

Correlation Study of StrongStep® Neisseria Gonorrhoeae Antigen Rapid Test with a Japanese existing product

March 18, 2020
SB Bioscience Co., LTD

Test Objective:

To evaluate clinical performance of StrongStep® Neisseria Gonorrhoeae Antigen Rapid Test to detect Neisseria gonorrhoeae antigen in the endocervical specimen by comparing with the Japanese existing product, "Clearview Gonorrhoeae".

Place where test was performed:

- **Facility which controlled the Tests:**
SB Bioscience Co., LTD
- **Facility which collect endocervical specimens:**
Three Clinics located in Osaka-City
- **Facility which conduct kits assay:**
SB Bioscience, Kobe Laboratory
- **Facility which conduct DNA-amplification assay:**
Commercial Clinical Laboratories

Responsible Person:

Satoshi Tanaka (Director, Business Development, SB Bioscience)

Period of Test:

September, 2019 - March, 2020

Tested Product:

StrongStep® Neisseria Gonorrhoeae Antigen Rapid Test
(Nanjing Liming Bio-Products Co., Ltd.)

Existing product to be compared:

Clearview Gonorrhoeae (Abbott Diagnostics Medical Co., Ltd.)
Registration number 22200AMX00337000

Test Method:

Endocervical specimens were collected from 391 female patients, who visited the three clinics during the period of test, including 300 patients suspected of gonococcal infection and 91 patients diagnosed with gonococcal infection by prior DNA amplification testing.

For this study, two cervical swabs were collected from a patient and one was assayed with the tested product and the other was assayed with the existing product following the assay procedures instructed in package inserts of the respective products.

Regarding 300 suspected patients, another endocervical swab was collected and tested by DNA amplification methods as reference.

Test Results:

All the results of tested product, compared product and DNA amplification testing for 391 patients are listed in the Table 1 - (1) ~ (4) in Page 3 ~ 6.

(1) Correlation with existing products

Correlation between tested product and compared product is as shown below:

		Clearview (Abbott)		
		POS	NEG	total
StrongStep (Liming Bio)	POS	45	20 ^{a)}	65
	NEG	8 ^{b)}	318	326
	total	53	338	391

a) DNA amplification test: positive 18, negative 2

b) DNA amplification test: positive 0, negative 8

Positive agreement rate: 84.9 % (45/53)

Negative agreement rate: 94.1 % (318/338)

Total agreement rate: 92.8 % (363/391)

(2) Correlation with DNA amplification testing

Correlation between tested product and DNA amplification testing is as shown below:

		DNA amplification testing		
		POS	NEG	total
StrongStep (Liming Bio)	POS	63	2	65
	NEG	30	296	326
	total	93	298	391

Positive agreement rate (Sensitivity): 67.7 % (63/93)

Negative agreement rate (Specificity): 99.3 % (296/298)

Total agreement rate (Accuracy): 91.8 % (359/391)

Conclusion:

It was shown that StrongStep[®] Neisseria Gonorrhoeae Antigen Rapid Test has comparable clinical performance to detect Neisseria gonorrhoeae antigen in the endocervical specimen with “Clearview Gonorrhoeae” which was already registered as an IVD product in Japan.

Results of correlation study are in compliance with all requirements to apply StrongStep[®] Neisseria Gonorrhoeae Antigen Rapid Test as an IVD product.

Regarding correlation with DNA amplification testing, sensitivity was not so high (67.7 %) but it was much higher compared to “Clearview Gonorrhoeae” (49.5%, 46/93). It suggests that StrongStep[®] Neisseria Gonorrhoeae Antigen Rapid Test has better performance than “Clearview Gonorrhoeae”.

Table 1 - (1)

(+: Positive, -: Negative)

