浙江东方基因生物制品股份有限公司
Zhejiang Orient Gene Biotech Co.,LTD

STATEMENT

We, Zhejiang Orient Gene Biotech Co., Ltd , having a registered office at 3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China assign SRL SANMEDICO having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova, as non-exclusive authorized representative for Orient Gene Brand product in correspondence with the conditions of directive 98/79/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement letter will be valid from Mar.22th,2024 to Mar.21th, 2025.

Zhejiang Orient Gene Biotech Co., Ltd

General Manager：

Date:2024/3/22

Digitally signed by Dolgopol Iulian
Date: 2025.03.06 11:32:03 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

地址：浙江省湖州市安吉县递铺镇阳光大道东段 3787 号
Add: **3787#, East Yangguang Avenue, Dipu Street Anji 313300, Huzhou, Zhejiang, China**
电话 Tel:+86-572-5226111　　传真 Fax: +86-572-5226222　邮编 P.C.:313300

浙江东方基因生物制品有限公司
Zhejiang Orient Gene Biotech Co.,LTD

Relationship between Healgen and OrientGene

Dete：Aug 13th，2020

To Whom it may concern,

This is to certify that Zhejiang Orient Gene Biotech Co.,Ltd,Located at NO.:3787# East Yangguang Avenue,Dipu Street,Anji313300,Huzhou,Zhejiang,China,and Healgen Scientific LLC,Located at 3818 Fuqua Street ,Houston,TX 77047,USA,are affiliated business divisions under the same management,Zhejiang Orient Gene Biotech Co.,Ltd is an ISO 13485 certificated medical device manufacturer.

Mr Bryan Fang
General Manger
Healgen Scientific LLC

Mr.Xiaoliang Fang
General Manager
Zhejiang OrientGene Biotech Co.,Ltd

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 092378 0004 Rev. 02

Manufacturer:

Healgen Scientific Limited Liability Company
3818 Fuqua Street
Houston TX 77047
USA

Product Category(ies):

Products for determination of infection markers
Tumor markers and products for self testing

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 092378 0004 Rev. 02

Report no.: SH21178302

Valid from: 2022-02-10
Valid until: 2025-05-26

Date, 2022-02-10

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 092378 0004 Rev. 02

Model(s):

In Vitro Diagnostic Rapid Test for Self-Testing, including
HCG Pregnancy Rapid Test,
LH Ovulation Rapid Test

In Vitro Diagnostic Rapid Test, including
Prostate Specific Antigen (PSA) Rapid Test
HCV Hepatitis C Virus Rapid Test
(Whole blood/Serum/Plasma)
HCV Hepatitis C Virus Rapid Test
(Serum/Plasma)
HIV 1/2 Human Immunodeficiency Virus Rapid Test
(Whole blood/Serum/Plasma)
HIV 1/2 Human Immunodeficiency Virus Rapid Test
(Serum/Plasma)

Facility(ies):

Healgen Scientific Limited Liability Company
3818 Fuqua Street, Houston TX 77047, USA

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Holder of Certificate: **Zhejiang Orient Gene Biotech Co., Ltd.**
3787#, East Yangguang Avenue, Dipu Street Anji
313300 Huzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagent and Instrument for the Detection of Drugs of Abuse, Fertility, Infectious Diseases, Oncology, Biochemistry, Cardiac Diseases, Allergic Disease based on Rapid Test, PCR and Liquid Biochip Method.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 092305 0001 Rev. 02

Report No.: SH2398804

Valid from: 2024-03-17
Valid until: 2027-03-16

Date, 2024-03-01

Christoph Dicks
Head of Certification/Notified Body

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 092305 0001 Rev. 02

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

Zhejiang Orient Gene Biotech Co., Ltd.
3787#, East Yangguang Avenue, Dipu Street Anji, 313300
Huzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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Evaluation Report for *HEALGEN/ORIENT GENE* HIV 1/2 Test Device

Objective: To evaluate the diagnostic sensitivity and specificity of the *HEALGEN/ORIENT GENE* HIV 1/2 Test Device

Institute	:	Biomex GmbH	Country	:	Germany
Name	:	Dr. Heike Lukhaup	Title	:	Quality control
Address	:	Siemensstraße 38 69123 Heidelberg			
Date	:	9th April 2015			

