

CS0 Semen Test Cassette

User Manual For Professional use

Rev.30-0CS0020
20190321



Introduction

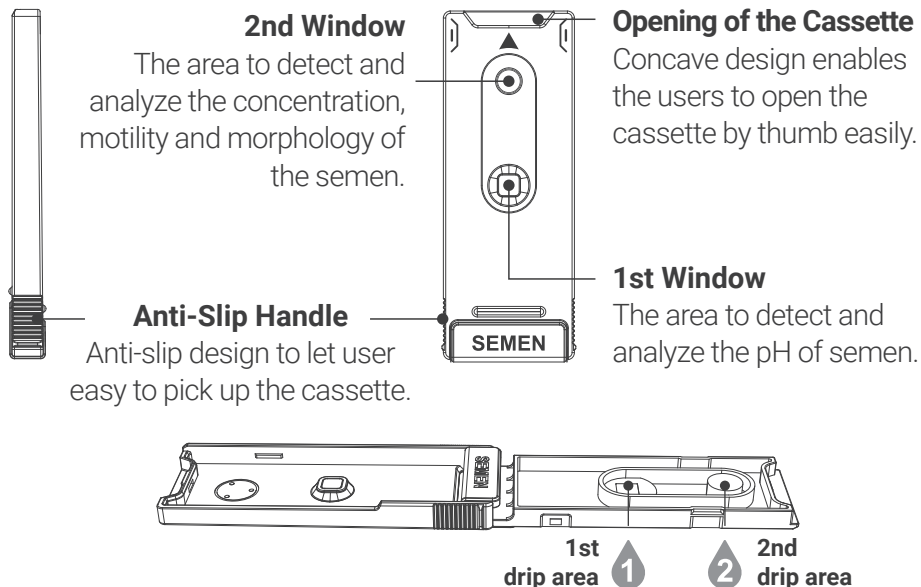
Please read this user manual carefully before using. This product is in vitro diagnostics only. LensHooke™ CS0 Semen Test Cassette is designed, manufactured and authorized by Bonraybio Co., LTD. If you have any questions about the product or require any assistance, please feel free to contact Bonraybio by calling the Service Hotline (+886-4-24912385) or contact your local distributor. Service Hotline time: Mon~Fri 08:30~17:30 (GMT+8)

Intended use

LensHooke™ CS0 Semen Test Cassette is using the Quantitative analysis method to analyze the pH, concentration, motility and morphology of human semen. This cassette is NOT reusable, please dispose it after use.

LensHooke™ CS0 Semen Test Cassette is used with LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic), LensHooke™ X1 Semen Quality Analyzer (For Couple), LensHooke™ X2 Home Fertility Test Device (For Couple), and also C-KUP™ Liquefaction Test Cup.

LensHooke™ CS0 Semen Test Cassette Illustration



LensHooke™ CS0 Semen Test Cassette Operating Steps

All of the operation procedures should follow the instruction of user manuals of LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic), LensHooke™ X1 Semen Quality Analyzer (For Couple), and LensHooke™ X2 Home Fertility Test Device (For Couple).

LensHooke™ CS0 Semen Test Cassette Test Result

- The test result will appear in the devices of LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic), LensHooke™ X1 Semen Quality Analyzer (For Couple), LensHooke™ X2 Home Fertility Test Device (For Couple).
- If you doubt the test result, please use another new test cassette to test again by following the semen analysis test steps of user manual.
- The test range of pH value for LensHooke™ CS0 Semen Test Cassette is pH6.0~8.0. If your pH value lower than 6.0, you will get the result of <6.0. If your pH value higher than 8.0, you will get the result of >8.0. Suggest to test again if you get the result of <6.0 or >8.0, and consult to your doctor if you still get the same result.

Reference of Parameter from WHO Laboratory Manual for the Examination and Processing of Human Semen

| Reference | WHO 5th Low Reference | WHO 4th Low Reference |
|---------------------------|----------------------------------|-----------------------------|
| Concentration | 15 x 10 ⁶ (12-16)/ ml | ≥ 20 x 10 ⁶ / ml |
| Motility | 40% (38-42%) | a + b ≥ 50% or a ≥ 25% |
| PR (Progressive Motility) | 32% (31-34%) | |
| Morphology(Normal) | 4% (3-4%) | ≥ 15% |

a : Rapid Progressive Motility(≥25μm/s) b: Slow or Sluggish Progressive Motility

Caution

⚠ Please DO NOT let the children reach the LensHooke™ CS0 Semen Test Cassette. If they swallow the cassettes by accident, please contact the professional doctor immediately for the assistance.

