
iCARE Gonorrhea Self-Test Kit (Fluid Specimen)

Clinical Report

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1. Trial Objectives

The purpose of this evaluation is to establish the clinical performance of the iCARE Gonorrhea Self-Test Kit (Fluid Specimen).

2. Administrative Information

2.1 The protocol should be read carefully, the protocol and 'Test Procedure' supplied with the reagents must be followed exactly unless explicitly stated.

2.2 The assays during the period of the evaluation should be double checked by another technician.

2.3 The results for both iCARE Gonorrhea Self-Test Kit (Fluid Specimen) and any alternative assay methods must be properly identified. The data should be clearly legible and marked with the name of the laboratory and initialed by Coordinator.

2.4 All original raw data must be made available for further information.

3. Study Design

3.1 Random blinding requirements: According rules of Random coding, Set blinding, and Unblind.

3.2 Time Scale of Evaluation

The evaluation should be completed within 24 weeks.

3.3 Materials Used

3.3.1 Target reagent: A lot of qualified iCARE Gonorrhea Self-Test Kit (Fluid Specimen) produced based on technological process and the outputted Standard Operating Procedure. Test result with no analyzer or reader.

3.4 Specimens' collection and testing site: The Red flag Hospital of Mudanjiang, Infectious diseases hospital of Xinjiang Autonomous Region, Hebei Chest Hospital.

3.5 User training: In case of the Antigen Test kit operator, training will be conducted on sample collection, transportation and treatment to ensure the correct use of the extract R1, sample processing, sample loading and result reading. The relevant operation video will also provide reference.

The applicant should be trained in the use of test reagents, especially the standardized training of random blind method according to the relevant national requirements.

3.6 Specimens to be tested

All the specimens used in this evaluation were form The Red flag Hospital of Mudanjiang, Infectious diseases hospital of Xinjiang Autonomous Region, Hebei Chest Hospital.

3.6.1 Specimen types

Female Cervical Swab Specimens; Male Urethral Swab Specimens

3.6.2 Specimen quantity

Specimens above should be collected with known Culture positive and known Culture

negative patients' samples after.

3.6.3 Specimen number:

Positive samples should not less than 50.

Negative samples should not less than 100.

3.7 Data analysis

The product of this research is a qualitative detection clinical trial. The detection results of the two methods will be summarized in the form of 2×2 spreadsheet, and the sensitivity (positive coincidence rate), specificity (negative coincidence rate), total coincidence rate and other indicators will be calculated based on this and its 95% confidence interval.

3.8 Storage and Reporting

All data will be filed both on hard copy and in electronically files. The clinical trial date is March 2022 and all clinical trial data will be stored for 5 years. All laboratory results are strictly confidential. Copies of raw data were retained under the internal R&D department of for future reference.

iCARE Gonorrhea Self-Test Kit (Fluid Specimen) Performance on clinical Study Report

1. Purpose

To study the performance of the iCARE Gonorrhea Self-Test Kit (Fluid Specimen) with specimens.

2. Method and material

Specimen collected in hospital by qualified medical personnel and coded with random number blindly. Specimens collected according to proper procedure.

iCARE Gonorrhea Self-Test Kit (Fluid Specimen) (LOT NO. RD0918D1; LOT NO. RD0918D2) was used for evaluation.

Random blinding requirements: According rules of random coding, set blinding, and Unblind.

3. The results table (random blind testing)

3.1 For Female Cervical Swab Specimens

A total of 204 **Female Cervical Swab Specimens** consisting of 89 positive, 115 negative **Female Cervical Swab Specimens**, were considered evaluable in this study. The performance of the iCARE Gonorrhea Self-Test Kit (Fluid Specimen) compared to the Culture as the reference method are presented in the table below:

iCARE Gonorrhea Self-Test Kit (Fluid Specimen)	Culture		
	Positive	Negative	Total
Positive	85	3	88
Negative	4	112	116
Total	89	115	204

Sensitivity (Positive Percent Agreement): $95.50\% = 85/89$ (95% CI: 89.01%~98.24%)

Specificity (Negative Percent Agreement): $97.39\% = 112/115$ (95% CI: 92.61%~99.11%)

Accuracy (Overall Percent Agreement): $96.56\% = (85+112)/204$ (95% CI: 93.09%~98.33%)

PPV (positive predictive value): $96.59\% = 85/(85+3)$

NPV (negative predictive value): $96.55\% = 112/(112+4)$

3.2 For Male Urethral Swab Specimens

A total of 275 **Male Urethral Swab Specimens** consisting of 115 positive, 160 negative **Male Urethral Swab Specimens**, were considered evaluable in this study. The performance of the iCARE Gonorrhea Self-Test Kit (Fluid Specimen) compared to the Culture as the reference method are presented in the table below:

The iCARE Gonorrhea Self-Test Kit (Fluid Specimen)	Culture		
	Positive	Negative	Total
Positive	106	4	110
Negative	9	156	165
Total	115	160	275

Sensitivity (Positive Percent Agreement): $92.17\% = 106/115$ (95% CI: 85.79%~95.83%)

Specificity (Negative Percent Agreement): $97.50\% = 156/160$ (95% CI: 93.75%~99.02%)

Accuracy (Overall Percent Agreement): $95.27\% = (106+156)/275$ (95% CI: 92.08%~97.22%)

PPV (positive predictive value): $96.36\% = 106/(106+4)$

NPV (negative predictive value): $94.55\% = 156/(156+9)$

*** 95% Confidence Interval**

Notes: 1. **Sensitivity:** The percentage of the number of positive specimens detected by the test kit compared to the number of Gonorrhea positive specimens detected by Culture.