	Details of the *HEALGEN/ORIENT GENE* HIV 1/2 test devices used in this study	Details of the reference test used in this study
Name	*HEALGEN/ORIENT GENE* HIV 1/2 Rapid Test Device (Whole Blood/ Serum/Plasma)	Abbott Architect HIV Ag/Ab Combo DRK HIV-1 PCR Kit PRISM HIV Ag/Ab Combo ChLIA_Abbott Diagnostics
Manufacturer	*Zhejiang Orient Gene Biotech Co., LTD*	
Lot No.	S1411003	
Exp.	2016-10	

Diagnostic Sensitivity - anti-HIV 1 positive samples (any subtype)

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
1	K00013	Serum	√	√	positive	918,5	s/co	positive
2	K00016	Serum	√	√	positive	1040,4	s/co	positive
3	K00017	Serum	√	√	positive	713,6	s/co	positive
4	K00019	EDTA plasma	√	√	positive	837,8	s/co	positive
5	K00024	EDTA plasma	√	√	positive	947,3	s/co	positive
6	K00025	EDTA plasma	√	√	positive	940,3	s/co	positive
7	K00028	EDTA plasma	√	√	positive	823,5	s/co	positive
8	K00029	EDTA plasma	√	√	positive	749,6	s/co	positive
9	K00030	Serum	√	√	positive	807,0	s/co	positive
10	K00031	EDTA plasma	√	√	positive	1046,0	s/co	positive
11	K00036	Serum	√	√	positive	729,0	s/co	positive
12	K00037	EDTA plasma	√	√	positive	822,0	s/co	positive
13	K00040	EDTA plasma	√	√	positive	844,0	s/co	positive
14	K00043	Serum	√	√	positive	835,0	s/co	positive
15	K00044	Serum	√	√	positive	875,0	s/co	positive
16	K00046	EDTA plasma	√	√	positive	896,0	s/co	positive
17	K00048	Serum	√	√	positive	1070,0	s/co	positive
18	K00050	EDTA plasma	√	√	positive	787,0	s/co	positive
19	K00052	Serum	√	√	positive	779,0	s/co	positive
20	K00053	EDTA plasma	√	√	positive	879,0	s/co	positive
21	K00058	Serum	√	√	positive	764,0	s/co	positive

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
22	K00060	EDTA plasma	√	√	positive	1085,0	s/co	positive
23	K00061	Serum	√	√	positive	974,0	s/co	positive
24	K00062	EDTA plasma	√	√	positive	589,0	s/co	positive
25	K00064	Serum	√	√	positive	532,0	s/co	positive
26	K00066	EDTA plasma	√	√	positive	1233,0	s/co	positive
27	K00068	EDTA plasma	√	√	positive	559,0	s/co	positive
28	K00069	EDTA plasma	√	√	positive	767,0	s/co	positive
29	K00071	EDTA plasma	√	√	positive	648,0	s/co	positive
30	K00072	EDTA plasma	√	√	positive	904,0	s/co	positive
31	K00074	Serum	√	√	positive	932,0	s/co	positive
32	K00075	EDTA plasma	√	√	positive	387,0	s/co	positive
33	K00078	EDTA plasma	√	√	positive	762,0	s/co	positive
34	K00079	EDTA plasma	√	√	positive	829,0	s/co	positive
35	K00080	Serum	√	√	positive	1074,0	s/co	positive
36	K00082	EDTA plasma	√	√	positive	863,0	s/co	positive
37	K00083	Serum	√	√	positive	784,0	s/co	positive
38	K00085	EDTA plasma	√	√	positive	598,0	s/co	positive
39	K00087	Serum	√	√	positive	1278,0	s/co	positive
40	K00090	EDTA plasma	√	√	positive	1203,0	s/co	positive
41	K00092	EDTA plasma	√	√	positive	575,0	s/co	positive
42	K00093	EDTA plasma	√	√	positive	487,0	s/co	positive
43	K00094	Serum	√	√	positive	1114,0	s/co	positive
44	K00097	EDTA plasma	√	√	positive	740,0	s/co	positive
45	K00098	Serum	√	√	positive	527,0	s/co	positive
46	K00099	EDTA plasma	√	√	positive	1126,0	s/co	positive
47	K00100	Serum	√	√	positive	854,0	s/co	positive
48	K00102	EDTA plasma	√	√	positive	946,0	s/co	positive
49	K00104	EDTA plasma	√	√	positive	893,0	s/co	positive
50	K00105	Serum	√	√	positive	1061,0	s/co	positive
51	K00106	EDTA plasma	√	√	positive	969,0	s/co	positive
52	K00107	Serum	√	√	positive	622,0	s/co	positive
53	K00108	Serum	√	√	positive	1165,0	s/co	positive
54	K00109	EDTA plasma	√	√	positive	496,0	s/co	positive
55	K00110	EDTA plasma	√	√	positive	954,0	s/co	positive
56	K00113	Serum	√	√	positive	1026,0	s/co	positive
57	K00114	EDTA plasma	√	√	positive	1161,0	s/co	positive
58	K00115	Serum	√	√	positive	1266,0	s/co	positive
59	K00116	Serum	√	√	positive	635,0	s/co	positive
60	K00117	EDTA plasma	√	√	positive	842,0	s/co	positive