Limitation

- When you see the mark of “*” beside your result, it means the sample has crystal or other impurity. Please consult your doctor since it will affect the result.
- LensHooke™ CS0 Semen Test Cassette is designed ONLY for human semen testing, please DO NOT use it to test other kind of sample.

- It might affect the result, if the sample is contaminated by the lubricant or saliva.
- Please DO NOT test under the operating temperature lower than 15°C (59°F) or higher than 38°C (100°F), and the humidity higher than 70%.

LensHooke™ CS0 Semen Test Cassette Storage & Process

- Please Store the cassette under the temperature higher than 2°C (36°F) and lower than 30°C (86°F). Do not Refrigerate it.
- Please DO NOT touch the drip and window area.
- Please use it immediately when you open the package of the cassette. It will affect the pH test result if you leave the test cassette too long to absorb the humidity.
- Please follow the standard medical waste procedure to dispose the used LensHooke™ CS0 Semen Test Cassette and gloves to prevent the cross contamination.

LensHooke™ License Dongle Operating Steps

All of the operation procedures should follow the instruction of user manuals of LensHooke™ X1 PRO Semen Quality Analyzer (For Clinic), and LensHooke™ X1 Semen Quality Analyzer (For Couple).

LensHooke™ CS0 Semen Test Cassette Specification

| | | | |
|---------------|--|-----------------------|--|
| Product Name | LensHooke™ CS0 Semen Test Cassette | Total Motility | <1-100% |
| Size | L75 x W28.6 x H7.96 mm | Morphology | <1-100% |
| pH | pH6.0 ~ 8.0 (Each Scale Range: 0.2) | Operation Environment | 15°C ~ 38°C (59°F~100°F), humidity <70% |
| Concentration | <0.1 - 300 (10 ⁶ /ml) | Storage Environment | 2°C ~ 30°C (36°F~86°F) (DO NOT Refrigerate) |

We suggest to apply 0.04ml sample.
(one drop from the tip of C-KUP™ Liquefaction Test Cup).

⚠ Too much sample might be contaminated the whole Test Cassette.

LensHooke™ CS0 Semen Test Cassette Extra Information for Professional

Detect Method

Optical Image Technology with Artificial Intelligence Algorithm to detect and analyze the semen.

Operation Notice

- Please clean LensHooke™ X1 PRO Semen Quality analyzer (For Clinic), LensHooke™ X1 Semen Quality analyzer (For Couple), LensHooke™ X2 Home Fertility Test Device (For Couple) after testing.

- Please change the gloves for different sample's examination.

Precision

The precision was evaluated including 6 concentration (Conc.)/motility(Mot.) levels.

| Sample levels | LM40 | LM60 | MM40 | MM60 | HM40 | HM60 |
|----------------------------------|------|------|-------|-------|-------|-------|
| Conc. Mean (10 ⁶ /mL) | 16.0 | 19.2 | 116.2 | 130.2 | 157.5 | 172.4 |
| Conc. SD (10 ⁶ /mL) | 0.7 | 0.6 | 4.6 | 5.3 | 5.3 | 5.1 |
| Conc. CV (%) | 4.2 | 3.3 | 3.9 | 3.3 | 3.4 | 3.0 |

Accuracy

Comparison studies on LensHooke™ Semen Quality Analyzer with medical technologists' concurrent visual analysis results via using the microscope were performed in a clinical laboratory. Semen quality results were compared and the correlation of coefficient was > 0.96.

Interference

Vitamin B, Testosterone, Yeast, E. coli, RBC, WBC, Urine, Saliva, Agglutination, D-norgestrel, and B-estradiol do not significantly affect results. However, abnormally high concentrations in semen may cause inaccurate results.

Reagents

Each test Cassette includes the reagents as below :











w/w bromcresol green 3.3%
w/w bromthymol blue 55.0%
w/w nonreactive ingredients 41.7%

LensHooke™ CS0 Semen Test Cassette

The test results above come from LensHooke™ X series Semen Quality Analyzer.

Reference

WHO laboratory manual for the Examination and processing of human semen.

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|  In vitro diagnostic |  Consult instructions for use |  Use by |
|  Manufacturer |  CE mark |  Batch code |
|  Do not use repetitively |  Store at the room temperature between 2°C ~ 30°C (36°F ~ 86°F) |  Caution |
|  European authorized representative | | |



Manufacturer : Bonraybio Co., LTD.
Address : 4F., No.118, Gongye 9th Rd.,
Dali Dist., Taichung City 41280, Taiwan(R.O.C.)
Tel : +886-4-2491-2385
Fax : +886-4-2491-2885
Email : support@bonraybio.com



MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany



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