase Pancreas- $\alpha$ -Amylase $\alpha$ -Amylase pancréatique $\alpha$ -Amylase pancreática $\alpha$ -Панкреатическая амилаза	EPS-G7	modified. IFCC, $\varepsilon$ p-Nitrophenol IFCC modifizierte, $\varepsilon$ p-Nitrophenol modifié de l'IFCC, $\varepsilon$ p-Nitrophénol modifica IFCC, $\varepsilon$ p-nitrofenol	37°C  168 2,79	U/L $\mu$ kat/L
<b>D-BIL</b> Direct Bilirubin Direktes Bilirubin Bilirubine directe Bilirrubina directa Прямой билирубин	DCA ДХА	Jendrassik-Grof	2,37 40,6 23,7	mg/dL $\mu$ mol/L mg/L
	Jendrassik-Grof		2,45 41,9 24,5	mg/dL $\mu$ mol/L mg/L
<b>T-BIL</b> Bilirubin total Bilirubin Gesamt Bilirubine Bilirrubina Общий билирубин	DCA ДХА	SRM 916a	4,03 68,9 40,3	mg/dL $\mu$ mol/L mg/L
	Jendrassik-Grof	Jendrassik-Grof	5,32 91,0 53,2	mg/dL $\mu$ mol/L mg/L
<b>BUN</b> Urea N Harnstoff-N Urée N Азот крови	Urease-GLDH UV uréase-GLDH UV ureasa GLDH UV Уреазный – ГЛДГ УФ	SRM 909b Level 1	49,5 17,6 0,495	mg/dL mmol/L g/L
	colorimetric, Berthelot	SRM 909b Level 1	52 18,5 0,52	mg/dL mmol/L g/L
<b>CA</b> Calcium Calcio Кальций	Arsenazo III, CPC arsénazo III, CPC Арсеназо III, ОКФ	AAS	2,57 5,15 10,3	mmol/L mEq/L = mval/l mg/dL
<b>CHE</b> Cholinesterase Cholinestérase Colinesterasa Холинэстераза	opt. DGKC, butyrylthiocholine opt. DGKC, Butyrylthiocholin DGKC opt., butyrylthiocholine DGKC opt., butiriltiocolina Бутирилхолиновый	DGKC recommended formulation Test nach DGKC Empfehlung Méthode recommand. de la DGKC Test acuerdo a la DGKC	37 °C  4558 76,0	U/L $\mu$ kat/L
<b>CL</b> Chloride Chlorid Chlorures Chloruro Хлориды	Thiocyanate Thiocyanat Тиоцианато Тиоцианатный	SRM 999	102	mmol/L =mEq/L =mval/L
<b>CHOL</b> Cholesterol Cholesterin Cholestérol Colesterolo Холестерин	CHOD-PAP	GC-IDMS	168 4,34 1,68	mg/dL mmol/L g/L

