



DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Hangzhou Tongzhou Biotechnology Co., Ltd.
Address: Room 102, Building 4, No. 191, Xintian Road, Yunhe Street,
Linping District, Hangzhou, China.

EC Representative: VidaQuick Biotech S.L.
Address: No.132, Rosello Street, Barcelona, Barcelona Province, 08036,
Spain

Product Name: See attachment

Classification: Other

Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO13485:2016, EN ISO14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2021

Signature: Steve Shao
Name / Position: Steve Shao / General Manager

Date: 25/05/2022

Place: Hangzhou / China



No.	Product Description
1	Pregnancy (hCG) Rapid Test
2	Pregnancy (hCG) Rapid Test (Urine)
3	Pregnancy (hCG) Rapid Test Midstream
4	Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine)
5	Pregnancy (hCG) Rapid Test (Whole Blood/Serum/Plasma)
6	Ovulation (LH) Rapid Test
7	Ovulation (LH) Rapid Test Midstream
8	FSH Rapid Test
9	AMH Rapid Test
10	Fetal Fibronectin (fFN) Rapid Test
11	Insulin-like Growth Factor-binding Protein 1 (IGFBP-1) Rapid Test
12	HSV 1/2 IgM Rapid Test (Serum/Plasma)
13	HSV 1/2 IgM Rapid Test (Whole Blood/Serum/Plasma)
14	HSV 1/2 IgG/IgM Rapid Test (Serum/Plasma)
15	HSV 1/2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)
16	HSV 1/2 IgG/IgM Combo Rapid Test
17	HSV 1/2 IgG Rapid Test (S/P)
18	HSV 1/2 IgG Rapid Test (WB/S/P)
19	Candida albicans Rapid Test
20	Gonorrhea Rapid Test
21	Strep B Rapid Test
22	Trichomonas Vaginalis Rapid Test
23	Candida albicans and Trichomonas Vaginalis Combo Rapid Test
24	Shigella Rapid Test
25	Shigella Flexneri Antigen Rapid Test
26	Shigella Sonnei Antigen Rapid Test
27	Adenovirus Rapid Test
28	Rotavirus Rapid Test
29	Norovirus Rapid Test

30	Rotavirus and Adenovirus Combo Rapid Test
31	Rotavirus and Adenovirus Combo Rapid Test Cup
32	Norovirus, Rotavirus and Adenovirus Combo Rapid Test
33	Astrovirus Rapid Test
34	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test
35	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test Cup
36	Entamoeba histolytica Rapid Test
37	Giardia Lamblia Rapid Test
38	Cryptosporidium Rapid Test
39	Cryptosporidium and Giardia Lamblia Combo Rapid Test
40	Entamoeba/Giardia/Crypto Rapid Test (1 Window)
41	Entamoeba/Giardia/Crypto Combo Rapid Test (3 Windows)
42	Campylobacter Rapid Test
43	Clostridium difficile GDH Rapid Test
44	Clostridium difficile Toxin A+Toxin B Combo Rapid Test
45	Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test
46	H. pylori Antibody Rapid Test (Serum/Plasma)
47	H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma)
48	H. pylori Antigen Rapid Test
49	H. pylori Antigen Rapid Test Cup
50	Vibrio cholerae O1 (VC O1) Rapid Test
51	Vibrio cholerae O139 (VC O139) Rapid Test
52	Vibrio cholerae O1/O139 Combo Rapid Test
53	Chagas Rapid Test (Serum/Plasma)
54	Chagas Rapid Test (Whole Blood/Serum/Plasma)
55	Chikungunya IgG/IgM Rapid Test (Serum/Plasma)
56	Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)
57	Dengue IgG/IgM Rapid Test
58	Dengue NS1 Rapid Test
59	Dengue IgG/IgM And NS1 Combo Rapid Test

