

# 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:

**AccuBioTech Co., Ltd.  
Building 4, Maohua Industry Park, No. 1,  
CAIDA Third Street, Nancai Town, Shunyi District,  
101399 Beijing  
CHINA**

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 2022-07-26**

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.

2022-07-26



Dr. Patrick Pille  
Consultant  
MDSS GmbH

**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
-	Accu-Tell® Urine Reagent Test Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A36	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A42	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A252	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A253	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A243	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A37	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A38	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A334	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A39	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A40	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A41	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A34	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A380	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-UM-A381	Accu-Tell® Urine Reagent Strips	Strip	11 70 02 02	Urine Multi-constituent Test Strips (manual)	"Other"	N/A	DE/CA09/00035534
ABT-INF-B299	Accu-Tell® Calprotectin Semi-Quantitative Cassette	Cassette	12 01 90 10	Calprotectin	"Other"	N/A	DE/CA09/00103912
ABT-FOB-A22	Accu-Tell® FOB Strip	Cassette	12 03 90 04	Faecal Occult Blood (IC)	"Other"	N/A	DE/CA09/00087395
ABT-FOB-B22	Accu-Tell® Rapid FOB Test	Cassette	12 03 90 04	Faecal Occult Blood (IC)	"Other"	N/A	DE/CA09/00087395
ABT-CT-B59	Accu-Tell® Rapid Troponin I Test	Cassette	12 13 01 07	Troponin I/T	"Other"	N/A	DE/CA09/00086198
ABT-FT-A2	Accu-Tell® One Step HCG Urine/Serum Test	Strip	12 70 05 02	HCG - RT & POC	"Other"	N/A	DE/CA09/00087392
ABT-FT-B2	Accu-Tell® One Step HCG Urine/Serum Test	Cassette	12 70 05 02	HCG - RT & POC	"Other"	N/A	DE/CA09/00087392
ABT-FT-A387	Accu-Tell® HCG Multi-Line Strip (Urine)	Strip	12 70 05 02	HCG - RT & POC	"Other"	N/A	DE/CA09/00087392