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<b>CK</b> Creatine kinase Creatinkinase Créatine kinase Creatin-quinasa Креатинкиназа	DGKC opt. IFCC 37°C	Original IFCC formulation Original IFCC Formulierung formule originale de l'IFCC original fórmula IFCC	37 °C  <b>363</b> <b>6,05</b>	U/L µkat/L
<b>CREA</b> Creatinine Kreatinin Créatinine Creatinina Креатинин	enzymatic, PAP enzymatisch, PAP enzymatique, PAP enzimático, PAP Ферментативный	GC-IDMS	<b>3,90</b> <b>345</b> <b>39,0</b>	mg/dL µmol/L mg/L
	Jaffé with compensation Jaffé mit Kompensation Jaffé avec compensation Jaffé con compensación Яффе с компенсацией	GC-IDMS	<b>4,35</b> <b>385</b> <b>43,5</b>	mg/dL µmol/L mg/L
	Jaffé without compensation Jaffé ohne Kompensation Jaffé sans compensation Jaffé sin compensación Яффебез компенсации	GC-IDMS	<b>3,87</b> <b>342</b> <b>38,7</b>	mg/dL µmol/L mg/L
<b>FE</b> Iron Eisen Fer Hierro Железо	Ferene Ферен	SRM 682	<b>188</b> <b>33,6</b> <b>1,88</b>	µg/dL µmol/L mg/L
<b>GGT</b> γ-GT γ-ГТ	Szasz	Original form. Persijn/v.d. Slik 1976 Original Form. Persijn/v.d. Slik 1976 form. originale de Persijn/v.d. Slik 1976 original form. Persijn/v.d. Slik 1976	37 °C  <b>128</b> <b>2,14</b>	U/L µkat/L
	stand. to IFCC	Original IFCC formulation Original IFCC Formulierung formule originale de l'IFCC original fórmula IFCC	37 °C  <b>145</b> <b>2,41</b>	U/L µkat/L
<b>GLDH</b> Glutamate dehydrogenase Glutamatdehydrogenase Glutamate-déshydrogénase Glutamato deshidrogenasa Глутаматдегидрогеназа	DGKC (1970) 37°C	DGKC recommended formulation Test nach DGKC Empfehlung Méthode recommand. de la DGKC Test acuerdo a la DGKC	37 °C  <b>27,0</b> <b>0,451</b>	U/L µkat/L
<b>GLUC</b> Glucose Glucosa Глюкоза	HK G6PDH GK G6PDH GOD-PAP	ID-MS	<b>192</b> <b>10,6</b> <b>1,92</b>	mg/dL mmol/L g/L
<b>HBDH</b> α-HBDH α-ГБДГ	DGKC 37°C	DGKC recommended formulation Test nach DGKC Empfehlung Méthode recommand. de la DGKC Test acuerdo a la DGKC	37 °C  <b>283</b> <b>4,71</b>	U/L µkat/L

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<b>LACT</b> Lactate Lactat Lactato Лактат	enzymatic (LDH) UV	Primary reference material Primäres Referenz Material Matérielle de référence primaire Material de referencia primario	28,0 3,10 280	mg/dL mmol/L mg/L
<b>LDH</b> Lactate dehydrogenase Lactatdehydrogenase Lactate déshydrogénase Lactacto deshidrogenasa лактатдегидрогеназой	LDH-L: IFCC / DGKC (1994)	Original IFCC formulation Original IFCC Formulierung formule originale de l'IFCC original fórmula IFCC	37 °C 276 4,60	U/L µkat/L
	LDH-P: DGKC (1970)	DGKC recommended formulation Test nach DGKC Empfehlung Méthode recommand. de la DGKC Test acuerdo a la DGKC	37 °C 460 7,66	U/L µkat/L
<b>LPS</b> Lipase Lipasa Липаза	Colorimetric test Farbtest test colorimétrique test-color Колориметрический тест	Molar extinction coefficient Molarer Extinktionskoeffizient Coefficient molaire d'extinction Coeficiente molar de la extinción	37 °C 95,6 1,59	U/L µkat/L
<b>MG</b> Magnesium Magnésium Magnesio Магний	xylidyl blue method Xylidylblau-Methode méthode au bleu de xylidyle método azul de xilidil Ксилидиновый синий	AAS	1,17 2,35 2,85	mmol/L mval/L mg/dL
<b>PO3</b> Inorganic phosphate Phosphat anorganisch Phosphore inorganique Fósforo inorgánico Фосфор	Molybdate UV Molybdat UV Molibdato UV Молибдат УФ	Internal Standard Interner Standard Standard interne Standard interno	5,65 1,82 56,5	mg/dL mmol/L mg/L
<b>TG</b> Triglycerides Triglyceride Triglycérides Triglycéridos Триглицериды	GPO-PAP	GC-IDMS	136 1,53 1,36	mg/dL mmol/L g/L
<b>TP</b> Total protein Total Protein Protéines totales Proteínas totales Общий белок	Biuret, with sample blank Biuret, mit Probenleerwert Biuret, avec echantillon témoins Biuret, con muestra blancos Биуретовый с сывороточным бланком	Modified Biuret method	5,25 52,5	g/dL g/L
	Biuret, without sample blank Biuret, ohne Probenleerwert Biuret, sans echantillon témoins Biuret, sin muestra blancos Биуретовый без сывороточного бланка	Modified Biuret method	5,75 57,5	g/dL g/L
<b>UA</b> Uric Acid Harnsäure Acide urique Acido úrico Мочевая кислота	Uricase, AOX, TOOS	GC ID-MS	5,51 328 55,1	mg/dL µmol/L mg/L
	Uricase, TBHBA	GC ID-MS	5,44 323 54,4	mg/dL µmol/L mg/L

