



Certificate of CE-Registration

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

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

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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	γ- 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	γ- 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 Density 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 Density 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 Density 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	FERRITIN	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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REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
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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REF	Device Names (notified)	Optional information	Nomenclature (notified)	Code (notified)	Description (notified)	Class (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
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, Pyruvate 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, Pyruvate 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, Pyruvate 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

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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

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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

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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

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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 D-806 003	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 718 002-BO	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

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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

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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