Certificate of CE-Registration

MDSS Medical Device Safety Service

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Egyptian Company for Biotechnology-
Spectrum Diagnostics
Obour City Industrial Area, Block 20008
Piece 19 A, PO Box 30
Cairo
EGYPT

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated June 08, 2022

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2022-06-08

Dr. Philipp Hohenbrink
Director AR Services
MDSS GmbH

Digitally signed by Ceaicovschi Tudor
Date: 2024.09.04 15:39:09 EEST
Reason: MoldSign Signature
Location: Moldova

Annex A dated June 08, 2022

Manufacturer: Egyptian Company for Biotechnology Spectrum Diagnostics

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
262 001 262 002 262 003 262 004 262 005 262 006	Alanine aminotransferase (ALT/GPT) – Liquizyme (9+1)		EDMA	11 01 01 03	Alanine Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/039-02**
263 001 263 002 263 003	Alanine aminotransferase (ALT/GPT) – Liquizyme (1+1)		EDMA	11 01 01 03	Alanine Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/039-02**
264 001 264 002	Alanine aminotransferase (ALT/GPT) Colorimetric		EDMA	11 01 01 03	Alanine Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/039-02**
265 001 265 002 265 003 ZL -265 001 D-605 001 D-605 002 D-605 003	Alanine aminotransferase (ALT/GPT) - single reagent		EDMA	11 01 01 03	Alanine Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/039-02**
292 000 292 001 292 002 292 003 292 004 292 005 292 006 292 007 292 008	Alanine aminotransferase (ALT/GPT) - Liquizyme (4+1)		EDMA	11 01 01 03	Alanine Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/039-02**

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D-604 001 D-604 002 D-604 003 D-604 004 D-604 005	Alanine Aminotransferase (ALT/GPT)-(4+1) UV Kinetic Method	-	EDMA	11 01 01 03	Alanine Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/039-02**
215 001 215 002	Alkaline Phosphatase (ALP) - Liquizyme (1+1) IFCC		EDMA	11 01 01 05	Alkaline Phosphatase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/038-02**
214 001 214 002 214 003 214 004 214 005, ZL -214 001	Alkaline Phosphatase (ALP) - Liquizyme (9+1) IFCC		EDMA	11 01 01 05	Alkaline Phosphatase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/038-02**
216 001	Alkaline Phosphatase (ALP) - Colorimetric		EDMA	11 01 01 05	Alkaline Phosphatase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/038-02**
217 001 217 002 217 003	Alkaline Phosphatase (ALP)- Liquizyme (single reagent)		EDMA	11 01 01 05	Alkaline Phosphatase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/038-02**
D-602 001 D-602 002 D-602 004 D-602 005	Alkaline Phosphatase (4+1) (Kinetic IFCC Method)	-	EDMA	11 01 01 05	Alkaline Phosphatase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/038-02**
D-652 001 D-652 002	Alkaline phosphatase (9 + 1) (Kinetic IFCC Method)	-	EDMA	11 01 01 05	Alkaline Phosphatase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/038-02**
D-603 001 D-603 002 D-603 003 D-603 004	Alkaline Phosphatase (Single Reagent) (Kinetic IFCC Method)	-	EDMA	11 01 01 05	Alkaline Phosphatase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/038-02**

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
219 001 219 002	Amylase - single reagent		EDMA	11 01 01 07	Amylase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/009-02**
ZL -219 001	Amylase (4+1)		EDMA	11 01 01 07	Amylase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/009-03**
D-606 001 D-606 002	Alpha Amylase (4+1) GALG2-CNP	-	EDMA	11 01 01 07	Amylase - Total	Other	N/A	**DE/CA09/0170/E05/IVD/009-04**
258 001 258 002 258 003 258 004 258 005 258 006	Aspartate aminotransferase (AST/GOT) – Liquizyme (9+1)		EDMA	11 01 01 10	Aspartate Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/041-02**
259 001 259 002 259 003	Aspartate aminotransferase (AST/GOT) – Liquizyme (1+1)		EDMA	11 01 01 10	Aspartate Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/041-02**
260 001 260 002	Aspartate aminotransferase (AST) Colorimetric		EDMA	11 01 01 10	Aspartate Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/041-02**
261 001 262 002 261 003 261 004 261 005 261 006 261 007 ZL -261 001	Aspartate aminotransferase (AST/GOT) – single reagent		EDMA	11 01 01 10	Aspartate Amino-Transferase	Other	N/A	**DE/CA09/0170/E05/IVD/041-02**

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291 000 291 001 291 002 291 003 291 004 291 005 291 006 291 007 291 008	Aspartate aminotransferase (AST/GOT) – Liquizyme (4+1)		EDMA	11 01 01 10	Aspartate Amino-Transferase	Other	N/A	DE/CA09/0170/E05/IVD/041-02
D-607 001 D-607 002 D-607 003 D-607 004 D-607 005	Aspartate aminotransferase (AST/GOT) (4+1) UV Kinetic Method	-	EDMA	11 01 01 10	Aspartate Amino-Transferase	Other	N/A	DE/CA09/0170/E05/IVD/041-02
D-608 001 D-608 002 D-608 003	Aspartate aminotransferase (AST/GOT) (Single Reagent)	-	EDMA	11 01 01 10	Aspartate Amino-Transferase	Other	N/A	DE/CA09/0170/E05/IVD/041-02
418 001 418 002 D-662 001 D-662 002	Cholinesterase DGKC		EDMA	11 01 01 11	Cholinesterase	Other	N/A	DE/CA09/0170/E05/IVD/076
238 001 238 002, 238 004 D-614 001 D-614 002	Creatine Kinase (CK)		EDMA	11 01 01 13	Creatinine Kinase - Total	Other	N/A	DE/CA09/0170/E05/IVD/073-01
ZL -238 001	Creatine Kinase - CK (4+1)		EDMA	11 01 01 13	Creatinine Kinase - Total	Other	N/A	DE/CA09/0170/E05/IVD/073-01

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239 001 239 002 239 003 239 004	Creatine Kinase MB		EDMA	11 01 01 14	Creatine Kinase - MB "Activity"(CC)	Other	N/A	**DE/CA09/0170/E05/IVD/047-02**
ZL -239 001	Creatine Kinase MB - CK- MB (4+1)		EDMA	11 01 01 14	Creatine Kinase - MB "Activity"(CC)	Other	N/A	**DE/CA09/0170/E05/IVD/047-02**
D-615 001 D-615 002	Creatine Kinase MB (CK-MB)	-	EDMA	11 01 01 14	Creatine Kinase - MB "Activity"(CC)	Other	N/A	**DE/CA09/0170/E05/IVD/047-02**
246 001 246 002 246 003 246 004 246 005 ZL -246 001	γ - Glutamyltransferase (GGT) – Liquizyme (9+1)		EDMA	11 01 01 16	Gamma Glutamyltransferase	Other	N/A	**DE/CA09/0170/E05/IVD/048-02**
247 001 247 002	γ - Glutamyltransferase (GGT) – Liquizyme (1+1)		EDMA	11 01 01 16	Gamma Glutamyltransferase	Other	N/A	**DE/CA09/0170/E05/IVD/048-02**
D-621 001 D-621 002 D-621 003	Ɣ- Glutamyl transferase (GGT) (4+1)	-	EDMA	11 01 01 16	Gamma Glutamyltransferase	Other	N/A	**DE/CA09/0170/E05/IVD/048-02**
D-622 001	Ɣ- Glutamyltransferase- (GGT) (9+1)	-	EDMA	11 01 01 16	Gamma Glutamyltransferase	Other	N/A	**DE/CA09/0170/E05/IVD/048-02**
D-629 001 D-629 002 D-629 003 D-629 004	Lactate dehydrogenase (LDH 4+1)	-	EDMA	11 01 01 19	Lactate Dehydrogenase L (LDH - L --> P)	Other	N/A	**DE/CA09/0170/E05/IVD/079**

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278 001 278 002 278 003 278 004 278 005	Lactate dehydrogenase (LDH) – Liquizyme (9+1)		EDMA	11 01 01 20	Lactate Dehydrogenase P (LDH - P --> L)	Other	N/A	DE/CA09/0170/E05/IVD/054-01
279 001 279 002	Lactate dehydrogenase (LDH) – Liquizyme (1+1)		EDMA	11 01 01 20	Lactate Dehydrogenase P (LDH - P --> L)	Other	N/A	DE/CA09/0170/E05/IVD/054-01
283 001 283 002 283 003 283 004 283 005, ZL -283 001	Lactate dehydrogenase (LDH) – liquizyme (4+1)		EDMA	11 01 01 20	Lactate Dehydrogenase P (LDH - P --> L)	Other	N/A	DE/CA09/0170/E05/IVD/054-01
283 001 283 002 283 003	Lactate dehydrogenase (LDH) (Single Reagent)		EDMA	11 01 01 20	Lactate Dehydrogenase P (LDH - P --> L)	Other	N/A	DE/CA09/0170/E05/IVD/054-01
281 001	Lipase w. Calibrator		EDMA	11 01 01 23	Lipase	Other	N/A	DE/CA09/0170/E05/IVD/006-02
ZL -281 001	Lipase (4+1)		EDMA	11 01 01 23	Lipase	Other	N/A	DE/CA09/0170/E05/IVD/006-02
D-632 001	Lipase Colorimetric (DGMRE)	-	EDMA	11 01 01 23	Lipase	Other	N/A	DE/CA09/0170/E05/IVD/006-02