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<b>UIBC</b>				
Unsat. iron-binding capacity	Ferrozine / Ferene	Internal Standard	200	µg/dL
Latente Eisenbnd. Kapazität	Ferrozine / Ferene	Internal Standard	35,9	µmol/L
Cap. fixation du fer, insaturé	Ferrozine / Ferene	Standard interne	2,00	mg/L
Cap. Insatu. fijación hierro	Ferrozina / Ferene	Standard interno		
<b>UREA</b>				
Harnstoff	Urease-GLDH UV	SRM 909b Level 1	106	mg/dL
Urée	uréase-GLDH UV		17,6	mmol/L
Мочевина	ureasa GLDH UV		1,06	g/L
	Уреазный-глутаматдегидрогеназный			
	colorimetric, Berthelot	SRM 909b Level 1	111	mg/dL
	Бергло		18,5	mmol/L
			1,11	g/L

### Short forms:

DGKC	Deutsche Gesellschaft für Klinische Chemie
IFCC	International Federation of Clinical Chemistry
SCE	Scandinavian Committee of Enzymes
SFBC	Société Française de Biologie Clinique
NVKC	Nederlandse Vereniging voor Klinische Chemie
SEQC	Sociedad Española de Química Clínica
AAS	Atomic absorption Spectrometry Atom absorptions Spektrometrie Spectrométrie d'adsorption atomique Espectroscopia de absorción atómica атом поглощение спектрометрии
GC-IDMS	Gas-Chromatography isotope dilution spectrometry Gaschromatographische Isotopenverdünnung-Massenspektrometrie Spectrométrie de dilution d'isotope de Gaz-Chromatographie Spectrometry de la dilución del isótopo de la Gas-Cromatografía газовая хроматография изотопного разбавления спектрометрии
ID-MS	Isotope dilution - mass spectrometry Isotopenverdünnung-Massenspektrometrie Spectrométrie de masse à dilution isotopique Espectrometria de masas con dilución isotópica изотопного разбавления масс-спектрометрии
ERM-DA470	European Reference Material DA470
SRM	Standard Reference material Standardisiertes Referenzmaterial Matérielle de référence standard Material de referencia estándar Стандартный Справочные материалы
INSTAND	Gesellschaft zur Förderung der Qualitätssicherung in medizinischen Laboratorien e.V., Düsseldorf / Germany

### Notes:

- \* Data not available at the time of printing. Please inquire.  
Daten zum Zeitpunkt des Drucks nicht verfügbar. Bitte nachfragen.  
Données non disponibles à la date d'impression. Piétre de se renseigner.  
No se disponía de información en el momento en que se imprimió este prospecto. Consulte cualquier dilda.
- \*\* In diesem Sollwertzettel wird immer ein Komma als Dezimaltrennzeichen verwendet. Tausendertrennzeichen werden nicht verwendet.  
A comma is always used in this value sheet as decimal separator. Separators for thousands are not used.  
Dans ce fiche des valeurs de références, la virgule représente le caractère séparateur décimal. Des séparateurs pour 'mille' ne sont pas employés.  
La coma representa el carácter separador decimal. No se utilizan caracteres para separar el 'mil'.  
Это список литературы всегда запятая используется в качестве десятичного разделителя. Сепараторы для тысяч не используются.