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
61	K00120	EDTA plasma	√	√	positive	918,0	s/co	positive
62	K00122	EDTA plasma	√	√	positive	1007,0	s/co	positive
63	K00124	EDTA plasma	√	√	positive	983,0	s/co	positive
64	K00132	Serum	√	√	positive	872,0	s/co	positive
65	K00133	Serum	√	√	positive	698,0	s/co	positive
66	K00135	Serum	√	√	positive	1168,0	s/co	positive
67	K00136	EDTA plasma	√	√	positive	1167,0	s/co	positive
68	K00138	EDTA plasma	√	√	positive	700,0	s/co	positive
69	K00139	EDTA plasma	√	√	positive	921,0	s/co	positive
70	K00140	EDTA plasma	√	√	positive	785,0	s/co	positive
71	K00142	Serum	√	√	positive	1145,0	s/co	positive
72	K00143	EDTA plasma	√	√	positive	1205,0	s/co	positive
73	K00144	EDTA plasma	√	√	positive	1085,0	s/co	positive
74	K00145	Serum	√	√	positive	1008,0	s/co	positive
75	K00147	EDTA plasma	√	√	positive	1141,0	s/co	positive
76	K00152	EDTA plasma	√	√	positive	810,0	s/co	positive
77	K00155	EDTA plasma	√	√	positive	254,0	s/co	positive
78	K00156	EDTA plasma	√	√	positive	1064,0	s/co	positive
79	K00159	EDTA plasma	√	√	positive	1123,0	s/co	positive
80	K00161	Serum	√	√	positive	1184,0	s/co	positive
81	K00163	Serum	√	√	positive	1167,0	s/co	positive
82	K00167	EDTA plasma	√	√	positive	770,0	s/co	positive
83	K00171	EDTA plasma	√	√	positive	1022,0	s/co	positive
84	K00176	EDTA plasma	√	√	positive	842,0	s/co	positive
85	K00177	EDTA plasma	√	√	positive	769,0	s/co	positive
86	K00178	Serum	√	√	positive	594,0	s/co	positive
87	K00180	EDTA plasma	√	√	positive	976,0	s/co	positive
88	K00182	EDTA plasma	√	√	positive	1009,0	s/co	positive
89	K00185	EDTA plasma	√	√	positive	541,0	s/co	positive
90	K00186	EDTA plasma	√	√	positive	1140,0	s/co	positive
91	K00187	EDTA plasma	√	√	positive	1066,0	s/co	positive
92	K00188	EDTA plasma	√	√	positive	1072,0	s/co	positive
93	K00190	EDTA plasma	√	√	positive	927,0	s/co	positive
94	K00191	Serum	√	√	positive	424,0	s/co	positive
95	K00197	EDTA plasma	√	√	positive	155,9	s/co	positive
96	K00198	EDTA plasma	√	√	positive	1100,3	s/co	positive
97	K00199	EDTA plasma	√	√	positive	988,8	s/co	positive
98	K00200	EDTA plasma	√	√	positive	765,6	s/co	positive
99	K00203	EDTA plasma	√	√	positive	980,9	s/co	positive