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210 001 210 002 210 003 210 004 211 001 211 002 211 003 211 004 ZL-211 001	Albumin		EDMA	11 02 01 01	Albumin (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/037-02**
D-601 001 D-601 002 D-601 003	Albumin - BCG	-	EDMA	11 02 01 01	Albumin (CC) IC =>12.01.03.01, IC RT/POC => 12.70.01.01	Other	N/A	**DE/CA09/0170/E05/IVD/037-02**
305 001 ZI -305 001	Total Bile Acids (TBA)	(3+1)	EDMA	11 02 01 02	Bile acids	Other	N/A	**DE/CA09/0170/E05/IVD/034-01**
222 001 222 002 D-609 001 D-609 002	Bilirubin (TOTAL AND DIRECT) Jendrassik Grof		EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
224 001	Bilirubin (Direct)		EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
225 001 225 002	Bilirubin Total/Direct DMSO		EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
223 001 223 002 ZL --223 001	Bilirubin Total - single reagent		EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**

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365 001 365 002 365 003	Bilirubin Plus 5+1		EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
D-658 001	Bilirubin (Total & Direct) DMSO, Colorimetric	-	EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
D-663 001	Pediatric Total Bilirubin	-	EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
D-610 001 D-610 002 D-610 003 D-610 004	Total Bilirubin (Single Reagent) MODIFIED BERGH & MÜLLER METHOD	-	EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
D-657 001	Bilirubin Direct	-	EDMA	11 02 01 03	Bilirubin	Other	N/A	**DE/CA09/0170/E05/IVD/042-02**
319 001 319 002 319 003 319 004 319 005	Urea/BUN – Liquizyme (UV)		EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**
318 001 318 002 318 003 318 004	Urea/BUN – (Modified Urease - Berthlot Method)		EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**

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320 001 320 002 320 003 320 004 ZL -320 001	Urea/BUN – single reagent		EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**
D-640 001 D-640 002 D-640 003	Urea Colorimetric	-	EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**
D-641 001 D-641 002 D-641 003 D-641 004	Urea/BUN – (UV)(4+1)	-	EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**
D-664 001 D-664 002	Urea/BUN - LS (Modified Urease-Berthlot Method)	-	EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**
321 001 321 002 321 003 321 004	Urea/BUN - LS (Modified Urease-Berthlot Method)	-	EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**
D-650 001	Urea/BUN – (UV)(9+1)	-	EDMA	11 02 01 04	Urea/Blood Urea Nitrogen	Other	N/A	**DE/CA09/0170/E05/IVD/061-02**

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230 001 230 002 230 003 230 004 230 005 230 006 230 007 230 008, 230 009 230 010 230 011	Cholesterol – Liquizyme CHOD-PAP		EDMA	11 02 01 05	Cholesterol	Other	N/A	**DE/CA09/0170/E05/IVD/044-02**
ZL-230 001	Cholesterol – Liquizyme CHOD-PAP (Single Reagent)		EDMA	11 02 01 05	Cholesterol	Other	N/A	**DE/CA09/0170/E05/IVD/044-02**
D-613 001 D-613 002 D-613 003 D-613 004 D-613 005 D-613 006 D-613 007	Cholesterol CHOD-PAP	-	EDMA	11 02 01 05	Cholesterol	Other	N/A	**DE/CA09/0170/E05/IVD/044-02**
242 001 242 002	Copper		EDMA	11 02 01 06	Copper	Other	N/A	**DE/CA09/0170/E05/IVD/045-02**
232 001 232 002 ZL -232 001	Copper - Single reagent		EDMA	11 02 01 06	Copper	Other	N/A	**DE/CA09/0170/E05/IVD/045-03**
D-617 001 D-617 002 D-617 003	Copper Colorimetric Test with Dibromo-PAESA	-	EDMA	11 02 01 06	Copper	Other	N/A	**DE/CA09/0170/E05/IVD/045-04**

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235 001 235 002 235 003 235 004	Creatinine-Colorimetric		EDMA	11 02 01 07	Creatinine	Other	N/A	DE/CA09/0170/E05/IVD/046-02
234 001 234 002 234 003 234 004 234 005234 006	Creatinine-Jaffe		EDMA	11 02 01 07	Creatinine	Other	N/A	DE/CA09/0170/E05/IVD/046-02
237 001 237 002 237 003 ZL-237 001	Creatinine-Jaffe - single reagent		EDMA	11 02 01 07	Creatinine	Other	N/A	DE/CA09/0170/E05/IVD/046-02
368 001 368 002 368 003	Creatinine Plus (5+1)		EDMA	11 02 01 07	Creatinine	Other	N/A	DE/CA09/0170/E05/IVD/046-02
D-619 001 D-619 002 D-619 003	Creatinine - Jaffè	-	EDMA	11 02 01 07	Creatinine	Other	N/A	DE/CA09/0170/E05/IVD/046-02
D-618 001 D-618 002	Creatinine - Jaffè (Single Reagent)	-	EDMA	11 02 01 07	Creatinine	Other	N/A	DE/CA09/0170/E05/IVD/046-02

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250 001 250 002 250 003 250 004 250 005 250 006 250 007 ZL -250 001	Glucose Liquizyme GOD – PAP (Single Reagent)		EDMA	11 02 01 13	Glucose	Other	N/A	DE/CA09/0170/E05/IVD/049-02
251 001 251 002 251 003	Glucose - HK		EDMA	11 02 01 13	Glucose	Other	N/A	DE/CA09/0170/E05/IVD/049-02
D-622 001 D-622 002 D-622 003 D-622 004 D-622 005 D-622 006	Glucose GOD-PAP	-	EDMA	11 02 01 13	Glucose	Other	N/A	DE/CA09/0170/E05/IVD/049-02
254 001 255 000 255 001 255 002	Glycosylated Haemoglobin		EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
602 001 ZL-602 001	Glycosylated Haemoglobin (2 Reagents)		EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04

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401 001 401 002 401 003 401 004 401 005 401 006	HbA1c Plus		EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
D-659 001 D-659 002	Glycosylated Hemoglobin (HbA1c) (Ion Exchange)	-	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
D-858 001T	Hemoglobin A1c (HbA1c) Twin A1c Analyzer	-	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
602 001	Hemoglobin A1c (HbA1c) Twin A1c Analyzer	-	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
401 001-M	HbA1c plus	-	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
602 001-I 602 000-I	Hemoglobin A1c(HbA1c) Turbidimetric Immunoassay	-	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
401 001 401 002	Reagents for STAT LAB T Analyzer & Auto Chemistry Analyzer HbA1c kit	-	EDMA	11 02 01 14	Glycosylated/Glycated Haemoglobin	Other	N/A	DE/CA09/0170/E05/IVD/050-04
266 001 266 002	HDL Cholesterol - Precipitant		EDMA	11 02 01 15	High Densitiy Lipoprotein Cholesterol	Other	N/A	DE/CA09/0170/E05/IVD/051-02
267 001 267 002	HDL Cholesterol - Direct Reagent		EDMA	11 02 01 15	High Densitiy Lipoprotein Cholesterol	Other	N/A	DE/CA09/0170/E05/IVD/051-02
ZL -267 001	HDL Cholesterol - Direct Reagent (3+1)		EDMA	11 02 01 15	High Densitiy Lipoprotein Cholesterol	Other	N/A	DE/CA09/0170/E05/IVD/051-02
623 001 623 002	HDL Cholesterol - Precipitation	-	EDMA	11 02 01 15	High Density Lipoprotein Cholesterol	Other	N/A	DE/CA09/0170/E05/IVD/051-02

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D-624 001	HDL Cholesterol Direct Enzymatic colorimetric, Liquid	-	EDMA	11 02 01 15	High Density Lipoprotein Cholesterol	Other	N/A	**DE/CA09/0170/E05/IVD/051-02**
D-628 001 D-628 002 D-628 003 D-628 004 D-628 005	Total Iron Chromazurol B Single Reagent	-	EDMA	11 02 01 16	Iron (CC)	Other	N/A	DE/CA09/0170/E05/IVD/078
270 001	Total Iron and Total Iron Binding Capacity Reagent set		EDMA	11 02 01 17	Iron Binding Capacity - Total (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/052-02**
271 001 271 002 ZL -271 001	Iron-NP Single reagent		EDMA	11 02 01 17	Iron Binding Capacity - Total (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/052-02**
269 001 269 002	Total Iron chromazurol B (Single Reagent)		EDMA	11 02 01 17	Iron Binding Capacity - Total (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/052-02**
D-653 001	Direct Serum Total Iron Binding Capacity (TIBC)	-	EDMA	11 02 01 17	Iron Binding Capacity - Total (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/052-02**
274 001 274 002	Lactate - Liquizyme		EDMA	11 02 01 18	Lactate	Other	N/A	**DE/CA09/0170/E05/IVD/053-01**
ZL -274 001 D-648 001	Lactate - (9+1)		EDMA	11 02 01 18	Lactate	Other	N/A	**DE/CA09/0170/E05/IVD/053-01**
280 001 280 002	LDL-Cholestrol Direct Reagent		EDMA	11 02 01 21	Low Density Lipoprotein Cholesterol including sd-LDL	Other	N/A	**DE/CA09/0170/E05/IVD/007-02**
ZL -280 001	LDL-Cholestrol Direct Reagent (3+1)		EDMA	11 02 01 21	Low Density Lipoprotein Cholesterol including sd-LDL	Other	N/A	**DE/CA09/0170/E05/IVD/007-02**