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-FT-C387	Accu-Tell® HCG Multi-Line Midstream (Urine)	Midstream	12 70 05 02	HCG - RT & POC	"Other"	N/A	DE/CA09/00087392
ABT-FT-A1	Accu-Tell® One Step HCG Pregnancy Test	Strip	12 70 05 02	HCG - RT & POC	Self Test	0197/HL 2187098-1 2024-05-26	DE/CA09/00087391
ABT-FT-B1	Accu-Tell® One Step HCG Pregnancy Test	Cassette	12 70 05 02	HCG - RT & POC	Self Test	0197/HL 2187098-1 2024-05-26	DE/CA09/00087391
ABT-FT-C1	Accu-Tell® One Step HCG Pregnancy Test	Midstream	12 70 05 02	HCG - RT & POC	Self Test	0197/HL 2187098-1 2024-05-26	DE/CA09/00087391
ABT-DOA-A24	Accu-Tell® AMP Test	Strip	12 70 09 01	Amphetamines - RT & POC	Other	N/A	DE/CA09/00091639
ABT-DOA-B24	Accu-Tell® AMP Test	Cassette	12 70 09 01	Amphetamines - RT & POC	Other	N/A	DE/CA09/00091639
ABT-DOA-B46	Accu-Tell® AMP Cassette	Cassette	12 70 09 01	Amphetamines - RT & POC	Other	N/A	DE/CA09/00091639
ABT-DOA-A55	Accu-Tell® MDMA Test	Strip	12 70 09 02	Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC	Other	N/A	DE/CA09/00091638
ABT-DOA-B55	Accu-Tell® MDMA Test	Cassette	12 70 09 02	Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC	Other	N/A	DE/CA09/00091638
ABT-DOA-A25	Accu-Tell® MET Test	Strip	12 70 09 02	Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC	Other	N/A	DE/CA09/00091638
ABT-DOA-B25	Accu-Tell® MET Test	Cassette	12 70 09 02	Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC	Other	N/A	DE/CA09/00091638
ABT-DOA-B69	Accu-Tell® MET Cassette	Cassette	12 70 09 02	Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC	Other	N/A	DE/CA09/00091638
ABT-DOA-B87	Accu-Tell® MDMA Cassette	Cassette	12 70 09 02	Amphetamine/Methamphetamine Specific (+Ecstasy) - RT & POC	Other	N/A	DE/CA09/00091638
ABT-DOA-A28	Accu-Tell® BAR Test	Strip	12 70 09 03	Barbiturates - RT & POC	Other	N/A	DE/CA09/00091640
ABT-DOA-B28	Accu-Tell® BAR Test	Cassette	12 70 09 03	Barbiturates - RT & POC	Other	N/A	DE/CA09/00091640
ABT-DOA-B103	Accu-Tell® BAR Cassette	Cassette	12 70 09 03	Barbiturates - RT & POC	Other	N/A	DE/CA09/00091640
ABT-DOA-A29	Accu-Tell® BZO Test	Strip	12 70 09 04	Benzodiazepines - RT & POC	Other	N/A	DE/CA09/00091642
ABT-DOA-B29	Accu-Tell® BZO Test	Cassette	12 70 09 04	Benzodiazepines - RT & POC	Other	N/A	DE/CA09/00091642
ABT-DOA-B70	Accu-Tell® BZO Cassette	Cassette	12 70 09 04	Benzodiazepines - RT & POC	Other	N/A	DE/CA09/00091642
ABT-DOA-A165	Accu-Tell® Synthetic Marijuana (K2) Test	Strip	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-B165	Accu-Tell® Synthetic Marijuana (K2) Test	Cassette	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-B240	Accu-Tell® Synthetic Marijuana (K2) Cassette	Cassette	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-A27	Accu-Tell® THC Test	Strip	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-B27	Accu-Tell® THC Test	Cassette	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-B67	Accu-Tell® THC Cassette	Cassette	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-A267	Accu-Tell® Synthetic Marijuana K2 + (AB-Pinaca) Strip	Strip	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-B267	Accu-Tell® Synthetic Marijuana K2 + (AB-Pinaca) Cassette	Cassette	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-B392	Accu-Tell® THC Cassette (Saliva)	Cassette	12 70 09 05	Cannabinoids - RT & POC	Other	N/A	DE/CA09/00102773
ABT-DOA-A23	Accu-Tell® COC Test	Strip	12 70 09 06	Cocaine + Cocaine Metabolites - RT & POC	Other	N/A	DE/CA09/00091643
ABT-DOA-B23	Accu-Tell® COC Test	Cassette	12 70 09 06	Cocaine + Cocaine Metabolites - RT & POC	Other	N/A	DE/CA09/00091643
ABT-DOA-B48	Accu-Tell® COC Cassette	Cassette	12 70 09 06	Cocaine + Cocaine Metabolites - RT & POC	Other	N/A	DE/CA09/00091643
ABT-DOA-A30	Accu-Tell® MTD Test	Strip	12 70 09 07	Methadone incl. EDDP - RT & POC	Other	N/A	DE/CA09/00103061
ABT-DOA-B30	Accu-Tell® MTD Test	Cassette	12 70 09 07	Methadone incl. EDDP - RT & POC	Other	N/A	DE/CA09/00103061
ABT-DOA-B172	Accu-Tell® MTD Cassette	Cassette	12 70 09 07	Methadone incl. EDDP - RT & POC	Other	N/A	DE/CA09/00103061
ABT-DOA-A26	Accu-Tell® MOP Test	Strip	12 70 09 08	Opiates - RT & POC	Other	N/A	DE/CA09/00093542
ABT-DOA-B26	Accu-Tell® MOP Test	Cassette	12 70 09 08	Opiates - RT & POC	Other	N/A	DE/CA09/00093542
ABT-DOA-A161	Accu-Tell® OPI Test	Strip	12 70 09 08	Opiates - RT & POC	Other	N/A	DE/CA09/00093542
ABT-DOA-B161	Accu-Tell® OPI Test	Cassette	12 70 09 08	Opiates - RT & POC	Other	N/A	DE/CA09/00093542
ABT-DOA-B47	Accu-Tell® MOP Cassette	Cassette	12 70 09 08	Opiates - RT & POC	Other	N/A	DE/CA09/00093542
ABT-DOA-B244	Accu-Tell® OPI Cassette	Cassette	12 70 09 08	Opiates - RT & POC	Other	N/A	DE/CA09/00093542
ABT-DOA-B173	Accu-Tell® PCP Cassette	Cassette	12 70 09 09	Phencyclidine - RT & POC	Other	N/A	DE/CA09/00091862
ABT-DOA-A35	Accu-Tell® PCP Test	Strip	12 70 09 09	Phencyclidine - RT & POC	Other	N/A	DE/CA09/00091862
ABT-DOA-B35	Accu-Tell® PCP Test	Cassette	12 70 09 09	Phencyclidine - RT & POC	Other	N/A	DE/CA09/00091862
ABT-DOA-A54	Accu-Tell® TCA Test	Strip	12 70 09 10	Tricyclic Antidepressants - RT & POC	Other	N/A	DE/CA09/00093543
ABT-DOA-B54	Accu-Tell® TCA Test	Cassette	12 70 09 10	Tricyclic Antidepressants - RT & POC	Other	N/A	DE/CA09/00093543
ABT-DOA-G130	Accu-Tell® Multi-10 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G127	Accu-Tell® Multi-7 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G128	Accu-Tell® Multi-8 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G129	Accu-Tell® Multi-9 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