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
100	K00209	EDTA plasma	√	√	positive	1006,5	s/co	positive
101	K00210	EDTA plasma	√	√	positive	941,9	s/co	positive
102	K00216	EDTA plasma	√	√	positive	1121,3	s/co	positive
103	K00217	EDTA plasma	√	√	positive	808,8	s/co	positive
104	K00218	EDTA plasma	√	√	positive	1079,3	s/co	positive
105	K00224	EDTA plasma	√	√	positive	1187,7	s/co	positive
106	K00226	EDTA plasma	√	√	positive	918,1	s/co	positive
107	K00228	EDTA plasma	√	√	positive	832,6	s/co	positive
108	K00229	EDTA plasma	√	√	positive	807,8	s/co	positive
109	K00232	EDTA plasma	√	√	positive	446,9	s/co	positive
110	K00233	EDTA plasma	√	√	positive	690,2	s/co	positive
111	K00239	Serum	√	√	positive	424,3	s/co	positive
112	K00240	Serum	√	√	positive	836,6	s/co	positive
113	K00241	Serum	√	√	positive	230,4	s/co	positive
114	K00242	Serum	√	√	positive	1028,1	s/co	positive
115	K00243	EDTA plasma	√	√	positive	607,8	s/co	positive
116	K00245	Serum	√	√	positive	935,8	s/co	positive
117	K00246	Serum	√	√	positive	654,9	s/co	positive
118	K00247	EDTA plasma	√	√	positive	184,7	s/co	positive
119	K00248	Serum	√	√	positive	609,2	s/co	positive
120	K00249	Serum	√	√	positive	820,9	s/co	positive
121	K00258	EDTA plasma	√	√	positive	964,3	s/co	positive
122	K00261	Serum	√	√	positive	783,1	s/co	positive
123	K00263	Serum	√	√	positive	1065,4	s/co	positive
124	K00265	EDTA plasma	√	√	positive	119,7	s/co	positive
125	K00266	EDTA plasma	√	√	positive	1169,7	s/co	positive
126	K00269	EDTA plasma	√	√	positive	737,4	s/co	positive
127	K00273	Serum	√	√	positive	280,5	s/co	positive
128	K00275	EDTA plasma	√	√	positive	903,8	s/co	positive
129	K00279	EDTA plasma	√	√	positive	852,0	s/co	positive
130	K00280	Serum	√	√	positive	611,9	s/co	positive
131	K00284	Serum	√	√	positive	729,6	s/co	positive
132	K00285	EDTA plasma	√	√	positive	690,9	s/co	positive
133	K00292	Serum	√	√	positive	967,5	s/co	positive
134	K00294	EDTA plasma	√	√	positive	703,1	s/co	positive
135	K00302	EDTA plasma	√	√	positive	581,1	s/co	positive
136	K00306	Serum	√	√	positive	944,1	s/co	positive
137	K00307	EDTA plasma	√	√	positive	1110,7	s/co	positive
138	K00309	Serum	√	√	positive	1127,7	s/co	positive

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
139	K00313	EDTA plasma	√	√	positive	856,9	s/co	positive
140	K00315	EDTA plasma	√	√	positive	1136,0	s/co	positive
141	K00317	EDTA plasma	√	√	positive	985,4	s/co	positive
142	K00319	Serum	√	√	positive	1134,5	s/co	positive
143	K00323	EDTA plasma	√	√	positive	638,8	s/co	positive
144	K00324	EDTA plasma	√	√	positive	508,3	s/co	positive
145	K00326	Serum	√	√	positive	1108,1	s/co	positive
146	K00328	EDTA plasma	√	√	positive	847,4	s/co	positive
147	K00331	EDTA plasma	√	√	positive	640,9	s/co	positive
148	K00336	Serum	√	√	positive	314,3	s/co	positive
149	K00342	EDTA plasma	√	√	positive	366,2	s/co	positive
150	K00344	EDTA plasma	√	√	positive	781,6	s/co	positive
151	K00346	EDTA plasma	√	√	positive	895,3	s/co	positive
152	K00350	EDTA plasma	√	√	positive	914,9	s/co	positive
153	K00351	EDTA plasma	√	√	positive	622,1	s/co	positive
154	K00352	Serum	√	√	positive	850,1	s/co	positive
155	K00354	EDTA plasma	√	√	positive	381,7	s/co	positive
156	K00357	EDTA plasma	√	√	positive	781,0	s/co	positive
157	K00358	EDTA plasma	√	√	positive	536,8	s/co	positive

Diagnostic Sensitivity anti-HIV 1 positive samples - specified Subtypes

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T1	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
	Subtype A							
158	K00012	EDTA plasma	√	√	positive	614,07	s/co	positive
159	K00026	Serum	√	√	positive	927,49	s/co	positive
160	K00035	Serum	√	√	positive	315,00	s/co	positive
	Subtype B							
161	5477	Citrate plasma	√	√	positive	917,28	s/co	positive
162	5478	Citrate plasma	√	√	positive	1084,8	s/co	positive
163	5608	Citrate plasma	√	√	positive	945,36	s/co	positive
	Subtype C							
164	K00375	Serum	√	√	positive	749,46	s/co	positive
165	7434	Citrate plasma	√	√	positive	pos.		positive
166	HIV1C150204-01	Plasma	√	√	positive	pos.		positive
167	HIV1C150204-02	Plasma	√	√	positive	pos.		positive
	Subtype D							
168	K00077	Serum	√	√	positive	1089	s/co	positive
169	K00311	EDTA plasma	√	√	positive	1080	s/co	positive