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D-631 001	LDL Cholesterol Direct Enzymatic colorimetric, Liquid	-	EDMA	11 02 01 21	Low Density Lipoprotein Cholesterol including sd-LDL	Other	N/A	**DE/CA09/0170/E05/IVD/007-02**
290 001	Oxalic acid		EDMA	11 02 01 23	Oxalate	Other	N/A	**DE/CA09/0170/E05/IVD/056-01**
282 001 282 002 282 003 ZL -282 001	Micrototal Protein (MT-P)		EDMA	11 02 01 30	Total Protein	Other	N/A	**DE/CA09/0170/E05/IVD/055-02**
310 001 310 002 310 003 310 004 310 005, ZL -310 001	Total Protein (Single Reagent)		EDMA	11 02 01 30	Total Protein	Other	N/A	**DE/CA09/0170/E05/IVD/055-02**
D-634 001 D-634 002 D-634 003 D-634 004	Micrototal Protein (MT-P) Pyrogallol - Red	-	EDMA	11 02 01 30	Total Protein	Other	N/A	**DE/CA09/0170/E05/IVD/055-02**
D-638 001 D-638 002 D-638 003	Total protein (Biuret Reagent)	-	EDMA	11 02 01 30	Total Protein	Other	N/A	**DE/CA09/0170/E05/IVD/055-02**

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314 001 314 002 314 003 314 004 314 005 314 006 314 007 314 008 314 009 314 010 314 011, ZL -314 001	Triglycerides (Single Reagent)		EDMA	11 02 01 31	Triglycerides	Other	N/A	**DE/CA09/0170/E05/IVD/060-02**
D-639 001 D-639 002 D-639 003 D-639 004 D-639 005 D-639 006	Triglycerides GPO-PAP	-	EDMA	11 02 01 31	Triglycerides	Other	N/A	**DE/CA09/0170/E05/IVD/060-02**
322 001 322 002 322 003 322 004	Uric acid – Liquizyme (9+1) Uricase - PAP		EDMA	11 02 01 32	Uric Acid	Other	N/A	**DE/CA09/0170/E05/IVD/062-02**

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323 001 323 002 323 003 323 004 323 005 323 006 ZL -323 001	Uric acid - single reagent		EDMA	11 02 01 32	Uric Acid	Other	N/A	**DE/CA09/0170/E05/IVD/062-02**
D-643 001 D-643 002 D-643 003 D-643 004 D-643 005 D-643 006 D-643 007	Uric acid	-	EDMA	11.02.01.32	Uric Acid	Other	N/A	**DE/CA09/0170/E05/IVD/062-02**
330 001 330 002 ZL -330 001	Zinc - single reagent		EDMA	11 02 01 33	Zinc	Other	N/A	**DE/CA09/0170/E05/IVD/004-02**
D-644 001 D-644 002 D-644 003	Zinc Colorimetric Test with 5-Bromo-PAPS	-	EDMA	11 02 01 33	Zinc	Other	N/A	**DE/CA09/0170/E05/IVD/004-02**
218 001	Ammonia – Liquizyme (9+1)		EDMA	11 03 01 01	Ammonia	Other	N/A	**DE/CA09/0170/E05/IVD/040-02**
220 001 220 002 ZL -220 001	Ammonia – single reagent		EDMA	11 03 01 01	Ammonia	Other	N/A	**DE/CA09/0170/E05/IVD/040-02**

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D-645 001 D-645 002 D-645 003	Ammonia	-	EDMA	11 03 01 01	Ammonia	Other	N/A	**DE/CA09/0170/E05/IVD/040-02**
226 001 226 002 226 003	Calcium OCPC		EDMA	11 03 01 03	Calcium	Other	N/A	**DE/CA09/0170/E05/IVD/043-02**
D-616 001 D-616 002 D-616 003	Carbon Dioxide (CO2) (Colormetric PEPC)	-	EDMA	11 03 01 02	Bicarbonate	Other	N/A	**DE/CA09/0170/E05/IVD/081**
228 001 228 002	Carbon Dioxide (CO2) (Colorimetric PEPC)	-	EDMA	11 03 01 02	Bicarbonate	Other	N/A	**DE/CA09/0170/E05/IVD/081**
227 001 227 002 227 003 D-611 001 D-611 002 D-611 003	Calcium Arsenazo III		EDMA	11 03 01 03	Calcium	Other	N/A	**DE/CA09/0170/E05/IVD/043-02**
ZL -227 001	Calcium Arsenazo III (Single Reagent)		EDMA	11 03 01 03	Calcium	Other	N/A	**DE/CA09/0170/E05/IVD/043-03**
D-612 001 D-612 002	Calcium O-CPC	-	EDMA	11 03 01 03	Calcium	Other	N/A	**DE/CA09/0170/E05/IVD/043-03**
233 001 ZL -233 001 D-620 001 D-620 002 D-620 003 D-620 004	Chloride Single Reagent		EDMA	11 03 01 04	Chloride	Other	N/A	**DE/CA09/0170/E05/IVD/008-01**

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285 001 285 002 ZL -285 001	Magnesium - single reagent		EDMA	11 03 01 07	Magnesium	Other	N/A	DE/CA09/0170/E05/IVD/005-02
D-633 001 D-633 002 D-633 003	Magnesium Phosphonazo III	-	EDMA	11 03 01 07	Magnesium	Other	N/A	DE/CA09/0170/E05/IVD/005-02
294 001 294 002 294 003 ZL -294 001	Phosphorous UV (Single Reagent)		EDMA	11 03 01 08	Phosphate inorganic / Phosphorus	Other	N/A	DE/CA09/0170/E05/IVD/057-02
D-635 001 D-635 002 D-635 003	Phosphorus – UV Method	-	EDMA	11 03 01 08	Phosphate inorganic / Phosphorus	Other	N/A	DE/CA09/0170/E05/IVD/057-02
298 001 298 002 298 003 298 004 ZL -298 001	Potassium (Single Reagent)		EDMA	11 03 01 09	Potassium	Other	N/A	DE/CA09/0170/E05/IVD/058-02
D-636 001 D-636 002 D-636 003 D-636 004	Potassium Tetraphenylborate Method without Deproteinization	-	EDMA	11 03 01 09	Potassium	Other	N/A	DE/CA09/0170/E05/IVD/058-02
302 001 302 002	Sodium		EDMA	11 03 01 10	Sodium	Other	N/A	DE/CA09/0170/E05/IVD/059-01

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303 001 303 002 303 003 ZL -303 001 D-637 001 D-637 002 D-637 003 D-637 004	Sodium - single reagent		EDMA	11 03 01 10	Sodium	Other	N/A	**DE/CA09/0170/E05/IVD/059-01**
326 001 326 002	SP-Normotrol		EDMA	11 50 01 01	Assayed Multicomponent Sera (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/011-02**
327 001 327 002	SP-Pathotrol		EDMA	11 50 01 01	Assayed Multicomponent Sera (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/011-02**
328 001 328 002	SP-Multical		EDMA	11 50 03 01	Calibrators Multicomponent (CC)	Other	N/A	**DE/CA09/0170/E05/IVD/010-01**
1100 010 1100 020 1100 030 1100 050 1100 100	Uritrak - 1,2,3, 5 and 10		EDMA	11 70 02 02	Urine Multi-constituent Test Strips (manual)	Other	N/A	**DE/CA09/0170/E05/IVD/001-02**
D-795 001	Urine strips	-	EDMA	11 70 02 02	Urine Multi-constituent Test Strips (manual)	Other	N/A	**DE/CA09/0170/E05/IVD/001-02**
D-795 002	Urine strips Reagent strips for urinalysis for ten parameters	-	EDMA	11 70 02 02	Urine Multi-constituent Test Strips (manual)	Other	N/A	**DE/CA09/0170/E05/IVD/001-02**
350 001 350 002	Glucose Standard (For Urine)		EDMA	11 70 02 70	Urine Testing Calibrators and Standards	Other	N/A	**DE/CA09/0170/E05/IVD/015-01**
304 001	Sodium Standard Set (For Urine)		EDMA	11 70 02 70	Urine Testing Calibrators and Standards	Other	N/A	**DE/CA09/0170/E05/IVD/015-01**

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375 001	Kappa Light Chain serum Kit (KAP)		EDMA	12 01 01 20	Kappa and Lambda chain	Other	N/A	DE/CA09/0170/E05/IVD/028-02
378 001	Kappa Light Chain Urine Kit (KAP)		EDMA	12 01 01 20	Kappa and Lambda chain	Other	N/A	DE/CA09/0170/E05/IVD/028-02
381 001	Lambda Light Chain serum Kit (LAM)		EDMA	12 01 01 20	Kappa and Lambda chain	Other	N/A	DE/CA09/0170/E05/IVD/028-02
384 001	Lambda Light Chain Urine Kit (LAM)		EDMA	12 01 01 20	Kappa and Lambda chain	Other	N/A	DE/CA09/0170/E05/IVD/028-02
600 001 ZL-600 001	Microalbumin (MAU)	Immuno Turbidimetry	EDMA	12 01 03 01	Albumin (IC) incl. uAlbumin	Other	N/A	DE/CA09/0170/E05/IVD/025-02
D-859 001	MICROALBUMIN Immuno Turbidimetry	-	EDMA	12 01 03 01	Albumin (IC) incl. uAlbumin	Other	N/A	DE/CA09/0170/E05/IVD/025-02
592 001 ZL-592 001	Ceruloplasmin	Immuno-Turbidimetry	EDMA	12 01 03 02	Ceruloplasmin	Other	N/A	DE/CA09/0170/E05/IVD/024-01
594 001 ZL-594 001	Haptoglobin (HAP)	Immuno Turbidimetry	EDMA	12 01 03 03	Haptoglobin	Other	N/A	DE/CA09/0170/E05/IVD/026-01
550 001 ZL-550 001	LIPOPROTEIN (a) [Lp(a)]		EDMA	12 01 04 21	Lipoprotein (a)	Other	N/A	DE/CA09/0170/E05/IVD/022-01
548 001 ZL-548 001	IMMUNOGLOBULIN E (IgE)		EDMA	12 02 01 02	Immunoglobulin E - Total	Other	N/A	DE/CA09/0170/E05/IVD/023-01
399 001 399 002 399 003 399 004	25-OH Vitamin D		EDMA	12 06 03 10	25-Hydroxyvitamin D3	Other	N/A	DE/CA09/0170/E05/IVD/031-01
567 001 ZL-567 001	Procalcitonin Assay		EDMA	12 06 90 16	Procalcitonin	Other	N/A	DE/CA09/0170/E05/IVD/018-01