60	Zika NS1 Rapid Test
61	Zika IgG/IgM Rapid Test
62	Zika IgG/IgM and NS1 Combo Rapid Test
63	Filariasis IgG/IgM Rapid Test (Serum/Plasma)
64	Filariasis IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)
65	Typhoid IgG/IgM Rapid Test (Serum/Plasma)
66	Typhoid IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)
67	Salmonella typhi Antigen Rapid Test
68	Leishmania IgG/IgM Rapid Test
69	Leptospira IgG/IgM Rapid Test
70	Malaria P.f. Rapid Test
71	Malaria P.f./ Pan Rapid Test
72	Malaria P.f./P.v. Rapid Test
73	Malaria P.f./P.v./Pan Rapid Test
74	HEV IgG/IgM Rapid Test
75	Syphilis Rapid Test (S/P)
76	Syphilis Rapid Test
77	Strep A Rapid Test (Control Line in Red)
78	Strep A Rapid Test (Control Line in Blue)
79	Streptococcus pneumoniae Antigen Rapid Test
80	Mycoplasma pneumoniae Antigen Rapid Test
81	Mycoplasma Pneumoniae IgG/IgM Combo Rapid Test
82	MONO Rapid Test
83	Adenovirus pneumoniae Antigen Rapid Test
84	Influenza A+B Rapid Test
85	Influenza A Rapid Test
86	RSV Rapid Test
87	RSV&Influenza A+B Combo Rapid Test
88	Adenovirus&RSV Combo Rapid Test
89	Adenovirus, RSV and Influenza A+B Combo Rapid Test

90	Brucella Abortus Antigen Rapid Test
91	Lyme IgG/IgM Rapid Test
92	Tetanus Rapid Test
93	Tuberculosis (TB) Rapid Test
94	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test
95	SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test
96	SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test
97	SARS-CoV-2 and M.pneumoniae IgG Combo Rapid Test
98	SARS-CoV-2 and M.pneumoniae IgG/IgM Combo Rapid Test
99	SARS-CoV-2 IgG Rapid Test
100	SARS-CoV-2 S-RBD IgG Antibody Rapid Test
101	SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test
102	Legionella pneumophila Rapid Test
103	Mycoplasma Pneumoniae IgM Rapid Test
104	EBV VCA IgG Rapid Test
105	EBNA IgG Rapid Test
106	EBV VCA and EBNA IgG Combo Rapid Test
107	S. pneumoniae and L. pneumophila Combo Rapid Test
108	Scrub Typhus IgG/IgM Rapid Test
109	Cryptococcus Antigen Rapid Test
110	H1N1 Antigen Rapid Test
111	HAV IgM Rapid Test
112	HAV IgG/IgM Combo Rapid Test
113	Influenza A/B+H1N1 Combo Rapid Test
114	Salmonella paratyphi Antigen Rapid Test
115	Salmonella typhi and paratyphi Antigen Combo Rapid Test
116	Monkeypox Antibody Rapid Test
117	Monkeypox Antigen Rapid Test
118	2019-nCoV IgG/IgM Rapid Test
119	SARS-CoV-2 Neutralization Antibody Rapid Test

120	Salmonella typhi and paratyphi B Antigen Combo Rapid Test
121	SARS-CoV-2 and RSV Antigen Combo Rapid Test
122	HMPV Rapid Test
123	7-Aminoclonazepam (7-ACL) Rapid Test
124	Amphetamine (AMP) Rapid Test
125	Barbiturate (BAR) Rapid Test
126	Buprenorphine (BUP) Rapid Test
127	Benzodiazepines (BZO) Rapid Test
128	Cocaine (COC) Rapid Test
129	Cotinine (COT) Rapid Test
130	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test
131	Ethyl Glucuronide (ETG) Rapid Test
132	Fentanyl (FYL) Rapid Test
133	Ketamine (KET) Rapid Test
134	Ecstasy (MDMA) Rapid Test
135	Methamphetamine (MET) Rapid Test
136	Morphine (MOP) Rapid Test
137	Methylphenidate (MPD) Rapid Test
138	Methadone (MTD) Rapid Test
139	Opiates (OPI) Rapid Test
140	Oxycodone (OXY) Rapid Test
141	Phencyclidine (PCP) Rapid Test
142	Synthetic Marijuana (K2) Rapid Test
143	Tricyclic Antidepressants (TCA) Rapid Test
144	Marijuana (THC) Rapid Test
145	Zolpidem (ZOL) Rapid Test
146	Zopiclone (ZOP) Rapid Test
147	AB-PINACA (ABP) Rapid Test
148	α -Pyrrolidinovalerophenone (α -PVP) Rapid Test
149	Cathine (CAT) Rapid Test