-	Accu-Tell® One Step Multi-10 Drug of Abuse Test	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B144	Accu-Tell® Rapid Multi-4 Drug Test	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E31	Accu-Tell® Rapid Multi-5 Drug Test	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-E32	Accu-Tell® Rapid Multi-6 Drug Test	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G126	Accu-Tell® Multi-6 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H130	Accu-Tell® Multi-10 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA- B351	Accu-Tell® Multi-Line 12 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E73	Accu-Tell® Multi-7 Drug Panel	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E51	Accu-Tell® Multi-2 Drug Panel (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E44	Accu-Tell® Multi-3 Drug Panel (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E45	Accu-Tell® Multi-4 Drug Panel (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E74	Accu-Tell® Multi-8 Drug Panel (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E75	Accu-Tell® Multi-9 Drug Panel (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E319	Accu-Tell® Multi-11 Drug Panel (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-E320	Accu-Tell® Multi-12 Drug Panel (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D282	Accu-Tell® Multi-2 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D283	Accu-Tell® Multi-3 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D284	Accu-Tell® Multi-4 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D285	Accu-Tell® Multi-5 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D286	Accu-Tell® Multi-6 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D287	Accu-Tell® Multi-7 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D288	Accu-Tell® Multi-8 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-D289	Accu-Tell® Multi-9 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D290	Accu-Tell® Multi-10 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D355	Accu-Tell® Multi-11 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-D356	Accu-Tell® Multi-12 Drug Dip Card (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B112	Accu-Tell® Multi-2 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B113	Accu-Tell® Multi-3 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B114	Accu-Tell® Multi-4 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B115	Accu-Tell® Multi-5 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B116	Accu-Tell® Multi-Line 6 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B117	Accu-Tell® Multi-Line 7 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B118	Accu-Tell® Multi-Line 8 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B119	Accu-Tell® Multi-Line 9 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B120	Accu-Tell® Multi-Line 10 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B350	Accu-Tell® Multi-Line 11 Drug Cassette (Urine)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M122	Accu-Tell® Multi-2 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M123	Accu-Tell® Multi-3 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M124	Accu-Tell® Multi-4 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M125	Accu-Tell® Multi-5 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-M125	Accu-Tell® Multi-Line 5 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M126	Accu-Tell® Multi-Line 6 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M127	Accu-Tell® Multi-Line 7 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M128	Accu-Tell® Multi-Line 8 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M129	Accu-Tell® Multi-Line 9 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M130	Accu-Tell® Multi-Line 10 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M131	Accu-Tell® Multi-Line 11 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-M132	Accu-Tell® Multi-Line 12 Drug Cup W/Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H122	Accu-Tell® Multi-2 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H123	Accu-Tell® Multi-3 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H124	Accu-Tell® Multi-4 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H125	Accu-Tell® Multi-5 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H126	Accu-Tell® Multi-6 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H127	Accu-Tell® Multi-Line 7 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H128	Accu-Tell® Multi-Line 8 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H129	Accu-Tell® Multi-Line 9 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H131	Accu-Tell® Multi-Line 11 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-H132	Accu-Tell® Multi-Line 12 Drug Cup W/Lock (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-L122	Accu-Tell® Multi-2 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L123	Accu-Tell® Multi-3 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L124	Accu-Tell® Multi-4 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L125	Accu-Tell® Multi-5 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L126	Accu-Tell® Multi-6 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L127	Accu-Tell® Multi-7 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L128	Accu-Tell® Multi-8 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L129	Accu-Tell® Multi-9 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L130	Accu-Tell® Multi-10 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L131	Accu-Tell® Multi-11 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L132	Accu-Tell® Multi-12 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L133	Accu-Tell® Multi-13 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L134	Accu-Tell® Multi-14 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L135	Accu-Tell® Multi-15 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L136	Accu-Tell® Multi-16 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-L137	Accu-Tell® Multi-17 Drug Cup W/Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G122	Accu-Tell® Multi-2 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G123	Accu-Tell® Multi-3 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAH