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562 001 ZL-562 001	FERRTIN	Turbi Latex	EDMA	12 07 01 02	Ferritin	Other	N/A	DE/CA09/0170/E05/IVD/027-02
D-562 000 D-562 001	Ferritin Turbi Latex	-	EDMA	12 07 01 02	Ferritin	Other	N/A	DE/CA09/0170/E05/IVD/027-02
562 001 562 002 562 001-1 562 002-1	Ferritin Turbi Latex	-	EDMA	12 07 01 02	Ferritin	Other	N/A	DE/CA09/0170/E05/IVD/027-02
D-860 000 D-860 001	Vitamin D	-	EDMA	12 07 02 05	Vitamin D (Cholecalciferol)	Other	N/A	DE/CA09/0170/E05/IVD/089
D-836 000 D-836 001 D-836 002	Antistreptolysin O Titre (ASOT)	-	EDMA	12 11 01 04	Anti-Streptolysin O Reaction Time / Titre (qualitative)	Other	N/A	DE/CA09/0170/E05/IVD/088
510 001 510 002 510 003 510 004 510 005 510 006	Antistreptolysin O Titre (ASOT)	-	EDMA	12 11 01 04	Anti-Streptolysin O Reaction Time / Titre (qualitative)	Other	N/A	DE/CA09/0170/E05/IVD/088
510 000 510 001 510 002 510 003 510 004 510 005 559 001 596 001	Antistreptolysin O Titre (ASOT)		EDMA	12 11 01 05	Anti-Streptolysin O (quantitative)	Other	N/A	DE/CA09/0170/E05/IVD/063-02

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ZL - 596-001	Antistreptolysin O Titre - ASOT (2 Reagents)		EDMA	12 11 01 05	Anti-Streptolysin O (quantitative)	Other	N/A	**DE/CA09/0170/E05/IVD/063-02**
D-851 001	Antistreptolysin O (ASO) Turbi Latex	-	EDMA	12 11 01 05	Anti-Streptolysin O (quantitative)	Other	N/A	**DE/CA09/0170/E05/IVD/063-02**
559 001 559 002	Antistreptolysin O (ASO) Turbi Latex	-	EDMA	12 11 01 05	Anti-Streptolysin O (quantitative)	Other	N/A	**DE/CA09/0170/E05/IVD/063-02**
596 001	Antistreptolysin O (ASO) Immuno-Turbidimetry	-	EDMA	12 11 01 05	Anti-Streptolysin O (quantitative)	Other	N/A	**DE/CA09/0170/E05/IVD/063-02**
560 001 588 001 ZL -588 001	C Reactive Protein (CRP) (2 Reagents		EDMA	12 11 01 09	C-Reactive Protein	Other	N/A	**DE/CA09/0170/E05/IVD/064-03**
514 000 514 001 514 002 514 003 514 004 514 005	C Reactive Protein (CRP) (Latex)		EDMA	12 11 01 09	C-Reactive Protein	Other	N/A	**DE/CA09/0170/E05/IVD/064-03**
D-837 000 D-837 001 D-837 002	C Reactive Protein (CRP)	-	EDMA	12 11 01 09	C-Reactive Protein	Other	N/A	**DE/CA09/0170/E05/IVD/064-03**
D-852 001	C Reactive Protein (CRP) Turbi Latex	-	EDMA	12 11 01 09	C-Reactive Protein	Other	N/A	**DE/CA09/0170/E05/IVD/064-03**
560 001 560 002 560 003	C Reactive Protein (CRP) Turbi Latex	-	EDMA	12 11 01 09	C-Reactive Protein	Other	N/A	**DE/CA09/0170/E05/IVD/064-03**
588 001 588 002	C Reactive Protein (CRP) Immuno-Turbidimetry	-	EDMA	12 11 01 09	C-Reactive Protein	Other	N/A	**DE/CA09/0170/E05/IVD/064-03**

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518 000 518 001 518 002 518 003 518 004 518 005 561 001 598 001 ZL -598 001	Rheumatoid Factors (RF) 2 Reagents		EDMA	12 11 01 10	Rheumatoid Factors	Other	N/A	**DE/CA09/0170/E05/IVD/065-03**
D-838 000 D-838 001 D-838 002	Rheumatoid Factor (RF)	-	EDMA	12 11 01 10	Rheumatoid Factors	Other	N/A	**DE/CA09/0170/E05/IVD/065-03**
518 001 518 002 518 003 518 004 518 005 518 006	Rheumatoid Factor (RF)	-	EDMA	12 11 01 10	Rheumatoid Factors	Other	N/A	**DE/CA09/0170/E05/IVD/065-03**
D-853 001	Rheumatoid Factor (RF) Turbi Latex	-	EDMA	12 11 01 10	Rheumatoid Factors	Other	N/A	**DE/CA09/0170/E05/IVD/065-03**
598 001	RHEUMATOID FACTOR (RF) ImmunoTurbidimetry 3rd Generation (Aggregated human IgG method)	-	EDMA	12 11 01 10	Rheumatoid Factors	Other	N/A	**DE/CA09/0170/E05/IVD/065-03**
561 001	RHEUMATOID FACTOR (RF) Turbi Latex	-	EDMA	12 11 01 10	Rheumatoid Factors	Other	N/A	**DE/CA09/0170/E05/IVD/065-03**

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545 001 ZL-545 001	CRP/hs(C- Reactive protein)		EDMA	12 13 01 10	High-Sensitivity C-Reactive Protein	Other	N/A	DE/CA09/0170/E05/IVD/020-01
340 001	ASO Control		EDMA	12 50 01 06	Specific Protein Controls	Other	N/A	DE/CA09/0170/E05/IVD/017-01
343 001	CRP Control		EDMA	12 50 01 06	Specific Protein Controls	Other	N/A	DE/CA09/0170/E05/IVD/017-01
405 001	D-Dimer Control Set		EDMA	12 50 01 06	Specific Protein Controls	Other	N/A	DE/CA09/0170/E05/IVD/017-01
353 001	Microalbumin Control set		EDMA	12 50 01 06	Specific Protein Controls	Other	N/A	DE/CA09/0170/E05/IVD/017-01
396 001	25-OH Vitamin D Control Set		EDMA	12 50 01 12	Anaemia Related/Vitamin Controls	Other	N/A	DE/CA09/0170/E05/IVD/029-01
344 001	RF Control		EDMA	12 50 01 14	Rheumatoid/Autoimmune Controls	Other	N/A	DE/CA09/0170/E05/IVD/013-01
608 001 608 002	Immunology Control	High	EDMA	12 50 02 30	Multi Constituents Immunochemistry Controls	Other	N/A	DE/CA09/0170/E05/IVD/014-01
606 001 606 002	Immunology Control	Low	EDMA	12 50 02 30	Multi Constituents Immunochemistry Controls	Other	N/A	DE/CA09/0170/E05/IVD/014-01
345 001	ASO Standard Super High		EDMA	12 50 03 05	Specific Protein Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/016-02
347 000 347 001	CRP Standard Super High		EDMA	12 50 03 05	Specific Protein Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/016-02
402 001	D-Dimer Calibrator		EDMA	12 50 03 05	Specific Protein Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/016-02

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354 001	Fibrinogen Standard		EDMA	12 50 03 05	Specific Protein Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/016-02
352 001	Microalbumin Standard		EDMA	12 50 03 05	Specific Protein Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/016-02
604 001 604 002	Protein Standard High		EDMA	12 50 03 05	Specific Protein Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/016-02
387 001	Specific Protein Standard		EDMA	12 50 03 05	Specific Protein Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/016-02
393 001	25-OH Vitamin D Calibrator Set		EDMA	12 50 03 11	Anaemia Related/Vitamin Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/030-01
349 001	RF Standard Super High		EDMA	12 50 03 13	Rheumatoid/Autoimmune Standards and Calibrators	Other	N/A	DE/CA09/0170/E05/IVD/012-01
1176 001 1176 002	HCG One Step pregnancy Test	Device	EDMA	12 70 05 02	HCG - Rapid Test	Other	N/A	DE/CA09/0170/E05/IVD/035-02
D-787 001	HCG Pregnancy Rapid Test Cassette (Serum, Plasma and Urine)	-	EDMA	12 70 05 02	HCG - RT & POC	Other	N/A	DE/CA09/0170/E05/IVD/035-02
1178 001	HCG Pregnancy Rapid Test Cassette (Serum, Plasma and Urine)	-	EDMA	12 70 05 02	HCG - RT & POC	Other	N/A	DE/CA09/0170/E05/IVD/035-02
1172 001 1172 002	Troponin - I		EDMA	12 70 13 03	Troponin I/T - RT & POC	Other	N/A	DE/CA09/0170/E05/IVD/033-02
D-789 001	Cardiac Troponin I Rapid Test Cassette (Serum/Plasma/Whole Blood)	-	EDMA	12 70 13 03	Troponin I/T - RT & POC	Other	N/A	DE/CA09/0170/E05/IVD/033-02
D-626 001 D-626 002	Haemoglobin (Single Reagent) Drabkin's Solution	-	EDMA	13 01 02 01	Haemoglobin determinations (Total Hb)	Other	N/A	DE/CA09/0170/E05/IVD/087

