

Precision/Sensitivity Study Report

1. Purpose

To verify the precision/Reproducibility/Sensitivity of Safecare COVID-19 Antigen test

2. Sample

Recombinant COVID-19 antigen were diluted at the concentration 1ng/ml,500pg/ml,250pg/ml , 125pg/ml,0pg/ml (all the concentration was determined by immunoassay of ELISA).Each concentration samples were blind coded and divided into 60sets (one set per lot per run). Samples were also randomized prior to testing. All aliquots were blinded labeled by the person who prepared the samples and won't take part in the sample testing.

Sample blind list

Day#	Concentration	LOT1		LOT2		LOT3	
		Run1	Run2	Run1	Run2	Run1	Run2
Day1	0pg/mL	SP369	SP115	SP060	SP179	SP473	SP226
	125pg/mL	SP206	SP499	SP377	SP374	SP056	SP333
	250pg/mL	SP328	SP312	SP040	SP356	SP424	SP325
	500pg/mL	SP061	SP386	SP332	SP161	SP327	SP014
	1ng/mL	SP241	SP024	SP274	SP390	SP250	SP087
	2ng/mL	SP285	SP044	SP488	SP089	SP184	SP257
Day2	0pg/mL	SP376	SP147	SP389	SP111	SP461	SP275
	125pg/mL	SP265	SP091	SP453	SP113	SP233	SP220
	250pg/mL	SP215	SP189	SP015	SP231	SP440	SP209
	500pg/mL	SP288	SP047	SP437	SP450	SP452	SP316
	1ng/mL	SP249	SP291	SP090	SP012	SP345	SP239
	2ng/mL	SP128	SP282	SP480	SP277	SP436	SP449
Day3	0pg/mL	SP425	SP057	SP395	SP423	SP410	SP041
	125pg/mL	SP171	SP211	SP372	SP096	SP030	SP149
	250pg/mL	SP474	SP469	SP330	SP210	SP439	SP159
	500pg/mL	SP145	SP027	SP300	SP079	SP109	SP373
	1ng/mL	SP105	SP059	SP252	SP065	SP306	SP384
	2ng/mL	SP314	SP350	SP123	SP150	SP411	SP146
Day4	0pg/mL	SP038	SP418	SP493	SP482	SP088	SP154
	125pg/mL	SP313	SP151	SP068	SP497	SP290	SP280
	250pg/mL	SP031	SP421	SP137	SP344	SP037	SP152
	500pg/mL	SP434	SP464	SP451	SP119	SP207	SP399
	1ng/mL	SP248	SP307	SP097	SP022	SP283	SP124
	2ng/mL	SP408	SP370	SP255	SP353	SP392	SP214

Day5	0pg/mL	SP278	SP470	SP003	SP475	SP412	SP484
	125pg/mL	SP018	SP136	SP326	SP492	SP195	SP443
	250pg/mL	SP008	SP098	SP043	SP042	SP366	SP158
	500pg/mL	SP254	SP110	SP243	SP190	SP268	SP404
	1ng/mL	SP428	SP396	SP273	SP103	SP071	SP157
	2ng/mL	SP385	SP456	SP458	SP362	SP232	SP246
Day6	0pg/mL	SP383	SP490	SP303	SP143	SP420	SP062
	125pg/mL	SP415	SP225	SP016	SP417	SP201	SP270
	250pg/mL	SP193	SP438	SP295	SP173	SP169	SP297
	500pg/mL	SP026	SP181	SP279	SP202	SP431	SP099
	1ng/mL	SP021	SP398	SP148	SP284	SP460	SP175
	2ng/mL	SP234	SP138	SP445	SP054	SP361	SP039
Day7	0pg/mL	SP122	SP363	SP219	SP130	SP032	SP483
	125pg/mL	SP118	SP139	SP053	SP478	SP078	SP256
	250pg/mL	SP292	SP496	SP126	SP010	SP310	SP197
	500pg/mL	SP317	SP163	SP432	SP465	SP382	SP251
	1ng/mL	SP367	SP331	SP133	SP444	SP034	SP462
	2ng/mL	SP156	SP405	SP092	SP082	SP212	SP112
Day8	0pg/mL	SP035	SP455	SP176	SP498	SP023	SP481
	125pg/mL	SP422	SP177	SP299	SP002	SP084	SP063
	250pg/mL	SP309	SP238	SP134	SP407	SP406	SP048
	500pg/mL	SP375	SP409	SP164	SP132	SP403	SP036
	1ng/mL	SP013	SP086	SP261	SP052	SP489	SP101
	2ng/mL	SP354	SP319	SP242	SP302	SP218	SP397
Day9	0pg/mL	SP264	SP083	SP183	SP315	SP338	SP180
	125pg/mL	SP028	SP457	SP224	SP125	SP260	SP194
	250pg/mL	SP276	SP236	SP266	SP286	SP468	SP064
	500pg/mL	SP131	SP342	SP005	SP017	SP237	SP346
	1ng/mL	SP413	SP049	SP072	SP045	SP029	SP471
	2ng/mL	SP427	SP221	SP178	SP263	SP349	SP141
Day10	0pg/mL	SP235	SP188	SP495	SP322	SP009	SP368
	125pg/mL	SP050	SP433	SP318	SP216	SP296	SP426
	250pg/mL	SP340	SP223	SP104	SP393	SP051	SP491
	500pg/mL	SP339	SP430	SP011	SP074	SP308	SP240
	1ng/mL	SP120	SP320	SP170	SP166	SP222	SP129
	2ng/mL	SP298	SP165	SP343	SP487	SP199	SP155