**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-G124	Accu-Tell® Multi-4 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G125	Accu-Tell® Multi-5 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G131	Accu-Tell® Multi-11 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G132	Accu-Tell® Multi-12 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G133	Accu-Tell® Multi-13 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G134	Accu-Tell® Multi-14 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G135	Accu-Tell® Multi-15 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G136	Accu-Tell® Multi-16 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G137	Accu-Tell® Multi-17 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-G138	Accu-Tell® Multi-18 Drug Cup (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B142	Accu-Tell® Multi-2 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B143	Accu-Tell® Multi-3 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B145	Accu-Tell® Multi-5 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B146	Accu-Tell® Multi-Line 6 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B147	Accu-Tell® Multi-Line 7 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B148	Accu-Tell® Multi-Line 8 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B149	Accu-Tell® Multi-Line 9 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B150	Accu-Tell® Multi-Line 10 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-B388	Accu-Tell® Multi-Line 11 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-B389	Accu-Tell® Multi-Line 12 Drug Cassette (Saliva)	Cassette	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N340	Accu-Tell® Multi-2 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N341	Accu-Tell® Multi-3 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N342	Accu-Tell® Multi-4 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N343	Accu-Tell® Multi-5 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N344	Accu-Tell® Multi-6 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N345	Accu-Tell® Multi-7 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N346	Accu-Tell® Multi-8 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N347	Accu-Tell® Multi-9 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N348	Accu-Tell® Multi-10 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N390	Accu-Tell® Multi-11 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-N391	Accu-Tell® Multi-12 Drug Cup W/Indicator (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K340	Accu-Tell® Multi-2 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K341	Accu-Tell® Multi-3 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K342	Accu-Tell® Multi-4 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K343	Accu-Tell® Multi-5 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K344	Accu-Tell® Multi-6 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-K345	Accu-Tell® Multi-7 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K346	Accu-Tell® Multi-8 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K347	Accu-Tell® Multi-9 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K348	Accu-Tell® Multi-10 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-K390	Accu-Tell® Multi-11 Drug Cup W/Indicator & Alcohol (Saliva)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O51	Accu-Tell® Multi-2 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O44	Accu-Tell® Multi-3 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O45	Accu-Tell® Multi-4 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O31	Accu-Tell® Multi-5 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O32	Accu-Tell® Multi-6 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O73	Accu-Tell® Multi-7 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O74	Accu-Tell® Multi-8 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O75	Accu-Tell® Multi-9 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-O53	Accu-Tell® Multi-10 Drug Panel W/Alcohol & Adulteration Strip (Urine)	Panel	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-P122	Accu-Tell® Multi-Line 2 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-P123	Accu-Tell® Multi-Line 3 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-P124	Accu-Tell® Multi-Line 4 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-P125	Accu-Tell® Multi-Line 5 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAA