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D-625 000 D-625 001 D-625 002 D-625 003	Haemoglobin (Ready-To-Use) Drabkin's Solution	-	EDMA	13 01 02 01	Haemoglobin determinations (Total Hb)	Other	N/A	**DE/CA09/0170/E05/IVD/087**
D-660 001 D-660 002	Haemoglobin Drabkin's Solution		EDMA	13 01 02 01	Haemoglobin determinations (Total Hb)	Other	N/A	**DE/CA09/0170/E05/IVD/087**
D-749 001 D-749 002	Normal QC	-	EDMA	13 01 50 01	Blood Normal Controls	Other	N/A	**DE/CA09/0170/E05/IVD/086**
D-750 001 D-750 002	Abnormal QC	-	EDMA	13 01 50 02	Blood Abnormal Controls	Other	N/A	**DE/CA09/0170/E05/IVD/085**
D-751 001 D-751 002	Multical	-	EDMA	13 01 50 03	Blood Multilevel Controls	Other	N/A	**DE/CA09/0170/E05/IVD/084**
610 001 610 002 610 003 610 004 ZL -610 001	Haemoglobin (Single Reagent)		EDMA	13 01 70 01	Haemoglobin (Hb)	Other	N/A	**DE/CA09/0170/E05/IVD/068-02**
611 001 611 002 611 003	Haemoglobin (Ready to Use)		EDMA	13 01 70 01	Haemoglobin (Hb)	Other	N/A	**DE/CA09/0170/E05/IVD/068-02**
612 001 612 002	Haemoglobin Drabkin's Solution		EDMA	13 01 70 01	Haemoglobin (Hb)	Other	N/A	**DE/CA09/0170/E05/IVD/068-02**
252 001	G6PD		EDMA	13 01 90 01	Cellular enzyme determination reagents (G-6-PDH, Pyuvate Kinase)	Other	N/A	**DE/CA09/0170/E05/IVD/066-02**

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253 001	G6PD - single reagent		EDMA	13 01 90 01	Cellular enzyme determination reagents (G-6-PDH, Pyuvate Kinase)	Other	N/A	**DE/CA09/0170/E05/IVD/066-02**
D-655 001	Glucose-6-Phosphate Dehydrogenase (G-6-PD) Quantitative Assay	-	EDMA	13 01 90 01	Cellular enzyme determination reagents (G-6-PDH, Pyuvate Kinase)	Other	N/A	**DE/CA09/0170/E05/IVD/066-02**
614 001 614 002	PT Reagent (SP-Normoplastin)		EDMA	13 02 01 01	Prothrombin time (Quick Test)	Other	N/A	**DE/CA09/0170/E05/IVD/069-03**
624 000 624 001 624 002 624 003	Recoplastin ISI 1.0 PT Reagent		EDMA	13 02 01 01	Prothrombin time (Quick Test)	Other	N/A	**DE/CA09/0170/E05/IVD/069-03**
D-704 001 D-704 002 D-704 003	Liquid PT Reagent ISI 1.0	-	EDMA	13 02 01 01	Prothrombin time (Quick Test)	Other	N/A	**DE/CA09/0170/E05/IVD/069-03**
D-707 001 D-707 002 D-707 003	PT Reagent ISI 1.5	-	EDMA	13 02 01 01	Prothrombin time (Quick Test)	Other	N/A	**DE/CA09/0170/E05/IVD/069-03**
626 001 626 002	APTT Reagent (SP-UNICELIN)		EDMA	13 02 01 02	Activated Partial Thromboplastin Time	Other	N/A	**DE/CA09/0170/E05/IVD/067-02**
D-705 001	PTT Reagent	-	EDMA	13 02 01 02	Activated Partial Thromboplastin Time	Other	N/A	**DE/CA09/0170/E05/IVD/067-02**
590 001 ZL-590 001	FIBRINOGEN	Immuno-Turbidimetry	EDMA	13 02 02 01	Fibrinogen Assays (Factor I)	Other	N/A	**DE/CA09/0170/E05/IVD/021-03**
D-708 001	Fibrinogen-LS Clauss Clotting Time Method	-	EDMA	13 02 02 01	Fibrinogen Assays (Factor I)	Other	N/A	**DE/CA09/0170/E05/IVD/021-03**

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
631 001 631 002	FIBRINOGEN-LS Clauss Clotting Time Method	-	EDMA	13 02 02 01	Fibrinogen Assays (Factor I)	Other	N/A	DE/CA09/0170/E05/IVD/021-03
585 001 ZL-585 001	D-Dimer	Immuno-Turbidimetry	EDMA	13 02 05 03	D-Dimer	Other	N/A	DE/CA09/0170/E05/IVD/019-02
D-856 001	D-Dimer Turbi Latex	-	EDMA	13 02 05 03	D-Dimer	Other	N/A	DE/CA09/0170/E05/IVD/019-02
585 001 585 002 585 003 585 004 585 001-1 585 002-1	D-Dimer Turbi Latex	-	EDMA	13 02 05 03	D-Dimer	Other	N/A	DE/CA09/0170/E05/IVD/019-02
390 001	Specific Protein Control		EDMA	13 50 01 06 00	Specific Protein Controls	Other	N/A	DE/CA09/0170/E05/IVD/017-01
1417 001 1417 002	Blood Agar Base		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1400 001 1400 002	Brain Heart Infusion Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1401 001 1401 002	Brain Heart Infusion Broth		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1403 001 1403 002	Cetrimide agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1402 001 1402 002	Cled agar with Bromothymol Blue		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1419 001 1419 002	Cled agar with Andrade Indicator		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
1404 001 1404 002	Lactose Broth		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1405 001 1405 002	MaCconkey Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1420 001 1420 002	MACCONKEY BROTH		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1418 001 1418 002	Mannitol Salt Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1406 001 1406 002	Mueller Hinton Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1407 001 1407 002	Nutrient Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1421 001 1421 002	Nutrient Broth		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1410 001 1410 002	Plate count agar (Standard methods agar)		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1408 001 1408 002	PPLO Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1409 001 1409 002	PPLO broth		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1412 001 1412 002	Sabouraud Dextrose Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1413 001 1413 002	Salmonella Shigella Agar (SS Agar)		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01
1416 001 1416 002	Thioglycollate broth		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	DE/CA09/0170/E05/IVD/075-01

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
1422 001 1422 002	Triple Sugar Iron Agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	**DE/CA09/0170/E05/IVD/075-01**
1414 001 1414 002	Tryptic soy agar		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	**DE/CA09/0170/E05/IVD/075-01**
1415 001 1415 002	Tryptic soy Broth		EDMA	14 01 01 01	Dehydrated Culture Media (DCM)	Other	N/A	**DE/CA09/0170/E05/IVD/075-01**
1452 001 1452 002 1452 003 1452 004 1452 005 1452 006 D-940 001 D-940 002 D-940 003	Blood Culture Medium		EDMA	14 01 11 01	Manual Blood Culture bottles	Other	N/A	**DE/CA09/0170/E05/IVD/074**
D-796 001	Malaria Antigen Test (Whole Blood) For Plasmodium falciparum & vivax	-	EDMA	14 05 02 02	Plasmodium falciparum	Other	N/A	**DE/CA09/0170/E05/IVD/083**
1150 001 1150 002	Malaria Antigen Test Card		EDMA	14 05 02 90	Other Parasite Antigen Detection	Other	N/A	**DE/CA09/0170/E05/IVD/003-01**
D-804 001	RPR Syphilis Test	-	EDMA	15 01 03 03	Syphilis Antibody Assays Total	Other	N/A	**DE/CA09/0170/E05/IVD/082**
725 001 725 002 725 000	RPR Syphilis Test		EDMA	15 01 03 09	Other Syphilis Reagents	Other	N/A	**DE/CA09/0170/E05/IVD/036-01**
714 001	Urease test for H.Pylori		EDMA	15 01 04 90	Other H. Pylori Reagents	Other	N/A	**DE/CA09/0170/E05/IVD/072-02**

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
1154 001 1154 002	S. Typhi/Para Typhi A Antigen		EDMA	15 01 10 01	Salmonella Antigen Detection	Other	N/A	DE/CA09/0170/E05/IVD/002-01
718 001	Widal Test (Salmonella Abs)		EDMA	15 01 10 03	Salmonella Antibody Assays	Other	N/A	DE/CA09/0170/E05/IVD/071-03
D-806 000-O D-806 000-H D-806 000-AH D-806 000-BH D-806 000-CO D-806 000-AO D-806 000-BO D-806 001 D-806 002	Widal Test (Salmonella Ab)	-	EDMA	15 01 10 03	Salmonella Antibody Assays	Other	N/A	DE/CA09/0170/E05/IVD/071-02
718 000 718 001 718 002 718 003 718 004 718 005 718 006 718 002-O 718 002-H 718 002-AH 718 002-BH 718 002-AO	Widal Test (Salmonella Ab)	-	EDMA	15 01 10 03	Salmonella Antibody Assays	Other	N/A	DE/CA09/0170/E05/IVD/071-02
D-792 001	Typhoid IgG/IgM Rapid Test-Cassette	-	EDMA	15 01 10 03	Salmonella Antibody Assays	Other	N/A	DE/CA09/0170/E05/IVD/071-02