3. Test procedure

The study was conducted 2 runs / day and lasted 10 days and was conducted by by three lab technicians using three lots of the test.

4. Result

4.1 Product:

Product name	LOT1	LOT2	LOT3
Safecare COVID-19 Antigen Test	COV20081001	COV20081002	COV20081003

4.2 The result was recorded as the following:

Concentration	LOT1		LOT2		LOT3	
	Sample No.	Result	Sample No.	Result	Sample No.	Result
0pg/mL	SP369	-	SP060	-	SP473	-
	SP376	-	SP389	-	SP461	-
	SP425	-	SP395	-	SP410	-
	SP038	-	SP493	-	SP088	-
	SP278	-	SP003	-	SP412	-
	SP383	-	SP303	-	SP420	-
	SP122	-	SP219	-	SP032	-
	SP035	-	SP176	-	SP023	-
	SP264	-	SP183	-	SP338	-
	SP235	-	SP495	-	SP009	-
	SP115	-	SP179	-	SP226	-
	SP147	-	SP111	-	SP275	-
	SP057	-	SP423	-	SP041	-
	SP418	-	SP482	-	SP154	-
	SP470	-	SP475	-	SP484	-
	SP490	-	SP143	-	SP062	-
	SP363	-	SP130	-	SP483	-
	SP455	-	SP498	-	SP481	-
	SP083	-	SP315	-	SP180	-
SP188	-	SP322	-	SP368	-	
125pg/mL	SP206	-	SP377	-	SP056	-
	SP265	-	SP453	-	SP233	-
	SP171	-	SP372	-	SP030	-
	SP313	-	SP068	-	SP290	-
	SP018	-	SP326	-	SP195	-
	SP415	-	SP016	-	SP201	-
	SP118	-	SP053	-	SP078	-
	SP422	-	SP299	-	SP084	-
	SP028	-	SP224	-	SP260	-
	SP050	-	SP318	-	SP296	-
	SP499	-	SP374	-	SP333	-