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-P126	Accu-Tell® Multi-Line 6 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-P127	Accu-Tell® Multi-Line 7 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-P128	Accu-Tell® Multi-Line 8 Drug Cup W/Alcohol & Lock & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q122	Accu-Tell® Multi-2 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q123	Accu-Tell® Multi-3 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q124	Accu-Tell® Multi-4 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q125	Accu-Tell® Multi-5 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q126	Accu-Tell® Multi-6 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q127	Accu-Tell® Multi-7 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q128	Accu-Tell® Multi-8 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q129	Accu-Tell® Multi-9 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q130	Accu-Tell® Multi-10 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q131	Accu-Tell® Multi-11 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q132	Accu-Tell® Multi-12 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q133	Accu-Tell® Multi-13 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q134	Accu-Tell® Multi-14 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q135	Accu-Tell® Multi-15 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-Q136	Accu-Tell® Multi-16 Drug Cup W/Alcohol & Adulteration Strip (Urine)	Cup	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-C144	Accu-Tell® Multi-Line 4 Drug Device (Saliva)	Device	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-C145	Accu-Tell® Multi-Line 5 Drug Device (Saliva)	Device	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-C146	Accu-Tell® Multi-Line 6 Drug Device (Saliva)	Device	12 70 09 70	Multiple Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00087393
ABT-DOA-A140	Accu-Tell® BUP Test	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B140	Accu-Tell® BUP Test	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-A141	Accu-Tell® COT Test	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B141	Accu-Tell® COT Test	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-A170	Accu-Tell® Ethyl Glucuronide (ETG) Test	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B170	Accu-Tell® Ethyl Glucuronide (ETG) Test	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-A159	Accu-Tell® FYL Test	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B159	Accu-Tell® FYL Test	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-A102	Accu-Tell® KET Test	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B102	Accu-Tell® KET Test	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-A162	Accu-Tell® OXY Test	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B162	Accu-Tell® OXY Test	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-A164	Accu-Tell® TML Test	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B164	Accu-Tell® TML Test	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	Other	N/A	DE/CA09/00091641
ABT-DOA-B104	Accu-Tell® BUP Cassette	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00091641
ABT-DOA-B175	Accu-Tell® COT Cassette	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00091641
ABT-DOA-B176	Accu-Tell® KET Cassette	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00091641