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T1	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
170	K00333	EDTA plasma	√	√	positive	368,17	s/co	positive
	Subtype F							
171	K00014	EDTA plasma	√	√	positive	1173	s/co	positive
172	K00088	Serum	√	√	positive	605,00	s/co	positive
173	K00095	EDTA plasma	√	√	positive	771,00	s/co	positive
	Subtype G							
174	K00047	EDTA plasma	√	√	positive	720,00	s/co	positive
175	K00073	EDTA plasma	√	√	positive	699,00	s/co	positive
176	K00089	Serum	√	√	positive	1107	s/co	positive
	Subtype H							
177	K00234	Serum	√	√	positive	51,17	s/co	positive
	Subtype K							
178	K00021	EDTA plasma	√	√	positive	1019	s/co	positive
	Subtype CRF01							
179	K00128	Serum	√	√	positive	266,00	s/co	positive
180	6931	Citrate plasma	√	√	positive	pos	s/co	positive
181	7222	Citrate plasma	√	√	positive	pos	s/co	positive
	Subtype CRF02							
182	K00290	EDTA plasma	√	√	positive	900,61	s/co	positive
183	K00361	EDTA plasma	√	√	positive	797,33	s/co	positive
184	K00362	EDTA plasma	√	√	positive	509,88	s/co	positive
185	K00363	EDTA plasma	√	√	positive	943,64	s/co	positive
186	K00364	Serum	√	√	positive	784,81	s/co	positive
	Subtype CRF11							
187	K00194	Serum	√	√	positive	856,40	s/co	positive
188	K00267	EDTA plasma	√	√	positive	1129,5	s/co	positive
189	K00282	Serum	√	√	positive	703,81	s/co	positive
	Subtype CRF18							
190	K00039	Serum	√	√	positive	922,00	s/co	positive
191	K00096	Serum	√	√	positive	345,00	s/co	positive
192	K00278	EDTA plasma	√	√	positive	754,68	s/co	positive
	Subtype CRF22							
193	K00111	Serum	√	√	positive	785,00	s/co	positive
194	K00260	Serum	√	√	positive	673,84	s/co	positive
195	K00320	EDTA	√	√	positive	598,99	s/co	positive
196	K00337	Serum	√	√	positive	719,41	s/co	positive
	Subtype CRF37							
197	K00121	EDTA	√	√	positive	854,00	s/co	positive

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* HIV 1/2			Result with reference test		
			Signal of T1	Signal of Control Line	Interpretation	Sample / Cut-Off OD Ratio		Interpretation
	Group O							
198	K00175	EDTA plasma	√	√	positive	14,43	s/co	positive
199	K00508	EDTA plasma	√	√	positive	113,47	s/co	positive
200	1342	Citrate plasma	√	√	positive	2940	IU/ml	positive
	HIV 2 Subtype A							
1	1186	Serum	√	√	positive	168,96	s/co	positive
2	1187	Serum	√	√	positive	224,76	s/co	positive

Diagnostic Specificity – Blood donor samples

No. of Negative Samples Tested	Samples negative by HIV 1/2 Rapid Test Device (Whole Blood/ Serum/ plasma)
500	500
% Specificity Observed	
> 99,9%	

Diagnostic Specificity – Cross reactivity Panel

	Details of the *HEALGEN/ORIENT GENE* HIV 1/2 test devices used in this study	Details of the reference test used in this study
Name	*HEALGEN/ORIENT GENE* HIV 1/2 Rapid Test Device (Whole Blood/ Serum/Plasma)	Abbott Architect HIV Ag/Ab Combo PRISM HIV Ag/Ab Combo ChLIA_Abbott Diagnostics
Manufacturer	*Zhejiang Orient Gene Biotech Co., LTD*	
Lot No.	1411198	
Exp.	2016-10	

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HIV 1/2			Results of potentially cross reacting substances	
			Signal of T	Signal of Control Line	Interpretation (*,**)	Sample / Cut-Off OD Ratio	
	Rheumatoid Factor						
1	5401	Citrate plasma	-	√	negative*	45,4	IU/ml
2	5729	Citrate plasma	-	√	negative*	49,1	IU/ml
	ANA						
3	4958	Citrate plasma	-	√	negative*	1:2560	titer
4	5729	Citrate plasma	-	√	negative*	1:160	titer
	Multipara						
5	8485	Citrate plasma	-	√	negative*	n.a.	n.a.
6	5436	Citrate plasma	-	√	negative*	n.a.	n.a.
7	7452	Citrate plasma	-	√	negative*	n.a.	n.a.
8	6975	Citrate plasma	-	√	negative*	n.a.	n.a.