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
1233 001	Typhoid Rapid Test Cassette (Serum/Plasma/Whole Blood)	-	EDMA	15 01 10 03	Salmonella Antibody Assays	Other	N/A	**DE/CA09/0170/E05/IVD/071-02**
710 001 710 002 710 003 710 004 710 005	Brucella A/M	-	EDMA	15 01 90 01	Brucella	Other	N/A	**DE/CA09/0170/E05/IVD/070-02**
D-801 001 D-802 001	Brucella A, Brucella M	-	EDMA	15 01 90 01	Brucella	Other	N/A	**DE/CA09/0170/E05/IVD/070-02**
D-803 001 D-803 002	Rose Bengal Brucella Antigen	-	EDMA	15 01 90 01	Brucella	Other	N/A	**DE/CA09/0170/E05/IVD/070-02**
711 001 711 002 711 003 711 004	Rose Bengal Brucella Antigen	-	EDMA	15 01 90 01	Brucella	Other	N/A	**DE/CA09/0170/E05/IVD/070-02**
1192 001	HAV IgM Rapid Test Cassette (Serum/Plasma)	-	EDMA	15 02 01 06	HAV Antibody IgM	Other	N/A	**DE/CA09/0170/E05/IVD/090**
1200 001	SARS COV-2 QUALITATIVE Real Time PCR KIT (DUAL PROBE ASSAY)		EDMA	15 04 40 19	Coronavirus - NA Reagents	Other	N/A	**DE/CA09/0170/E05/IVD/077**
1180 001	H. pylori Ab Test		EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	**DE/CA09/0170/E05/IVD/032-02**
1184 001	H. pylori Ag Test	(fecal)	EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	**DE/CA09/0170/E05/IVD/032-02**

Annex A dated June 08, 2022

Manufacturer: Egyptian Company for Biotechnology Spectrum Diagnostics

REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
D-793 001	H. pylori Ab Rapid Test Cassette (Serum, Plasma and Whole Blood)	-	EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	**DE/CA09/0170/E05/IVD/032-02**
D-794 001	H. pylori Ag Rapid Test Cassette (Fecal Specimen)	-	EDMA	15 70 01 02	H. pylori - RT & POC	Other	N/A	**DE/CA09/0170/E05/IVD/032-02**
D-788 001	HAV IgM Rapid Test Cassette (Serum/Plasma)	-	EDMA	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	**DE/CA09/0170/E05/IVD/080**

SPECTRUM

The Creative Approach to Bioscience

Bilirubin (TOTAL AND DIRECT)
Jendrassik Grof

REF: 222 001 (255ml)	100 Test	**REF:** 222 002 (750ml)	300 Test
R1 Sulphanilic Acid	1 x 45 ml	R1 Sulphanilic Acid	2 x 65 ml
R2 Nitrite	1 x 10 ml	R2 Nitrite	2 x 15 ml
R3 Caffeine	1 x 100 ml	R3 Caffeine	3 x 100 ml
R4 Tartarate	1 x 100 ml	R4 Tartarate	3 x 100 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum Diagnostics bilirubin reagent is intended for the in-vitro quantitative, diagnostic determination of bilirubin in human serum on both automated and manual systems.

Background

The average level of the bilirubin produced in humans from different sources ranges between 250 to 300 mg/day, of which 85% is derived from the heme moiety of the haemoglobin released from senescent erythrocytes that are destroyed in the reticuloendothelial system. The remaining 15 % is produced from erythrocytes destroyed in the bone marrow and from catabolism of other heme containing proteins such as cytochromes and myoglobin.
After it is produced in the peripheral tissues, bilirubin is transported to the liver in association with albumin. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract. Disease or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Method

Colorimetric Diazo method.

Assay Principle

The total bilirubin concentration is determined in presence of caffeine by the reaction with diazotized sulphanilic acid to produce an intensely colored diazo dye (560-600 nm). The intensity of color of this dye formed is proportional to the concentration of total bilirubin.
Direct bilirubin is determined in absence of caffeine by the direct reaction with diazotized sulphanilic acid to form red-colored azobilirubin, the color intensity of which measured at 546 nm is proportional to the concentration of the direct bilirubin in the sample.

$$\text{Sulfanilic acid} + NaNO_2 \xrightarrow{HCL} \text{Diazotized sulfanilic acid}$$

$$\text{Bilirubin} + \text{Diazotized sulfanilic acid} \xrightarrow{pH\ 1.4} \text{Azobilirubin}$$

Reagents

Reagent 1 (R1)
Sulfanilic acid 31.0 mmol/l
HCL 0.20 N

Reagent 2 (R2)
Sodium nitrite 28.0 mmol/l

Reagent 3 (R3)
Caffeine 0.28 mol/l
Sodium benzoate 0.55 mol/l

Reagent 4 (R4)
Tartarate 0.99 mol/l
Sodium hydroxide 2.0 N

Reagent 4 contains caustic material.
Corrosive (C)
R35 Causes severe burns.
R41 Risk of serious damage to eyes.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 After contact with skin, wash immediately with plenty of soap and water.
For further information, refer to the Bilirubin reagent material safety data sheet.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation, Storage and Stability

Spectrum bilirubin reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when stored at room temperature.The opened vials are stable for 6 months at the specified temperature if contamination is avoided.

Deterioration

Do not use the Spectrum bilirubin reagents if precipitate forms. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Specimen Collection and Preservation

Avoid exposure of the specimen to light. If plasma is used, only heparin and oxalate plasma are suitable. Other anticoagulants should not be used. The average half-life of total bilirubin and direct bilirubin in serum is 17 days and few hours respectively.

Stability:

	-20 °C	4 – 8 °C	20 – 25 °C
Total	6 months	7 days	1 day
Direct	6 months	7 days	2 days

Procedure

Total Bilirubin

	Sample blank	Sample
Reagent 1	200 µl	200 µl
Reagent 2	-----	1 drop
Reagent 3	1.0 ml	1.0 ml
Sample	200 µl	200 µl
Mix and incubate for 10 minutes at 20 – 25 °C. then add;		
Reagent 4	1.0 ml	1.0 ml

Mix and incubate for 5 minutes at 20 – 25 °C. Measure absorbance of sample (A_{sample}) against sample blank at 578 nm(560 - 600 nm) The color intensity is stable for 30 minutes.

Direct Bilirubin

	Sample blank	Sample
Reagent 1	200 µl	200 µl
Reagent 2	-----	1 drop
Saline 0.9% NaCl	2.0 ml	2.0 ml
Sample	200 µl	200 µl

Mix and incubate for exactly 5 minutes at 20 – 25 °C. Measure absorbance of sample (A_{sample}) against sample blank at 546 nm (530 - 560 nm).

Calculation

Total bilirubin (mg/dl) = $A_{Sample} \times 10.8$

Direct bilirubin (mg/dl) = $A_{Sample} \times 14.4$

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Total		Direct	
	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	0.79	4.37	0.299	0.77
SD	0.016	0.18	0.016	0.057
CV%	2.03	4.12	5.35	7.4

Run to run (Reproducibility)

	Total		Direct	
	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	0.82	4.52	0.32	0.82
SD	0.02	0.17	0.023	0.062
CV%	2.44	3.76	7.19	7.56

Methods Comparison

A comparison between Spectrum Diagnostics Bilirubin and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.975 was obtained.

Sensitivity

When run as recommended, the sensitivity of this assay is 0.1 mg/dL (1.7 µmol/L) for both total and direct bilirubin.

Linearity

The reaction is linear up to a total bilirubin concentration of 30 mg/dL (513 µmol/L) and a direct bilirubin concentration of 10 mg/dL (171 µmol/L). Specimens showing higher concentration should be diluted 1+4 with physiological saline and repeat the assay (result×5).

Interfering substances

Haemolysis
Avoid haemolysis since it interferes with the test.

Lipemia
Lipemic specimens interfere with the test.

Drugs
Theophylline and propranolol may cause artificially low total bilirubin levels.

Expected Values

Total Bilirubin

Adults and infants >1 month	< 0.2-1.0 mg/dL	(3.4 -17 µmol/l)
Newborns premature (3-5 d)	10-14 mg/dL	(171-239 µmol/l)

Newborns:

(3-5 d)	4.0 - 8.0 mg/dL	(68-137 µmol/l)
(<48 h)	6.0 - 10.0 mg/dL	(103-171 µmol/l)
(<24 h)	2.0 - 6.0 mg/dL	(34-103 µmol/l)

Direct Bilirubin 0 - 0.3 mg/dL (0 - 51 µmol/L)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

Total bilirubin : 0.1 – 30 mg/dL (1.7 – 513 µmol/L)
Direct bilirubin : 0.1 – 10 mg/dL (1.7 – 171 µmol/L)

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Balistreri WF, Shaw LM. Liver function. In: Tietz NW, ed. Fundamentals of clinical chemistry.3 rd ed. Philadelphia:WB Saunders: 1987:729-761.
2. Malloy HT, Evelyn KA. The determination of bilirubin with the photoelectric colorimetric method.J Biol Chem.1937:119:481-490.
3. Tietz NW, ed. Clinical guide to laboratory tests. 3rd ed.Philadephia: WB saunders; 1995:268-273.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
222 001	100 test
222 002	300 test

Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

TÜV SOUTHWEST CERTIFIED ISO 13485:2016

SPECTRUM

The Creative Approach to Bioscience

Bilirubin (TOTAL AND DIRECT)
Jendrassik Grof

REF: 222 001 (255ml)	100 Test	**REF:** 222 002 (750ml)	300 Test
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R4 Tartarate	1 x 100 ml	R4 Tartarate	3 x 100 ml

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
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After it is produced in the peripheral tissues, bilirubin is transported to the liver in association with albumin. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract. Disease or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

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$$\text{Bilirubin} + \text{Diazotized sulfanilic acid} \xrightarrow{pH\ 1.4} \text{Azobilirubin}$$

Reagents

Reagent 1 (R1)
Sulfanilic acid 31.0 mmol/l
HCL 0.20 N

Reagent 2 (R2)
Sodium nitrite 28.0 mmol/l

Reagent 3 (R3)
Caffeine 0.28 mol/l
Sodium benzoate 0.55 mol/l

Reagent 4 (R4)
Tartarate 0.99 mol/l
Sodium hydroxide 2.0 N

Reagent 4 contains caustic material.
Corrosive (C)
R35 Causes severe burns.
R41 Risk of serious damage to eyes.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
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For further information, refer to the Bilirubin reagent material safety data sheet.