TAH



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-DOA-B171	Accu-Tell® OXY Cassette	Cassette	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00091641
ABT-ACH-A187	Accu-Tell® Alcohol Strip	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00091641
ABT-ACH-A188	Accu-Tell® Alcohol Strip (Urine)	Strip	12 70 09 90	Other Drugs of Abuse/Toxicology RT & POC	"Other"	N/A	DE/CA09/00091641
ABT-CT-A251	Accu-Tell® CRP Test Semi-Quantitative Test	Strip	12 70 11 01	C-Reactive Protein - RT & POC	Other	N/A	DE/CA09/00091637
ABT-CT-B251	Accu-Tell® CRP Test Semi-Quantitative Test	Cassette	12 70 11 01	C-Reactive Protein - RT & POC	Other	N/A	DE/CA09/00091637
ABT-INF-B318	Accu-Tell® CRP Semi-Quantitative Cassette	Cassette	12 70 11 01	C-Reactive Protein - RT & POC	Other	N/A	DE/CA09/00091637
ABT-CT-A66	Accu-Tell® CK-MB Test	Strip	12 70 13 01	Creatine Kinase - MB mass - RT & POC	"Other"	N/A	DE/CA09/00090993
ABT-CT-B66	Accu-Tell® CK-MB Test	Cassette	12 70 13 01	Creatine Kinase - MB mass - RT & POC	"Other"	N/A	DE/CA09/00090993
ABT-CT-A68	Accu-Tell® Myoglobin Test	Strip	12 70 13 02	Myoglobin - RT & POC	Other	N/A	DE/CA09/00091634
ABT-CT-B68	Accu-Tell® Myoglobin Test	Cassette	12 70 13 02	Myoglobin - RT & POC	Other	N/A	DE/CA09/00091634
ABT-CT-A111	Accu-Tell® NT-proBNP Test	Strip	12 70 13 04	BNP / proBNP - RT & POC (including other Natriuric Peptides)	Other	N/A	DE/CA09/00091636
ABT-CT-B111	Accu-Tell® NT-proBNP Test	Cassette	12 70 13 04	BNP / proBNP - RT & POC (including other Natriuric Peptides)	Other	N/A	DE/CA09/00091636
ABT-CT-E71	Accu-Tell® Myoglobin/CK-MB/Troponin I Test	Cassette	12 70 13 70	Multiple Cardiac Markers - RT & POC	Other	N/A	DE/CA09/00091635
ABT-IDT-A266	Accu-Tell® PCT Semi-Quantitative Test	Strip	12 70 90 90	Other other RT and POC - Immunochemistry	"Other"	N/A	DE/CA09/00090960
ABT-IDT-B266	Accu-Tell® PCT Semi-Quantitative Test	Cassette	12 70 90 90	Other other RT and POC - Immunochemistry	"Other"	N/A	DE/CA09/00090960
ABT-CT-A110	Accu-Tell® Rapid D-Dimer Test	Strip	13 02 70 03	D-Dimer - RT & POC	"Other"	N/A	DE/CA09/00090992
ABT-CT-B110	Accu-Tell® Rapid D-Dimer Test	Cassette	13 02 70 03	D-Dimer - RT & POC	"Other"	N/A	DE/CA09/00090992
ABT-IDT-B370	Accu-Tell® SARS-CoV-2+Flu A&B Antigen Combo Cassette	Cassette	15 30 02 90	Other Multiple Viruses - Multiplex Assays	"Other"	N/A	DE/CA09/00098842
ABT-IDT-A13	Accu-Tell® H. pylori IgG Strip	Strip	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/00087396
ABT-IDT-B13	Accu-Tell® H. pylori IgG Cassette	Cassette	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/00087396
ABT-IDT-B76	Accu-Tell® Rapid H. pylori Antigen Test	Cassette	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/00087396
ABT-IDT-B262	Accu-Tell® H. pylori IgG Cassette	Cassette	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/00087396
ABT-IDT-B385	Accu-Tell® H. pylori IgG/IgM/IgA Cassette	Cassette	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/00087396
ABT-IDT-A385	Accu-Tell® H. pylori IgG/IgM/IgA Strip	Strip	15 70 01 02	H. Pylori - RT & POC	"Other"	N/A	DE/CA09/00087396
ABT-IDT-B15	Accu-Tell® Rapid Strep A Test	Cassette	15 70 01 03	Strep A - RT & POC	"Other"	N/A	DE/CA09/00087264
ABT-IDT-A15	Accu-Tell® Rapid Strep A Test	Strip	15 70 01 03	Strep A - RT & POC	"Other"	N/A	DE/CA09/00087264