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HIV 1/2			Results of potentially cross reacting substances	
			Signal of T	Signal of Control Line	Interpretation (*,**)	Sample / Cut-Off OD Ratio	
	anti-EBV						
9	7108	Citrate plasma	-	√	negative*	>160	s/co
10	9035	Citrate plasma	-	√	negative*	72.19	s/co
11	9055	Citrate plasma	-	√	negative*	67.72	s/co
	anti-CMV						
12	3630	Serum	-	√	negative*	20.9	AU/ml
13	6474	Citrate plasma	-	√	negative*	10.1	AU/ml
14	1379	Citrate plasma	-	√	negative*	718	AU/ml
15	1665	Citrate plasma	-	√	negative*	831	AU/ml
	Dialysis patients						
16	C	Serum	-	√	negative**	n.a.	n.a.
17	H	Serum	-	√	negative**	n.a.	n.a.
18	G	Serum	-	√	negative**	n.a.	n.a.
19	I	Serum	-	√	negative**	n.a.	n.a.
	anti-HBV						
20	208130806096	CPD plasma	-	√	negative*	446.1	s/co
21	208130806139	CPD plasma	-	√	negative*	380.3	s/co
	anti-HCV						
22	6937	Citrate plasma	-	√	negative*	pos	
23	6995	Citrate plasma	-	√	negative*	pos	
	anti-Syphillis						
24	4777	Citrate plasma	-	√	negative*	pos	
25	7467	Citrate plasma	-	√	negative*	pos	
26	22180	Citrate plasma	-	√	negative**	24.8	s/co
27	19507	Citrate plasma	-	√	negative**	42.32	s/co
	Anti-HAV IgM						
28	3319	Citrate plasma	-	√	negative*	3.4	s/co
29	3621	Citrate plasma	-	√	negative*	3.02	s/co
30	5188	Citrate plasma	-	√	negative*	5.88	s/co

* confirmed to be negative for anti-HIV, anti-HCV and HBsAg with the Abbott PRISM HIV Ag/Ab Combo ChLIA

** confirmed to be negative for anti-HIV, anti-HCV and HBsAg with the Abbott Architect HIV Ag/Ab Combo

Diagnostic Specificity – Inhibition Panel

	Details of the *HEALGEN/ORIENT GENE* HIV 1/2 test devices used in this study
Name	*HEALGEN/ORIENT GENE* HIV 1/2 Rapid Test Device (Whole Blood/ Serum/Plasma)
Manufacturer	*Zhejiang Orient Gene Biotech Co., LTD*
Lot No.	S1411003
Exp.	2016-10

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HIV 1/2			
			Signal of T	Signal of Control Line	Interpretation	Concentration
	Hemolytic (low)					
1	63238493	K2EDTA plasma	-	√	negative	600 mg/dl
2	63238581	K2EDTA plasma	-	√	negative	600 mg/dl
3	63238715	K2EDTA plasma	-	√	negative	600 mg/dl
	Hemolytic (medium)					
4	63238493	K2EDTA plasma	-	√	negative	1000 mg/dl
5	63238581	K2EDTA plasma	-	√	negative	1000 mg/dl
6	63238715	K2EDTA plasma	-	√	negative	1000 mg/dl
	Hemolytic (high)					
7	63238493	K2EDTA plasma	-	√	negative	2000 mg/dl
8	63238581	K2EDTA plasma	-	√	negative	2000 mg/dl
9	63238715	K2EDTA plasma	-	√	negative	2000 mg/dl
	Lipemic (low)					
10	494141143958	CPD plasma	-	√	negative	200 mg/dl
11	141037521	Na-citrate plasma	-	√	negative	319 mg/dl
12	141029931	Na-citrate plasma	-	√	negative	387 mg/dl
	Lipemic (medium)					
13	494141311159	Na-citrate plasma	-	√	negative	411 mg/dl
14	141095371	Na-citrate plasma	-	√	negative	440 mg/dl
15	10024 57020	CPD plasma	-	√	negative	450 mg/dl
	Lipemic (high)					
16	1002458127	CPD plasma	-	√	negative	635 mg/dl
17	1410 93301	Na-citrate plasma	-	√	negative	729 mg/dl
18	1002468323	CPD plasma	-	√	negative	1137 mg/dl
	Icteric (low)					
19	11231152	Serum	-	√	negative	10 mg/dl
20	11231153	Serum	-	√	negative	10,5 mg/dl
21	11231204	Serum	-	√	negative	10 mg/dl
	Icteric (medium)					
22	11231155	Serum	-	√	negative	15 mg/dl
23	11231205	Serum	-	√	negative	15,4 mg/dl
24	11231210	Serum	-	√	negative	15,9 mg/dl