Sample ID	StrongStep	Clearview	DNATest	Sample ID	StrongStep	Clearview	DNATest
T-001	-	-	-	T-051	-	-	-
T-002	-	-	-	T-052	-	-	-
T-003	-	-	-	T-053	-	-	-
T-004	-	-	-	T-054	-	-	-
T-005	-	-	-	T-055	-	-	-
T-006	-	-	-	T-056	-	-	-
T-007	-	-	-	T-057	-	-	-
T-008	-	-	-	T-058	-	-	-
T-009	-	-	-	T-059	-	-	-
T-010	-	-	-	T-060	-	-	-
T-011	-	-	-	T-061	-	-	-
T-012	-	-	-	T-062	-	-	-
T-013	-	-	-	T-063	-	-	-
T-014	-	-	-	T-064	-	-	-
T-015	-	-	-	T-065	-	-	-
T-016	-	-	-	T-066	-	-	-
T-017	-	-	-	T-067	-	-	-
T-018	-	-	-	T-068	-	-	-
T-019	-	-	-	T-069	-	-	-
T-020	-	-	-	T-070	-	+	-
T-021	-	-	-	T-071	-	-	-
T-022	-	-	-	T-072	-	-	-
T-023	-	-	-	T-073	-	-	-
T-024	-	-	-	T-074	-	+	-
T-025	-	-	-	T-075	+	-	-
T-026	-	-	-	T-076	-	-	-
T-027	-	-	-	T-077	-	-	-
T-028	-	-	-	T-078	-	-	-
T-029	-	-	-	T-079	-	-	-
T-030	-	-	-	T-080	-	-	-
T-031	-	-	-	T-081	-	-	-
T-032	-	-	-	T-082	-	-	-
T-033	-	-	-	T-083	-	-	-
T-034	-	-	-	T-084	-	-	-
T-035	-	-	-	T-085	-	-	-
T-036	-	-	-	T-086	-	-	-
T-037	-	-	-	T-087	-	-	-
T-038	-	-	-	T-088	-	-	-
T-039	-	-	-	T-089	-	-	-
T-040	-	-	-	T-090	-	-	-
T-041	-	-	-	T-091	-	-	-
T-042	-	-	-	T-092	-	-	-
T-043	-	-	-	T-093	-	+	-
T-044	-	-	-	T-094	-	-	-
T-045	+	-	+	T-095	-	-	-
T-046	-	-	-	T-096	-	-	-
T-047	-	-	-	T-097	-	-	-
T-048	-	-	-	T-098	-	-	-
T-049	-	-	-	T-099	-	-	-
T-050	-	-	-	T-100	-	-	-

Table 1 - (2)

(+: Positive, -: Negative)

Sample ID	StrongStep	Clearview	DNATest	Sample ID	StrongStep	Clearview	DNATest
T-101	-	-	-	T-151	-	-	-
T-102	-	+	-	T-152	-	-	-
T-103	-	-	-	T-153	-	-	-
T-104	-	-	-	T-154	-	-	-
T-105	-	-	-	T-155	-	-	-
T-106	-	-	-	T-156	-	-	-
T-107	-	-	-	T-157	-	-	-
T-108	-	-	-	T-158	-	-	-
T-109	-	-	-	T-159	-	-	-
T-110	-	-	-	T-160	-	-	-
T-111	-	-	-	T-161	-	-	-
T-112	-	-	-	T-162	-	-	-
T-113	-	-	-	T-163	-	-	-
T-114	-	-	-	T-164	-	-	-
T-115	-	-	-	T-165	-	-	-
T-116	-	-	-	T-166	-	-	-
T-117	-	-	-	T-167	-	-	-
T-118	-	-	-	T-168	-	-	-
T-119	-	-	-	T-169	-	-	-
T-120	-	-	-	T-170	-	-	-
T-121	-	-	-	T-171	-	-	-
T-122	-	-	-	T-172	-	-	-
T-123	-	-	-	T-173	-	-	-
T-124	-	-	-	T-174	-	-	-
T-125	-	-	-	T-175	-	-	-
T-126	-	-	-	T-176	-	-	-
T-127	-	-	-	T-177	-	-	-
T-128	-	+	-	T-178	-	-	-
T-129	-	-	-	T-179	-	-	-
T-130	-	-	-	T-180	-	-	-
T-131	-	-	-	T-181	-	-	-
T-132	-	-	-	T-182	-	-	-
T-133	-	-	-	T-183	-	-	-
T-134	-	-	-	T-184	-	-	-
T-135	-	-	-	T-185	-	-	-
T-136	-	-	-	T-186	-	-	-
T-137	-	-	-	T-187	-	-	-
T-138	-	-	-	T-188	-	-	-
T-139	-	-	-	T-189	-	-	-
T-140	-	-	-	T-190	-	-	-
T-141	-	-	-	T-191	-	-	-
T-142	-	-	-	T-192	-	-	-
T-143	-	-	-	T-193	-	-	-
T-144	-	-	-	T-194	-	-	-
T-145	-	-	-	T-195	-	-	-
T-146	-	-	-	T-196	-	-	-
T-147	-	-	-	T-197	-	-	-
T-148	-	-	-	T-198	-	-	-
T-149	-	-	-	T-199	-	-	-
T-150	-	-	-	T-200	-	-	-

Table 1 - (3)

(+: Positive, -: Negative)