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-STD-A60	Accu-Tell® Rapid Syphilis Test	Strip	15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/00088771
ABT-STD-B60	Accu-Tell® Rapid Syphilis Test	Cassette	15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/00088771
ABT-STD-A17	Accu-Tell® Syphilis Strip	Strip	15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/00088771
ABT-STD-B17	Accu-Tell® Syphilis Cassette	Cassette	15 70 01 05	Syphilis - RT & POC	"Other"	N/A	DE/CA09/00088771
ABT-IDT-B315	Accu-Tell® Clostridium difficile GDH Test	Cassette	15 70 01 06	Clost. diff. incl GDH and/or Toxin A and B - RT & POC	"Other"	N/A	DE/CA09/00090962
ABT-IDT-B316	Accu-Tell® Clostridium difficile GDH +Toxin A+ Toxin B Combo Test	Cassette	15 70 01 06	Clost. diff. incl GDH and/or Toxin A and B - RT & POC	"Other"	N/A	DE/CA09/00090962
ABT-IDT-B314	Accu-Tell® Clostridium difficile Toxin A+ Toxin B Combo Test	Cassette	15 70 01 06	Clost. diff. incl GDH and/or Toxin A and B - RT & POC	"Other"	N/A	DE/CA09/00090962
ABT-IDT-B303	Accu-Tell® Legionella Test	Cassette	15 70 01 08	Legionella - RT & POC	"Other"	N/A	DE/CA09/00093544
ABT-IDT-A57	Accu-Tell® Rapid Tuberculosis Test	Strip	15 70 01 90	Other Bacteriology - RT & POC	"Other"	N/A	DE/CA09/00087397
ABT-IDT-B57	Accu-Tell® Rapid Tuberculosis Test	Cassette	15 70 01 90	Other Bacteriology - RT & POC	"Other"	N/A	DE/CA09/00087397
-	Accu-Tell® Rapid Typhoid Test	Cassette	15 70 01 90	Other Bacteriology - RT & POC	"Other"	N/A	DE/CA09/00087397
ABT-IDT-B260	Accu-Tell® TB Cassette	Cassette	15 70 01 90	Other Bacteriology - RT & POC	"Other"	N/A	DE/CA09/00087397
ABT-IDT-B263	Accu-Tell® Typhoid Cassette	Cassette	15 70 01 90	Other Bacteriology - RT & POC	"Other"	N/A	DE/CA09/00087397
ABT-IDT-A218	Accu-Tell® HAV IgM Test	Strip	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00092337
ABT-IDT-B218	Accu-Tell® HAV IgM Test	Cassette	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00092337
ABT-IDT-A226	Accu-Tell® HAV IgM/IgG Test	Strip	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00092337
ABT-IDT-B226	Accu-Tell® HAV IgM/IgG Cassette	Cassette	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00092337
ABT-IDT-B246	Accu-Tell® HEV IgM Cassette	Cassette	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00092337
ABT-IDT-B231	Accu-Tell® HAV IgG Cassette	Cassette	15 70 02 90	Other Hepatitis Viruses - RT & POC	Other	N/A	DE/CA09/00092337
ABT-IDT-B58	Accu-Tell® Rapid Malaria P.f. /P.v. Test	Cassette	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/00089311
ABT-IDT-B236	Accu-Tell® Rapid Malaria P.f. /P.v./Pan Test	Cassette	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/00089311
ABT-IDT-A99	Accu-Tell® Rapid Malaria P.f. /Pan Test	Strip	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/00089311
ABT-IDT-B99	Accu-Tell® Rapid Malaria P.f. /Pan Test	Cassette	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/00089311
ABT-IDT-B85	Accu-Tell® Malaria P.f. Cassette	Cassette	15 70 05 01	Plasmodium (Malaria) - RT & POC	"Other"	N/A	DE/CA09/00089311
ABT-IDT-A219	Accu-Tell® Chagas Test	Strip	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00091861
ABT-IDT-B219	Accu-Tell® Chagas Test	Cassette	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00091861
ABT-IDT-A292	Accu-Tell® Entamoeba histolytica Test	Strip	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00091861
ABT-IDT-B292	Accu-Tell® Entamoeba histolytica Test	Cassette	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00091861
ABT-IDT-A255	Accu-Tell® Giardia lamblia Test	Strip	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00091861
ABT-IDT-B255	Accu-Tell® Giardia lamblia Test	Cassette	15 70 05 90	Other Parasites - RT & POC	Other	N/A	DE/CA09/00091861
ABT-IDT-B296	Accu-Tell® RSV Antigen Cassette	Cassette	15 70 90 02	RSV - RT & POC	Other	N/A	DE/CA09/00103063