#	Sample ID	Sample Matrix (Whole blood, serum or plasma)	*HEALGEN/ORIENT GENE* anti-HIV 1/2			
			Signal of T	Signal of Control Line	Interpretation	Concentration
	Icteric (high)					
25	11231150	Serum	-	√	negative	17 mg/dl
26	11231151	Serum	-	√	negative	17,9 mg/dl
27	11231156	Serum	-	√	negative	18,1 mg/dl

Overall Diagnostic Sensitivity and Specificity for all tested samples

No. of positive samples Tested	Samples positive by *HEALGEN/ORIENT GENE* HIV1/2 Test	No. of negative samples tested	Samples negative by *HEALGEN/ORIENT GENE* HIV 1/2 Test
202	202	557	557
% Sensitivity Observed		% Specificity Observed	
> 99.9 %		> 99.9 %	

Result Matrix

Method		Reference test			Total Results
	Results	Positive	Negative	Indeterminate	
HIV 1/2 Rapid Test Device	Positive	202	0	0	202
	Negative	0	557	0	557
	Invalid	0	0	0	0
Total Results		202	557	0	757

Performance of the test		Excellent	Very Good	Good	Satisfactory	Not Satisfactory
Clarity with clear background	:	√				
Signal of T Test Line	:	√				
Signal of Control Line	:	√				
Overall Performance of the Test kit	:	√				
Time Taken for final result	:	√				
Convenience in performing test	:	√				
Quantity of Buffer	:	√				
Quality of Buffer Bottle	:	√				
Appearance	:	√				

Heidelberg, 09th April 2015

Heike Lukhaup

Dr. Heike Lukhaup, Head of Quality Control

BIOMEX
BIOMEX GmbH
Siemensstraße 38
69123 Heidelberg
Tel. 0 62 21 - 89 46 89-0

Heike Lukhaup

HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

INTENDED USE

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay with a double antigen system for the qualitative detection of antibodies to HIV-1 and/or HIV-2 in whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with HIV. Any reactive specimen with the HIV 1/2 Ab Rapid Test Cassette must be confirmed with alternative testing method(s).

INTRODUCTION

HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from the host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV-1 has been isolated from patients with AIDS and AIDS-related complex,and from healthy people with a high potential risk for developing AIDS.[1] HIV-2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals.[2] Both HIV-1 and HIV-2 elicit an immune response.[3] Detection of HIV antibodies in serum or plasma is the most efficient and common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV.[4] Despite the differences in their biological characters, serological activities and genome sequences, HIV-1 and HIV-2 show strong antigenic cross-reactivity.[5] Most HIV-2 positive sera can be identified by using HIV-1 based serological tests.

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of antibodies to HIV-1 and/or HIV-2 in whole blood, serum or plasma specimens. The test utilizes gold conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1/2 in whole blood, serum or plasma.

PRINCIPLE

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The membrane is coated with recombinant HIV recombinant antigens on the test line region of the device. When a specimen is applied at one end of the membrane, it reacts with HIV recombinant antigen coated gold conjugate in the test. The mixture then migrates chromatographically by capillary action and reacts with the recombinant HIV recombinant antigens on the membrane in the test line region.

If the specimen contains antibodies to HIV-1 or HIV-2, a colored line will appear in the test line region, showing a positive result. The absence of the colored test line indicates that the specimen does not contain the anti-HIV antibodies, showing a negative result. A colored line will always appear at the control line region to serve as a procedural control. This indicates if the proper volume of specimen has been added and that membrane wicking has occurred.

PRODUCT CONTENTS

The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) contains HIV recombinant antigen coated particles and HIV recombinant antigens coated on the membrane.