Sample ID	StrongStep	Clearview	DNATest	Sample ID	StrongStep	Clearview	DNATest
T-201	-	-	-	T-251	-	-	-
T-202	-	-	-	T-252	-	-	-
T-203	-	-	-	T-253	-	-	-
T-204	-	-	-	T-254	-	-	-
T-205	-	-	-	T-255	-	-	-
T-206	-	-	-	T-256	-	-	-
T-207	-	-	-	T-257	-	-	-
T-208	-	-	-	T-258	-	-	-
T-209	+	-	-	T-259	-	-	-
T-210	-	-	-	T-260	-	-	-
T-211	-	-	-	T-261	-	-	-
T-212	-	-	-	T-262	-	-	-
T-213	-	-	-	T-263	-	-	-
T-214	-	-	-	T-264	-	-	-
T-215	-	-	-	T-265	-	-	-
T-216	-	-	-	T-266	-	-	-
T-217	-	-	-	T-267	-	-	-
T-218	-	-	-	T-268	-	-	-
T-219	-	-	-	T-269	-	-	-
T-220	-	+	-	T-270	-	-	-
T-221	-	-	-	T-271	-	-	-
T-222	-	+	-	T-272	-	-	-
T-223	-	-	-	T-273	-	-	-
T-224	-	-	-	T-274	-	-	-
T-225	-	-	-	T-275	-	-	-
T-226	-	-	-	T-276	+	-	+
T-227	-	-	-	T-277	-	-	-
T-228	-	-	-	T-278	-	-	-
T-229	-	-	-	T-279	-	-	-
T-230	-	-	-	T-280	-	-	-
T-231	-	-	-	T-281	-	-	-
T-232	-	-	-	T-282	-	-	-
T-233	-	-	-	T-283	-	-	-
T-234	-	-	-	T-284	-	-	-
T-235	-	-	-	T-285	-	-	-
T-236	-	-	-	T-286	-	-	-
T-237	-	-	-	T-287	-	-	-
T-238	-	-	-	T-288	-	-	-
T-239	-	-	-	T-289	-	-	-
T-240	-	-	-	T-290	-	-	-
T-241	-	-	-	T-291	-	-	-
T-242	-	-	-	T-292	-	-	-
T-243	-	-	-	T-293	-	-	-
T-244	-	-	-	T-294	-	-	-
T-245	-	-	-	T-295	-	-	-
T-246	-	-	-	T-296	-	-	-
T-247	-	-	-	T-297	-	-	-
T-248	-	-	-	T-298	-	-	-
T-249	-	-	-	T-299	-	-	-
T-250	-	-	-	T-300	-	-	-

Table 1 - (4)

(+: Positive, -: Negative)

Sample ID	StrongStep	Clearview	DNATest	Sample ID	StrongStep	Clearview	DNATest
N-001	+	+	+	N-051	-	-	+
N-002	-	-	+	N-052	+	+	+
N-003	+	+	+	N-053	+	+	+
N-004	+	+	+	N-054	+	+	+
N-005	-	-	+	N-055	+	-	+
N-006	+	+	+	N-056	-	-	+
N-007	-	-	+	N-057	+	-	+
N-008	+	+	+	N-058	-	-	+
N-009	-	-	+	N-059	+	+	+
N-010	+	-	+	N-060	-	-	+
N-011	+	+	+	N-061	+	-	+
N-012	-	-	+	N-062	+	+	+
N-013	+	+	+	N-063	-	-	+
N-014	-	-	+	N-064	+	-	+
N-015	+	-	+	N-065	+	-	+
N-016	+	+	+	N-066	+	+	+
N-017	-	-	+	N-067	-	-	+
N-018	+	+	+	N-068	+	+	+
N-019	-	-	+	N-069	+	+	+
N-020	+	+	+	N-070	+	-	+
N-021	-	-	+	N-071	-	-	+
N-022	+	-	+	N-072	-	-	+
N-023	+	+	+	N-073	+	+	+
N-024	-	-	+	N-074	+	+	+
N-025	+	+	+	N-075	-	-	+
N-026	-	+	+	N-076	+	-	+
N-027	-	-	+	N-077	+	+	+
N-028	+	+	+	N-078	+	+	+
N-029	-	-	+	N-079	-	-	+
N-030	+	+	+	N-080	+	-	+
N-031	-	-	+	H-001	+	+	+
N-032	+	+	+	H-003	+	+	+
N-033	+	+	+	H-004	-	-	+
N-034	+	+	+	H-005	+	+	+
N-035	+	-	+	H-006	+	+	+
N-036	+	+	+	H-007	+	+	+
N-037	+	-	+	H-008	+	-	+
N-038	-	-	+	H-009	-	-	+
N-039	-	-	+	H-010	+	+	+
N-040	+	+	+	H-011	+	-	+
N-041	-	-	+	H-012	+	+	+
N-042	+	+	+				
N-043	+	+	+				
N-044	+	+	+				
N-045	+	+	+				
N-046	-	-	+				
N-047	+	+	+				
N-048	-	+	+				
N-049	+	+	+				
N-050	+	+	+				