**Annex A: 2022-07-26**  
**Manufacturer: AccuBioTech Co., Ltd.**

REF, UDI, Model Number	Notified Device Names	Additional Information (optional)	Notified EDMA Code	Notified EDMA Description	Notified Class.	Notified EC Certificate No. & Expiry	German Registration Number
ABT-IDT-A247	Accu-Tell® Influenza A+B Test	Strip	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/00092338
ABT-IDT-B247	Accu-Tell® Influenza A+B Test	Cassette	15 70 90 04	Influenza A and /or B - RT & POC	Other	N/A	DE/CA09/00092338
ABT-IDT-B97	Accu-Tell® Rapid Dengue IgG/IgM Test	Cassette	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/00087425
ABT-IDT-B217	Accu-Tell® Rapid Dengue IgG/IgM/NS1 Test	Cassette	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/00087425
ABT-IDT-B216	Accu-Tell® Rapid Dengue NS1 Test	Cassette	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/00087425
ABT-IDT-B274	Accu-Tell® Dengue NS1 Antigen Cassette	Cassette	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/00087425
ABT-IDT-B259	Accu-Tell® Dengue IgG/IgM/NS1 Combo Cassette	Cassette	15 70 90 07	Dengue - RT & POC	"Other"	N/A	DE/CA09/00087425
ABT-IDT-B371; ABT-IDT-B373	Accu-Tell® SARS-CoV-2 Neutralizing Antibody Cassette	Cassette	15 70 90 08	Coronavirus - RT & POC	"Other"	N/A	DE/CA09/00098928
ABT-IDT-B372; ABT-IDT-B374; ABT-IDT-B384; ABT-IDT-B378	Accu-Tell® COVID-19 Antigen Cassette	Cassette	15 70 90 08	Coronavirus - RT & POC	"Other"	N/A	DE/CA09/00098928
ABT-IDT-B352	Accu-Tell® COVID-19 IgG/IgM Cassette	Cassette	15 70 90 08	Coronavirus - RT & POC	"Other"	N/A	DE/CA09/00098928
ABT-IDT-B367	Accu-Tell® SARS-CoV-2 Ag Cassette	Cassette	15 70 90 08	Coronavirus - RT & POC	"Other"	N/A	DE/CA09/00098928
ABT-IDT-B256	Accu-Tell® Norovirus Test	Cassette	15 70 90 90	Other Other Virology RT & POC	"Other"	N/A	DE/CA09/00087394
-	Accu-Tell® Rapid Chikungunya IgG/IgM Test	Cassette	15 70 90 90	Other Other Virology RT & POC	"Other"	N/A	DE/CA09/00087394
ABT-IDT-B63	Accu-Tell® Rotavirus Test	Cassette	15 70 90 90	Other Other Virology RT & POC	"Other"	N/A	DE/CA09/00087394
ABT-IDT-B64	Accu-Tell® Rotavirus/Adenovirus Test	Cassette	15 70 90 90	Other Other Virology RT & POC	"Other"	N/A	DE/CA09/00087394