MATERIALS SUPPLIED

1. Test cassette 2 Pipette dropper 3.Desiccant 4.Buffer 5.Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1.Specimen collection containers 2.Lancets (for fingerstick whole blood only)
3.Centrifuge (for plasma only) 4.Timer
5.Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

STORAGE AND STBILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents.Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results .
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

SPECIMEN COLLECTION

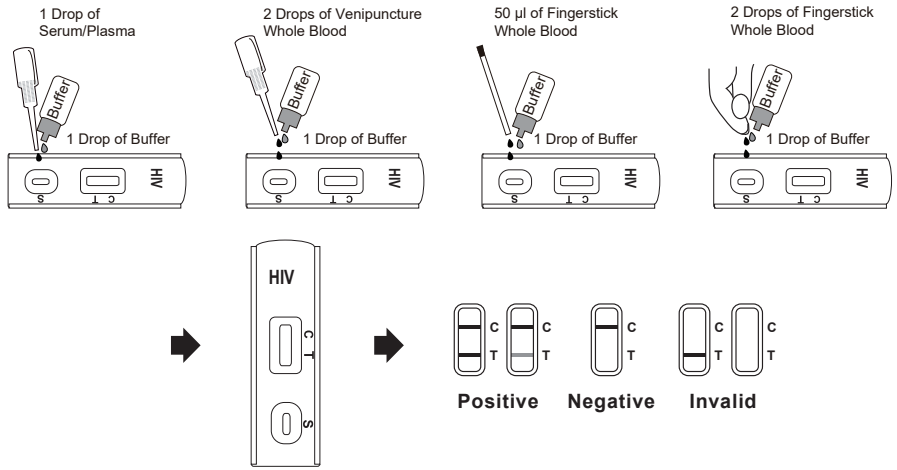
1.The HIV1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
2.To collect Fingerstick Whole Blood specimens:
◦ Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
◦ Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
◦ Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.
◦ Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
◦ Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:
・Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.
・Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.
◦ Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:
・Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
・Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).
3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4.Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
5.Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

TEST PROCEDURE

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1.Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.

HIV 1/2 Ab Rapid Test Cassette
(Whole Blood/Serum/Plasma)



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of HIV antibodies in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The HIV 1/2 Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of antibodies to HIV-1 and/or HIV-2 in whole blood, serum or plasma.
2. The HIV 1/2 Ab Rapid Test Cassette is limited to the qualitative detection of antibodies to HIV-1 or HIV-2 in human whole blood, serum or plasma. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable HIV-1 or HIV-2 antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with HIV-1 or HIV-2.
4. A negative result can occur if the quantity of the HIV-1 or HIV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5. Although a positive result may indicate infection with HIV-1 or HIV-2 virus, a diagnosis of AIDS can only be made on clinical grounds, if an individual meets the case definition for AIDS established by the Centers fir Disease Control. For samples repeatedly tested as positive, more specific supplemental tests must be performed.
6. Immunochomatographic testing alone cannot be used to diagnose AIDS even if the antibodies against HIV-1 and/or HIV-2 are present in a patient specimen.
7. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

PERFORMANCE CHARACTERISTICS

Sensitivity: The test has been compared with a leading commercial HIV EIA test using clinical specimens. Results showed the HIV 1/2 Ab Rapid Test Cassette is very sensitive to HIV-1 and/or HIV-2 antibodies.

Specificity: The specificity is comparable to a leading commercial HIV EIA test. The test is highly specific for anti-HIV-1 and/or HIV-2 when compared to a leading commercial HIV EIA test.

The HIV 1/2 Ab Rapid Test Cassette vs. EIA test

Method		EIA		Total Results
HIV 1/2 Rapid Test	Results	Positive	Negative	
	Positive	210	2	212
	Negative	1	1050	1051
Total Results		211	1052	1263

Relative sensitivity:99.5%
Relative specificity: 99.8%
Accuracy: 99.8%

REFERENCE

1. Arya SK, Beaver B, Jagodzinski L, Ensoli B, Kanki PJ,Albert J, Fenyo EM, Biberfeld G, Zagury JF and Laure F. New human and simian HIV-related retroviruses possess functional transactivator (tat) gene. Nature (1987) 328:548-550.
2. Caetano JA. Immunologic aspects of HIV infection. Acta Med Port (1991) 4 Suppl 1:52S-58S.
3. Chang SY, Bowman BH, Weiss JB, Garcia RE and White TJ. The Origin of HIV-1 isolate HTLV-IIIB. Nature (1993) 3:363:466-9.
4. Travers K, Mboup S, Marlink R, Gueye-Nidaye A, Siby T, Thior I, Traore I, Dieng-Sarr A, Sankale JL and Mullins C. Natural protection against HIV-1 infection provided by HIV-2.Science (1995) 268:1612-1615.
5. Greenberg AE, Wiktor SZ, DeCock KM, Smith P, Jaffe HW and Dondero TJ Jr. HIV-2 and natural protection against HIV-1 infection. Science (1996) 272:1959-1960

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Manufacturer		Warning		

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

Cat.No.: GCHIV-402a

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