150	Carisoprodol(CAR) Rapid Test
151	Carfentanyl(CFYL) Rapid Test
152	Citalopram(CIT) Rapid Test
153	Fluoketamine (FKET) Rapid Test
154	Fluoxetine (FLX) Rapid Test
155	Gabapentin(GAB) Rapid Test
156	Kratom(KRA) Rapid Test
157	Lysergic Acid Diethylamide (LSD) Rapid Test
158	Methcathinone(MCAT) Rapid Test
159	Mescaline (MES) Rapid Test
160	Meperidine (MPRD) Rapid Test
161	Methaqualone (MQL) Rapid Test
162	Pregabalin (PGB) Rapid Test
163	Tilidine (TLD) Rapid Test
164	Tramadol (TML) Rapid Test
165	UR-144 Rapid Test
166	6-Monoacetylmorphine (6-MAM) Rapid Test
167	Methylenedioxypyrovalerone (MDPV) Rapid Test
168	Acetaminophen (ACE) Rapid Test
169	Diazepam (DIA) Rapid Test
170	Tenamfetamine (MDA) Rapid Test
171	Propoxyphene (PPX) Rapid Test
172	Cannabinol (CNB) Rapid Test
173	Risperidone (RPD) Rapid Test
174	Papaverine (PAP) Rapid Test
175	Alprazolam(ALP) Rapid Test
176	Caffeine(CAF) Rapid Test
177	Clonazepam (CLO) Rapid Test
178	Mephedrone HCl(MEP) Rapid Test
179	Quetiapine(QTP) Rapid Test

180	Trazodone(TZD) Rapid Test
181	Zaleplon(ZAL) Rapid Test
182	Tropicamide(TRO)Rapid Test
183	Olanzapine (OZP) Rapid Test
184	N, N-Dimethyltryptamine (NND) Rapid Test
185	Mirtazapine (MTZ) Rapid Test
186	Scopolamine (SCOP) Rapid Test
187	Tapentadol (TAP) Rapid Test
188	Etomidate (ETO) Rapid Test
189	Psilocybin (PY) Rapid Test
190	Xylazine (XYL) Rapid Test
191	Multi-Drugs Rapid Test
192	Multi-Drugs Rapid Test 1-Step Cup
193	Multi-Drugs Rapid Test Key Cup
194	Adenovirus/RSV/HMPV/HPIV/Influenza A+B Combo Rapid Test
195	HPIV Rapid Test
196	Mycoplasma pneumoniae and Influenza A+B Antigen Combo Rapid Test
197	Measles IgG/IgM Rapid Test
198	SARS-CoV-2 NPAb and NAb Combo Rapid Test
199	Multiplex Respiratory Virus Antigen Rapid Test
200	Dengue/Zika/Chikungunya Combo Rapid Test
201	Bordetella pertussis Antigen Rapid Test
202	Amphetamine (AMP) Rapid Test (Oral Fluid)
203	Barbiturates (BAR) Rapid Test (Oral Fluid)
204	Buprenorphine (BUP) Rapid Test (Oral Fluid)
205	Benzodiazepines (BZO) Rapid Test (Oral Fluid)
206	Cocaine (COC) Rapid Test (Oral Fluid)
207	Cotinine (COT) Rapid Test (Oral Fluid)
208	Fentanyl (FYL) Rapid Test (Oral Fluid)
209	Ketamine(KET) Rapid Test (Oral Fluid)

210	Ecstasy (MDMA) Rapid Test (Oral Fluid)
211	Methamphetamine (MET) Rapid Test (Oral Fluid)
212	Methadone (MTD) Rapid Test (Oral Fluid)
213	Opiates (OPI) Rapid Test (Oral Fluid)
214	Oxycodone (OXY) Rapid Test (Oral Fluid)
215	Phencyclidine (PCP) Rapid Test (Oral Fluid)
216	Synthetic Marijuana (K2) Rapid Test (Oral Fluid)
217	Marijuana (THC) Rapid Test (Oral Fluid)
218	α -Pyrrolidinovalerophenone (α -PVP) Rapid Test (Oral Fluid)
219	Carfentanyl(CFYL) Rapid Test
220	Tramadol(TML) Rapid Test (Oral Fluid)
221	6-Monoacetylmorphine(6-MAM) Rapid Test (Oral Fluid)
222	Methylenedioxypyrovalerone (MDPV) Rapid Test (Oral Fluid)
223	Multi-Drug Rapid Test (Oral Fluid)
224	Multi-Drug Rapid Test Cassette (Oral Fluid)
225	Multi-Drug Rapid Test Cup (Oral Fluid)
226	AMP Rapid Test (WB/S/P)
227	BAR Rapid Test (WB/S/P)
228	BUP Rapid Test (WB/S/P)
229	BZO Rapid Test (WB/S/P)
230	COC Rapid Test (WB/S/P)
231	COT Rapid Test (WB/S/P)
232	EDDP Rapid Test (WB/S/P)
233	FYL Rapid Test (WB/S/P)
234	KET Rapid Test (WB/S/P)
235	MDMA Rapid Test (WB/S/P)
236	MET Rapid Test (WB/S/P)
237	MOP Rapid Test (WB/S/P)
238	MTD Rapid Test (WB/S/P)
239	OXY Rapid Test (WB/S/P)