2. **Specificity:** The percentage of the number of negative specimens detected by the test kit versus the number of Gonorrhea negative specimens detected by Culture.

Annex 1

Testing Result Record Sheet for Positive Specimens (For Female)

Sample ID	Gonorrhea Self-Test Kit	Culture	Sample ID	Gonorrhea Self-Test Kit	Culture
P001	+	+	P046	+	+
P002	+	+	P047	+	+
P003	+	+	P048	+	+
P004	+	+	P049	+	+
P005	+	+	P050	+	+
P006	+	+	P051	+	+
P007	+	+	P052	+	+
P008	+	+	P053	+	+
P009	+	+	P054	+	+
P010	+	+	P055	+	+
P011	+	+	P056	-	+
P012	+	+	P057	+	+
P013	+	+	P058	+	+
P014	+	+	P059	+	+
P015	+	+	P060	+	+
P016	+	+	P061	+	+
P017	+	+	P062	+	+
P018	-	+	P063	+	+
P019	+	+	P064	+	+
P020	+	+	P065	+	+

P021	+	+	P066	+	+
P022	+	+	P067	+	+
P023	+	+	P068	+	+
P024	+	+	P069	+	+
P025	+	+	P070	+	+
P026	+	+	P071	+	+
P027	+	+	P072	+	+
P028	+	+	P073	+	+
P029	+	+	P074	+	+
P030	+	+	P075	+	+
P031	+	+	P076	+	+
P032	+	+	P077	+	+
P033	+	+	P078	+	+
P034	+	+	P079	-	+
P035	+	+	P080	+	+
P036	+	+	P081	+	+
P037	+	+	P082	+	+
P038	-	+	P083	+	+
P039	+	+	P084	+	+
P040	+	+	P085	+	+
P041	+	+	P086	+	+
P042	+	+	P087	+	+
P043	+	+	P088	+	+
P044	+	+	P089	+	+
P045	+	+			

Result specification: “+”=Positive “-”=Negative

Annex 2

Testing Result Record Sheet for Positive Specimens (For Male)

Sample ID	Gonorrhea Self-Test Kit	Culture	Sample ID	Gonorrhea Self-Test Kit	Culture
P001	+	+	P059	+	+
P002	+	+	P060	+	+
P003	+	+	P061	+	+
P004	+	+	P062	+	+
P005	+	+	P063	+	+
P006	+	+	P064	+	+
P007	+	+	P065	-	+
P008	+	+	P066	+	+
P009	-	+	P067	+	+
P010	+	+	P068	+	+

P011	+	+	P069	+	+
P012	+	+	P070	+	+
P013	+	+	P071	+	+
P014	+	+	P072	+	+
P015	+	+	P073	+	+
P016	+	+	P074	+	+
P017	+	+	P075	+	+
P018	+	+	P076	+	+
P019	+	+	P077	+	+
P020	+	+	P078	+	+
P021	+	+	P079	+	+
P022	+	+	P080	+	+
P023	+	+	P081	+	+
P024	+	+	P082	-	+
P025	+	+	P083	+	+
P026	+	+	P084	+	+
P027	+	+	P085	+	+
P028	+	+	P086	+	+
P029	-	+	P087	+	+
P030	+	+	P088	+	+
P031	+	+	P089	+	+
P032	+	+	P090	+	+
P033	+	+	P091	+	+
P034	+	+	P092	+	+
P035	+	+	P093	-	+
P036	+	+	P094	+	+
P037	+	+	P095	+	+
P038	-	+	P096	+	+
P039	+	+	P097	+	+
P040	+	+	P098	+	+
P041	+	+	P099	+	+
P042	+	+	P100	+	+
P043	+	+	P101	+	+
P044	+	+	P102	+	+
P045	+	+	P103	+	+
P046	+	+	P104	+	+
P047	+	+	P105	+	+
P048	-	+	P106	+	+
P049	+	+	P107	+	+
P050	+	+	P108	+	+
P051	+	+	P109	+	+
P052	+	+	P110	+	+

P053	+	+	P111	+	+
P054	+	+	P112	-	+
P055	-	+	P113	+	+
P056	+	+	P114	+	+
P057	+	+	P115	+	+
P058	+	+			

Result specification: “+”=Positive “-”=Negative

4. Discussion and Conclusion

The results above showed that there was a good consistency between the iCARE Gonorrhea Self-Test Kit (Fluid Specimen) and the Culture results. So the iCARE Gonorrhea Self-Test Kit (Fluid Specimen) has a good clinical performance.