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Deterioration

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Specimen Collection and Preservation

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Total	6 months	7 days	1 day
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Sample	200 µl	200 µl
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Reagent 4	1.0 ml	1.0 ml

Mix and incubate for 5 minutes at 20 – 25 °C. Measure absorbance of sample (A_{sample}) against sample blank at 578 nm(560 - 600 nm) The color intensity is stable for 30 minutes.

Direct Bilirubin

	Sample blank	Sample
Reagent 1	200 µl	200 µl
Reagent 2	-----	1 drop
Saline 0.9% NaCl	2.0 ml	2.0 ml
Sample	200 µl	200 µl

Mix and incubate for exactly 5 minutes at 20 – 25 °C. Measure absorbance of sample (A_{sample}) against sample blank at 546 nm (530 - 560 nm).

Calculation

Total bilirubin (mg/dl) = $A_{Sample} \times 10.8$

Direct bilirubin (mg/dl) = $A_{Sample} \times 14.4$

Quality Control

Normal and abnormal commercial control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

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	Total		Direct	
	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	0.79	4.37	0.299	0.77
SD	0.016	0.18	0.016	0.057
CV%	2.03	4.12	5.35	7.4

Run to run (Reproducibility)

	Total		Direct	
	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	0.82	4.52	0.32	0.82
SD	0.02	0.17	0.023	0.062
CV%	2.44	3.76	7.19	7.56

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Interfering substances

Haemolysis
Avoid haemolysis since it interferes with the test.

Lipemia
Lipemic specimens interfere with the test.

Drugs
Theophylline and propranolol may cause artificially low total bilirubin levels.

Expected Values

Total Bilirubin

Adults and infants >1 month	< 0.2-1.0 mg/dL	(3.4 -17 µmol/l)
Newborns premature (3-5 d)	10-14 mg/dL	(171-239 µmol/l)

Newborns:

(3-5 d)	4.0 - 8.0 mg/dL	(68-137 µmol/l)
(<48 h)	6.0 - 10.0 mg/dL	(103-171 µmol/l)
(<24 h)	2.0 - 6.0 mg/dL	(34-103 µmol/l)

Direct Bilirubin 0 - 0.3 mg/dL (0 - 51 µmol/L)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

Total bilirubin : 0.1 – 30 mg/dL (1.7 – 513 µmol/L)
Direct bilirubin : 0.1 – 10 mg/dL (1.7 – 171 µmol/L)

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Balistreri WF, Shaw LM. Liver function. In: Tietz NW, ed. Fundamentals of clinical chemistry.3 rd ed. Philadelphia:WB Saunders: 1987:729-761.
2. Malloy HT, Evelyn KA. The determination of bilirubin with the photoelectric colorimetric method.J Biol Chem.1937:119:481-490.
3. Tietz NW, ed. Clinical guide to laboratory tests. 3rd ed.Philadephia: WB saunders; 1995:268-273.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
222 001	100 test
222 002	300 test

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Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
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SPECTRUM

The Creative Approach to Bioscience

Calcium
O-CPC

REF: 226 001 (2 x 30 ml) 60 test
REF: 226 002 (2 x100 ml) 200 test
REF: 226 003 (4 x100 ml) 400 test
REF: 226 004 (2 x 50 ml) 100 test

SYMBOLS IN PRODUCT LABELLING

EC REP Authorised Representative	Use by/Expiration Date
IVD For in-vitro diagnostic use	CAUTION. Consult instructions for use
LOT Batch Code/Lot number	
REF Catalogue Number	Manufactured by
Consult instructions for use	(Xi) - Irritant
Temperature Limitation	

Intended Use

Spectrum Diagnostics calcium reagent is intended for the in-vitro quantitative, diagnostic determination of calcium in human serum on both automated and manual systems.

Background

Calcium is the fifth most common element in the body, most of which (98 %) is present in the skeleton. One half of the remaining calcium is found in extracellular fluid and the rest in tissues. Calcium has a crucial role in bone mineralization and is also vital for basic physiological processes such as blood coagulation, neuromuscular conduction, and normal muscle tone. Calcium is constantly lost from the body through excretion in faeces, urine and to a small extent in sweat. The determination of serum calcium is useful for monitoring myeloma, renal failure, acid base balance,and cirrhosis. Both serum and tissue calcium in the body are controlled by parathyroid hormone, calcitonin and vitamin D. Hypocalcemia may be observed in hypoparathyrodism, steatorrhea, pancreatitis and nephrosis. Increased levels may be associated with multiple myeloma and other neoplastic diseases.

Method

O-cresolphthalein complexone colorimetric method.

Assay Principle

Calcium ions react with O-cresolphthalein complexone (O-CPC) under alkaline conditions to form a violet colored complex.

$$Ca^{2+} + \text{O-CPC} \xrightarrow{\textit{Alkaline pH}} \text{calcium-O-CPC complex}$$

The color intensity of the complex formed is directly proportional to the calcium concentration. It is determined by measuring the increase in absorbance at 578 nm.

Reagents

Standard Calcium (ST)
10 mg/dL 2.5 mmol/L

Reagent 1 (R1 Buffer)
2-Amino-2-methyl-1-propanol (pH 10.5) 0.3 mol / L

Reagent 2 (R2 Chromogen)
O-cresolphthalein complexone 0.16 mmol/L
8-hydroxyquinoline 7.0 mmol/L

Irritant (Xi)
R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
R38 Irritating to skin.
R41 Risk of serious damage to eyes.
S24/25 Avoid contact with skin and eyes.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

For further information, refer to the Calcium reagent material safety data sheet.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation, Storage and Stability

Spectrum Calcium reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles when stored sealed at 15 – 25 °C.
Once opened, the reagent and standard are stable for 3 months at the specified temperature.

Deterioration

Do not use the Spectrum Calcium reagents if turbid. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Specimen Collection and Preservation

Serum and plasma
Use nonhemolyzed serum.Heparin is the only acceptable anticoagulant. No other anticoagulant can be used. Fresh serum collected in the fasting state is the perferred specimen. Serum or plasma should be separated from cells as soon as possible, because prolonged contact with the clot may cause lower calcium values. Sera from patients receiving EDTA (treatment of hypercalcemia) are unsuitable for analysis, since EDTA will chelate the calcium and render it unavailable for reaction with O-cresolphthalein complexone. The biological half-life of calcium in blood is few hours.

Urine
Specimens should be collected in acid washed bottles. 24 hour Specimens should be collected in containers containing 5 ml of 6 mol/L HCl. If the specimen is collected without acid, the pH should be adjusted < 3 with 6 mol/L HCl. Dilute urine specimen 2 times with bidistilled water (1volume urine + 1volume distilled water) before assay.

Stability (serum): 7 days at 15 – 25 °C; 3 weeks at 4 – 8 °C ; 8 months at -20 °C

Stability (urine): 2 days at 15 – 25 °C; 4 days at 4 – 8 °C ; 3 weeks at -20 °C

Stored serum or urine specimens must be mixed well prior to analysis.

System Parameters

Wavelength	578 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample : Reagent Ratio	1 : 100
Temperature	15 - 25 °C
Zero adjustment	Reagent Blank
Reagent Blank Limits	Low 0.00 AU
	High 0.3 AU
Sensitivity	2 mg/dL (0.5 mmol/L)
Linearity	20 mg/dL (5 mmol/L)

Procedure

	Blank	Standard	Specimen
Standard	……	10 µl	……
Specimen	……	……	10 µl
Reagent 1	0.5 ml	0.5 ml	0.5 ml
Reagent 2	0.5 ml	0.5 ml	0.5 ml

Mix and incubate for 5 minutes at 20 - 25 °C. Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank.

Calculation

Serum calcium concentration (mg/dL) = $\frac{A_{specimen}}{A_{standard}}$ x 10

Urine calcium (mg/24 hrs)= $\frac{A_{specimen}}{A_{standard}}$ x10 x10*x 2**x V***

* The factor “10” converts mg/dl to mg/litre
** The factor “2” represents the dilution factor
*** “V” represents the 24-hour urine volume in litres

Quality Control

Normal and abnormal control serum of known concentrations should be analyzed with each run.

Performance Characterstics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	9.58	13.97
SD	0.12	0.207
CV%	1.25	1.48

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	9.62	14.15
SD	0.23	0.221
CV%	2.39	1.56

Methods Comparison

A comparison between Spectrum Diagnostics Calcium reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.979 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of this assay is 2.0 mg/dL.

Linearity

The reaction is linear up to calcium concentration of 20 mg/dl. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result × 2).

Interfering Substances:

Haemolysis
Avoid haemolysis.

Icterus
No significant interference.

Lipemia
No significant interference.

Anticoagulants
Complexing Anticoagulants such as citrate, oxalate and EDTA must be avoided.

Expected values

Serum, plasma

Adults		
20 - 50 years	8.8-10.2 mg/dl	(2.20-2.55 mmol/L)
>50 years	8.4- 9.7 mg/dl	(2.09-2.42 mmol/L)
Children		
4 -18years	9.2-11.0 mg/dl	(2.30-2.75 mmol/L)
>4 weeks	7.2-11.2 mg/dl	(1.80-2.8 mmol/L)
Urine (24 h)		
Females	<250 mg/day	(<6.25 mmol/day)
Males	<300 mg/day	(<7.5 mmol/day)
Childern	<6 mg/Kg/day	(<0.15 mmol/day)

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

2 – 20 mg/dl (0.5-5 mmol/L).