240	PCP Rapid Test (WB/S/P)
241	K2 Rapid Test (WB/S/P)
242	TCA Rapid Test (WB/S/P)
243	THC Rapid Test (WB/S/P)
244	LSD Rapid Test (WB/S/P)
245	TML Rapid Test (WB/S/P)
246	MDPV Rapid Test (WB/S/P)
247	MDA Rapid Test (WB/S/P)
248	PPX Rapid Test (WB/S/P)
249	Multi-drug Rapid Test (WB/S/P)
250	Amphetamine (AMP) Rapid Test (Hair)
251	Barbiturate (BAR) Rapid Test (Hair)
252	Buprenorphine (BUP) Rapid Test (Hair)
253	Benzodiazepines (BZO) Rapid Test (Hair)
254	Cocaine (COC) Rapid Test (Hair)
255	Cotinine (COT) Rapid Test (Hair)
256	Ketamine (KET) Rapid Test (Hair)
257	Ecstasy (MDMA) Rapid Test (Hair)
258	Methamphetamine (MET) Rapid Test (Hair)
259	Morphine (MOP) Rapid Test (Hair)
260	Oxycodone (OXY) Rapid Test (Hair)
261	Phencyclidine (PCP) Rapid Test (Hair)
262	Synthetic Marijuana (K2) Rapid Test (Hair)
263	AB-PINACA (ABP) Rapid Test (Hair)
264	6-Monoacetylmorphine (6-MAM) Rapid Test (Hair)
265	Multi-drug Rapid Test (Hair)
266	Cardiac Troponin I (cTnI) Rapid Test
267	Cardiac Troponin T (cTnT) Rapid Test
268	CK-MB Rapid Test
269	Myoglobin Rapid Test

270	H-FABP Rapid Test
271	H-FABP and cTnI Combo Rapid Test
272	Myoglobin/CK-MB/Troponin I Combo Rapid Test
273	H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test
274	NT-proBNP Rapid Test
275	D-dimer Rapid Test
276	C-reactive protein Rapid Test
277	C-reactive protein Semi-Quantitative Rapid Test
278	Procalcitonin (PCT) Rapid Test (Serum/Plasma)
279	Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/Plasma)
280	Ferritin Rapid Test
281	Ferritin Semi-Quantitative Rapid Test
282	SP-10 Male Fertility Rapid Test
283	TSH Rapid Test
284	Vitamin D Rapid Test
285	HbA1c Rapid Test
286	Human Semen Rapid Test
287	Calprotectin Rapid Test
288	Lactoferrin Rapid Test
289	Calprotectin and Lactoferrin Combo Rapid Test
290	IgE Rapid Test
291	Rheumatoid Factor Rapid Test
292	Micro-Albumin Semi-Quantitative Rapid Test
293	Micro-Albumin Qualitative Rapid Test
294	SAA Rapid Test
295	SAA and CRP Combo Rapid Test
296	Dust Mite IgE Rapid Test
297	Celiac Rapid Test
298	AFP Rapid Test
299	CEA Rapid Test