	SP091	-	SP113	-	SP220	-
	SP211	-	SP096	-	SP149	-
	SP151	-	SP497	-	SP280	-
	SP136	-	SP492	-	SP443	-
	SP225	-	SP417	-	SP270	-
	SP139	-	SP478	-	SP256	-
	SP177	-	SP002	-	SP063	-
	SP457	-	SP125	-	SP194	-
	SP433	-	SP216	-	SP426	-
250pg/mL	SP328	-	SP040	-	SP424	-
	SP215	-	SP015	-	SP440	-
	SP474	-	SP330	-	SP439	-
	SP031	-	SP137	-	SP037	-
	SP008	-	SP043	-	SP366	-
	SP193	-	SP295	-	SP169	-
	SP292	-	SP126	-	SP310	-
	SP309	-	SP134	-	SP406	-
	SP276	-	SP266	-	SP468	-
	SP340	-	SP104	-	SP051	-
	SP312	-	SP356	-	SP325	-
	SP189	-	SP231	-	SP209	-
	SP469	-	SP210	-	SP159	-
	SP421	-	SP344	-	SP152	-
	SP098	-	SP042	-	SP158	-
	SP438	-	SP173	-	SP297	-
	SP496	-	SP010	-	SP197	-
	SP238	-	SP407	-	SP048	-
SP236	-	SP286	-	SP064	-	
SP223	-	SP393	-	SP491	-	
500pg/mL	SP061	+	SP332	+	SP327	+
	SP288	+	SP437	+	SP452	+
	SP145	+	SP300	+	SP109	+
	SP434	+	SP451	+	SP207	+
	SP254	+	SP243	+	SP268	+
	SP026	+	SP279	+	SP431	+
	SP317	+	SP432	+	SP382	+
	SP375	+	SP164	+	SP403	+
	SP131	+	SP005	+	SP237	+
	SP339	+	SP011	+	SP308	+
	SP386	+	SP161	+	SP014	+
	SP047	+	SP450	+	SP316	+

	SP027	+	SP079	+	SP373	+
	SP464	+	SP119	+	SP399	+
	SP110	+	SP190	+	SP404	+
	SP181	+	SP202	+	SP099	+
	SP163	+	SP465	+	SP251	+
	SP409	+	SP132	+	SP036	+
	SP342	+	SP017	+	SP346	+
	SP430	+	SP074	+	SP240	+
1ng/mL	SP241	+	SP274	+	SP250	+
	SP249	+	SP090	+	SP345	+
	SP105	+	SP252	+	SP306	+
	SP248	+	SP097	+	SP283	+
	SP428	+	SP273	+	SP071	+
	SP021	+	SP148	+	SP460	+
	SP367	+	SP133	+	SP034	+
	SP013	+	SP261	+	SP489	+
	SP413	+	SP072	+	SP029	+
	SP120	+	SP170	+	SP222	+
	SP024	+	SP390	+	SP087	+
	SP291	+	SP012	+	SP239	+
	SP059	+	SP065	+	SP384	+
	SP307	+	SP022	+	SP124	+
	SP396	+	SP103	+	SP157	+
	SP398	+	SP284	+	SP175	+
	SP331	+	SP444	+	SP462	+
	SP086	+	SP052	+	SP101	+
	SP049	+	SP045	+	SP471	+
SP320	+	SP166	+	SP129	+	
2ng/mL	SP285	+	SP488	+	SP184	+
	SP128	+	SP480	+	SP436	+
	SP314	+	SP123	+	SP411	+
	SP408	+	SP255	+	SP392	+
	SP385	+	SP458	+	SP232	+
	SP234	+	SP445	+	SP361	+
	SP156	+	SP092	+	SP212	+
	SP354	+	SP242	+	SP218	+
	SP427	+	SP178	+	SP349	+
	SP298	+	SP343	+	SP199	+
	SP044	+	SP089	+	SP257	+
	SP282	+	SP277	+	SP449	+
	SP350	+	SP150	+	SP146	+

	SP370	+	SP353	+	SP214	+
	SP456	+	SP362	+	SP246	+
	SP138	+	SP054	+	SP039	+
	SP405	+	SP082	+	SP112	+
	SP319	+	SP302	+	SP397	+
	SP221	+	SP263	+	SP141	+
	SP165	+	SP487	+	SP155	+

5. Staticus

The results of precision

HCG concentration	LOT 1		LOT 2		LOT 3	
	positive	negative	positive	negative	positive	negative
0pg/mL	0	20	0	20	0	20
125pg/mL	0	20	0	20	0	20
250pg/mL	0	20	0	20	0	20
500pg/mL	20	0	20	0	20	0
1ng/mL	20	0	20	0	20	0
2ng/mL	20	0	20	0	20	0

6. Conclusion

6.1 The results show that the precision of COVID-19 Antigen rapid Test in 3 batches are good and exhibited reproducibility of results.

6.2 *Detection limit*/Sensitivity

According to above precision data, the sensitivity of the COVID-19 Antigen rapid Test is 500pg/ml.