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Barnett RN: A scheme for the comparison of quantitative methods. AM J Clin Pathol 43: 562, 1965.
2. Fiereck EA: Appendix. Normal values. in:Fundamentals of clinical chemistry. NW Tietz, editor,Saunders, Philadelphia, p1208,1976.
3. Kessler G, wolfman M: An automated procedure for the simultaneous determination of calcium and phosphorus.Clin Chem 10:686, 1964.
4. Peters JP, Van Slyke, DD: Quantitative clinical chemistry, vol 2,williams and wilkins, Baltimor (MD),1932, p 760.
5. Tietz NW: Blood gases and electrolytes. In:Fundamentals of clinical chemistry, NW tietz, editor,Saunders, Philadelphia, 176,pp 903, 908.
6. Young DS, Effects of drugs on clinical laboratory tests. AACC press, Washington, D.C. 1990.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
226 001	2 x 30 ml
226 002	2 x 100 ml
226 003	4 x 100 ml
226 004	2 x 50 ml

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Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
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www.spectrum-diagnostics.com
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EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

TÜV SÜDWEST CERTIFIED ISO 13485:2016

SPECTRUM

The Creative Approach to Bioscience

Urea/BUN - Liquizyme
(Modified Urease-Berthlot Method)

REF: 318 001	100 test	REF: 318 002	200 test
R1 Buffer	1 x 100 ml	R1 Buffer	2 x 100 ml
R2 Urease	1 x 6 ml	R2 Urease	2 x 6 ml
R3 Alkaline reagent	1 x 20 ml	R3 Alkaline reagent	1 x 45 ml

REF: 318 003	500 test	REF: 318 004	1000 test
R1 Buffer	5 x 100 ml	R1 Buffer	4 x 250 ml
R2 Urease	2 x 15 ml	R2 Urease	1 x 51 ml
R3 Alkaline reagent	2 x 55 ml	R3 Alkaline reagent	1 x 210 ml

Intended Use

Spectrum Diagnostics colorimetric urea reagent is intended for the in-vitro quantitative, diagnostic determination of urea in human serum,plasma or urine on both automated and manual systems.

Background

Urea is the major end product of protein nitrogen metabolism. It is synthesized by the urea cycle in the liver and excreted through the kidneys. The circulating levels of urea depend upon protein intake, protein catabolism and kidney function. Elevated urea levels can occur due to renal impairment or in some diseases such as diabetes, infection, congestive heart failure and during different liver diseases. Determination of blood urea nitrogen is the most widely used screening test for renal function together with serum creatinine.

Method

Urease-colorimetric method.

Assay Principle

The reaction involved in the assay system is as follows:
Urea is hydrolyzed in the presence of water and urease to produce ammonia and carbon dioxide.

$$Urea + H_2O \xrightarrow{Urease} 2NH_3 + CO_2$$

The free ammonia in an alkaline pH and in the presence of indicator forms coloured complex proportional to the urea concentration in the specimen.

Reagents

Standard urea (ST) Aqueous primary standard
50 mg/dL 8.33 mmol/l

Reagent 1 (R1 Buffer)

Phosphate buffer pH 8.0	100 mmol/l
Sodium salicylate	80 mmol/l
Sodium nitroprusside	6.0 mmol/l
EDTA	30.0 mmol/l

Reagent 2 (R2 Enzyme)
Urease >6000 U/l

Reagent 3 (R3 Alkaline Reagent)

Sodium hydroxide	400 mmol/l
Sodium hypochlorite	20.0 mmol/l

Irritant (xi) R36/38: Irritating to eyes and skin. **S26:** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. **S37/39:** Wear suitable gloves and eye/face protection.

For further information, refer to the Urea/BUN reagent material safety data sheet.

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Preparation, Storage and Stability

Spectrum colorimetric urea reagents are supplied ready-to-use and stable up to the expiry date labeled on the bottles at(2 – 8 ^{o}C). Once opened, the reagent and standard are stable for 3 months at the specified temperature.

NB: For mega labs having high numbers of patient specimens,working buffer reagent can be prepared .(**Stability 1 week**)

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

REF:318 001: add 5 ml from R2 to one bottle of R1; mix gently.
REF:318 002: add 5 ml from R2 to one bottle of R1; mix gently.
REF:318 003: add 5 ml from R2 to one bottle of R1; mix gently.
REF:318 004: add 12.5 ml from R2 to one bottle of R1; mix gently.

Deterioration

Do not use the reagent if it is turbid. Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Specimen Collection and Preservation

Serum and plasma
No special preparation of the patient is required. Use non haemolyzed serum or plasma.The only acceptable anticoagulants are heparin, EDTA and flouride.Do not use ammonium heparin plasma.
Stability: 7 days at 15 –25^{o}C ; 7 days at 2 – 8 ^{o}C;
1 year at -20 ^{o}C

Urine
Urine samples are prediluted 1 : 50 with ammonium free water prior to assay.
Stability: 2 days at 15 –25 ^{o}C ; 7 days at 2 – 8 ^{o}C;
1 month at -20 ^{o}C

System Parameters

Wavelength	578 nm (578-623 nm)
Optical path	1 cm
Assay type	End-point
Direction	increase
temperature	15-25 ^{o}C or 37 ^{o}C
Zero adjustment	Against Reagent blank
Reagent Blank Limits	Low 0.02 AU
	High 0.2 AU
Sensitivity	0.6 mg/dL (0.1 mmol/l)
Linearity	200 mg/dL (33.3 mmol/l)

Procedure 1

	Blank	Standard	Specimen
R1(Buffer)	1.0 ml	1.0 ml	1.0 ml
R2(Enzyme)	one drop (50 µl)	one drop (50 µl)	one drop (50 µl)
Standard	-----	10 µl	-----
Sample	-----	-----	10 µl
Mix and incubate for at least 3 minutes at 37 ^{o}C or 5 minutes at 20-25 ^{o}C.			
R3(Alk.Reagent)	200 µl	200 µl	200 µl

Mix and incubate for 5 minutes at 37 ^{o}C or 10 minutes at 20-25 ^{o}C Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank.

Procedure 2 (Using working solution)

	Blank	Standard	Specimen
Working solution	1.0 ml	1.0 ml	1.0 ml
Standard	-----	10 µl	-----
Sample	-----	-----	10 µl
Mix and incubate for at least 3 minutes at 37 ^{o}C or 5 minutes at 20 -25 ^{o}C.			
R3(Alk.Reagent)	200 µl	200 µl	200 µl

Mix and incubate for 5 minutes at 37 ^{o}C or 10 minutes at 20-25 ^{o}C. Measure absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank.

Calculation

Serum urea concentration (mg/dl) = $\frac{A_{specimen}}{A_{standard}}$ x n

where n = 50.0 mg/dl (8.33 mmol/l)

Urine urea concentration is determined by multiplying the result by the dilution factor (50).

Urea Nitrogen: To convert the result from urea to urea nitrogen multiply the result by 0.467.

Quality Control

Normal and abnormal control serum of known concentrations should be analyzed with each run.

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	60	144
SD	1.87	2.1
CV%	3.12	1.46

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mg/dL)	62	146
SD	1.92	2.5
CV%	3.10	1.71

Methods Comparison

A comparison between Spectrum Diagnostics Urea/BUN reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.97 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of the assay is 0.6 mg/dL.

Linearity

The reaction is linear up to a urea concentration of (200 mg/dl) 33.3 mmol/L. Specimens showing higher concentrations should be diluted 1+2 with physiological saline and repeat the assay (result×3).

Interfering Substances

Haemolysis
Erythrocyte contamination doesn't elevate results.

Icterus
No significant interference.

Lipemia
Lipemic specimens interfere with the method of Berthlot.

Anticoagulants
Ammonium heparin should not be used.

Others
Ammonium ions should be avoided since it may cause erroneously elevated results. Color development in the Berthlot reaction is suppressed by amines, thiols, steroids and ascorbic acid.

Expected Values

Urea(Serum)

Adults ⩽ 65 years : 15 – 50 mg/dL (2.5-8.33 mmol/L)
Adults ⩾ 65 years : ⩽ 70 mg/dL (⩽11.66 mmol/L)

BUN(Serum)

Adults ⩽ 65 years : 7 – 23.5 mg/dL
Adults ⩾ 65 years : 7 – 32.9 mg/dL
Children : 5 – 18 mg/dL

Urine (24) hours

Urea : 20 – 35 g/24hrs (330-580 mmol/24hrs)
BUN : 9.3 – 16.4 g/24hrs

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Analytical Range

0.6 – 200 mg/dL (0.1 - 33.3 mmol/L).

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Batton, C. J & crouch, S.R : Anal. Chem., 1977,49:464-469.
2. Shephard MD, Mezzachi RD : Clin Biochem Revs, 4:61-7, 1983.
3. Tietz NW, ED. Clinical guide to Laboratory tests. 2ND ED. Philadelphia: WB Saunders; 1990:566.
4. Tiffany to, jansen JM, Burtis CA,Overton JB, Scott CD. Enzymatic Kinetic Rate and end Point analyses of Substrate, By USE of A Gemsaec fast analyzer. Clin Chem.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
318 001	100 Test
318 002	200 Test
318 003	500 Test
318 004	1000 Test

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TÜV SOUTHWEST CERTIFIED ISO 13485:2016

ABC CERTIFICATE

ABC CERTIFICATION hereby certifies that

Egyptian Company for Biotechnology (S.A.E) – Spectrum Diagnostics

Industrial Area Obour City Piece 19A, Block 20008, PO Box 30, Cairo - Egypt

Has been audited by ABC CERTIFICATION and has implemented

Medical Devices - Quality Management Systems

ISO 13485:2016

Scope of Certification

IVD Design, Development and Manufacturing

Code: A.1.4
Original Date: 25.06.2022
Re-certification 24.06.2025
Approval Date : 21.05.2023
Valid Period : 25.06.2023 ~ 24.06.2024
Certificate No : ABC-22-MD22

EGAC Accredited
MDQMS Certification
CAB # 012109

MDQMS Certification
CAB # 012109

CHIEF EXECUTIVE

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