300	CA125 Rapid Test
301	CA15-3 Rapid Test
302	CA19-9 Rapid Test
303	FOB Rapid Test
304	FOB Rapid Test Cup
305	Calprotectin and FOB Combo Rapid Test
306	Transferrin and FOB Combo Rapid Test
307	Hb+Hb-Hp Combo Rapid Test
308	Transferrin/FOB and Hb-Hp Combo Rapid Test
309	HPV Antigen Rapid Test
310	SARS-CoV-2 Antigen Test
311	SARS-CoV-2 Antigen Test-Saliva
312	Coronavirus (SARS-CoV-2) Ag Self Test
313	Urinalysis Reagent Dipsticks-Multi Parameters
314	Urinalysis Reagent Strips--Multi Parameters
315	Vaginal pH Rapid Test
316	Alcohol (ALC) Rapid Test (Urine)
317	Alcohol (ALC) Rapid Test (Oral Fluid)
318	Breast Milk Alcohol Rapid Test
319	Sperm Concentration Rapid Test
320	γ -Hydroxybutyric acid (GHB) Rapid Test
321	Adulteration Rapid Test
322	H. pylori Antibody control
323	H. pylori Antigen control
324	Cardiac Troponin I (cTnI) control
325	Pregnancy (hCG) control
326	FOB control
327	Influenza A+B control
328	Syphilis control
329	Calprotectin control

330	Adenovirus control
331	Malaria P.f./Pan control
332	Rotavirus and Adenovirus control
333	Rotavirus control
334	SARS-CoV-2/Influenza A+B/RSV control
335	Mycoplasma pneumoniae Antigen control
336	Mycoplasma Pneumoniae IgM control
337	Mycoplasma Pneumoniae IgG/IgM control
338	CRP control
339	D-dimer control
340	NT-proBNP control
341	Micro-Albumin control
342	TSH control
343	COVID-19 Antigen Test Kit
344	COVID-19 S-RBD IgG Antibody Test Kit
345	CRP Test Kit
346	PCT Test Kit
347	IL-6 Test Kit
348	SAA Test Kit
349	MPO Test Kit
350	Rheumatoid Factor IgM Test Kit
351	Anti-CCP Test Kit
352	Clostridium difficile Toxin A/ toxin B Combo Test Kit
353	Legionella pneumophila Test Kit
354	Streptococcus pneumoniae Test Kit
355	AFP Test Kit
356	CEA Test Kit
357	FOB Test Kit
358	cTnI Test Kit
359	cTnT Test Kit

360	NT-proBNP Test Kit
361	CK-MB Test Kit
362	H-FABP Test Kit
363	Myoglobin Test Kit
364	Troponin I/Myoglobin/CK-MB (3 in 1) Test Kit
365	Troponin T/Myoglobin/CK-MB (3 in 1) Test Kit
366	Calprotectin Test Kit
367	ST2 Test Kit
368	Lp-PLA2 Test Kit
369	D-Dimer Test Kit
370	FSH Test Kit
371	LH Test Kit
372	T3 Test Kit
373	T4 Test Kit
374	Testosterone Test Kit
375	Beta-hCG Test Kit
376	Progesterone (P4) Test Kit
377	Ferritin Test Kit
378	TSH Test Kit
379	AMH Test Kit
380	Prolactin Test Kit
381	iGFBP-1 Test Kit
382	Fetal Fibronectin (fFN) Test Kit
383	Estradiol (E2) Test Kit
384	Cortisol Test Kit
385	Microalbumin Test Kit
386	Cys-C Test Kit
387	β 2MG Test Kit
388	NGAL Test Kit
389	ASO Test Kit

390	HbA1c Test Kit
391	Strep A Test Kit
392	FLU A+B Test Kit
393	RSV Test Kit
394	Dengue IgG/IgM Test Kit
395	Dengue NS1 Test Kit
396	Syphilis Test Kit
397	H.pylori Antigen Test Kit
398	Adenovirus Antigen Test Kit
399	Clostridium Difficile GDH Test Kit
400	Malaria P.f./P.v./Pan Test Kit
401	Chikungunya IgG/IgM Test Kit
402	Typhoid Test Kit
403	Monkeypox Virus Antigen Test Kit
404	Monkeypox Virus Antibody Test Kit
405	IgE Test Kit
406	Vitamin D Test Kit
407	Zika Antigen Test Kit
408	Zika IgM Test Kit
409	Monkeypox Virus Real Time PCR-Kit
410	Hb Hemoglobin Test Strip
411	Inhalant-Food Allergen-specific IgE Antibodies Test Kit(Immunoblotting)
412	Disposable Vacuum Blood Collection
413	Blood Lipid Test Strip (Dry Chemistry)
414	Uric Acid Test Strip
415	Blood Glucose Test Strip
416	Mycoplasma Pneumoniae IgG Rapid Test