

QwikCheck *Gold* Equine Sperm Analyzer User Guide

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Section 1: Overview

The QwikCheck™ Gold Equine sperm quality analyzer is used to test and report the quality of FRESH, EXTENDED, COOLED and FROZEN equine semen. The following semen parameters are reported:

Reported Semen Parameters	
Total Sperm Concentration*	Millions/milliliter
Motility	%
Progressive Motility	%
Motile Sperm Concentration	Millions/milliliter
Progressively Motile Sperm Concentration	Millions/milliliter
Velocity	Microns/second

*Not reported for FROZEN

Section 2: System Overview

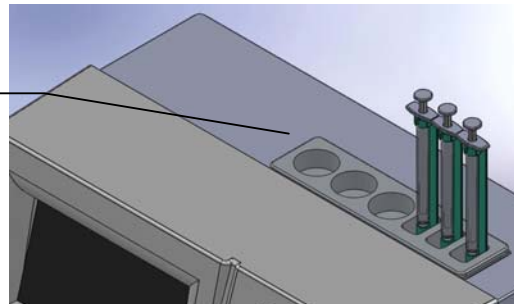
**QwikCheck™
Gold Equine
Sperm Quality
Analyzer**



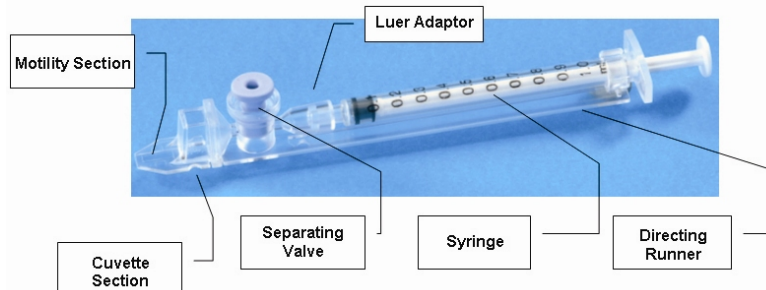
**QwikCheck™
Gold Equine
on-board sample
heating unit**

On-board sample heating unit will pre-heat:

- 3 testing capillaries
- 3 – 10ml sample containers



**QwikCheck™
Gold Equine
testing capillary**



- Plastic, multi-use (10X for animal use only), disposable.
- Refer to the appendix section of this guide for instructions on how to use the capillary and how to clean it.



Section 3: Operating the QwikCheck GOLD Equine

- Turn on the main switch on the rear panel of the QwikCheck GOLD Equine.
- Press the On/Off key on the keypad.
- Wait for the system to complete auto-calibration and self-testing.
- Press ENTER to view the **MAIN MENU**.

Three options are available from the **MAIN MENU**:

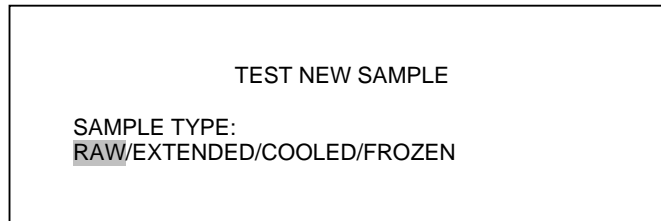
- **TEST NEW SAMPLE**
- **ADD I-BUTTON TESTS**
- **SERVICE**

When using the system for the first time please:

- Load I-Button tests: Go to: **MAIN MENU>ADD I-BUTTON TESTS**
- Set-up the system defaults: Go to: **MAIN MENU > SERVICE > DEFAULT SETTINGS**

Section 4: Sample Testing

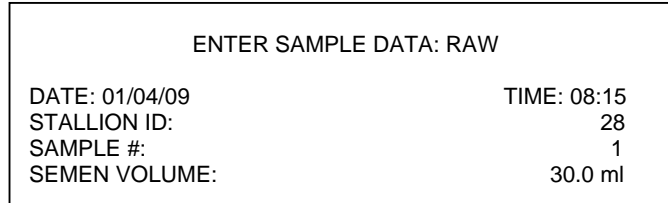
- Select **TEST NEW SAMPLE** from the MAIN MENU to open the screen below which displays four sample type testing options:



NOTE: Load I-button tests and set system defaults **PRIOR** to testing (see Section 6 for full instructions)

Raw Samples

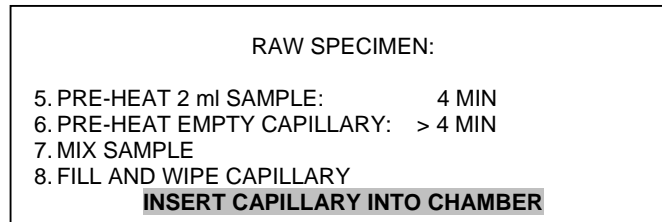
Select **RAW** sample type and the ENTER SAMPLE DATA screen will be displayed:



Enter the following STALLION information using the keypad:

- **Stallion ID:** up to 8 digits
- **Sample #:** up to 10 digits
- **Semen Volume** (Gel free): up to 3 integers and 1 decimal point.

Press **ENTER** and the SAMPLE PREPARATION screen below will be displayed:



NOTE: Raw samples need to be preheated for 4 minutes prior to testing.

- Prepare the RAW semen sample for testing according to the instructions on the screen.
- Wait for a “beep” and a screen message before inserting the testing capillary into the

QwikCheck™ Gold



- Insert the prepared testing capillary when instructed. Testing will begin automatically after an initial pre-heating.

PLEASE WAIT
PRE-HEATING CAPELLARY

- A “beep” will indicate that testing is complete after about 45-60 seconds.
- Test results will then be displayed on the screen below:

SEMEN ANALYSIS REPORT: RAW SAMPLE

DATE: 01/04/09	TIME: 08:15
STALLION ID:	28
SAMPLE #:	1
SEMEN VOLUME:	30.0 ml

- Press ENTER to view the test results:

TEST RESULTS: RAW SAMPLE

CONC. 332.6 M/ml	MSC 259.1 M/ml
MOTILITY 77.9 %	PMSC 183.9 M/ml
PROG. MOT. 55.3 %	VELOC. 32 mic/sec

Extended/Cooled Samples

EXTENDED SEMEN is defined as RAW semen diluted with a commercial extender.

COOLED SEMEN is defined as EXTENDED semen kept in cooling conditions.

- Select: **TEST NEW SAMPLE** from the **Main Menu**
- Select: **EXTENDED** or **COOLED** sample type to display the screen below:

ENTER SAMPLE DATA: EXTENDED/COOLED

DATE: 01/04/09	TIME: 08:15
STALLION ID:	28
SAMPLE #:	1
SEMEN VOLUME:	20.0 ml

Enter the following:

- **Stallion ID:** up to 8 digits
- **Sample #:** up to 10 digits
- **Semen Volume:** up to 3 integers and 1 decimal point.

When a COOLED sample is run, it is necessary to know if the sample has been cooled for more than 24 hours. Select YES/NO in the screen below:

PLEASE SELECT:
SAMPLE COOLED > 24 HOURS
YES/NO



NOTE:
 Preheat samples prior to testing:
EXTENDED:
 4 minutes
COOLED:
 7 minutes

Press **ENTER** and the SAMPLE PREPARATION screen below will be displayed:

EXTENDED SPECIMEN:

1. PRE-HEAT 2 ml SAMPLE: **4 MIN**
2. PRE-HEAT EMPTY CAPILLARY: > 4 MIN
3. MIX SAMPLE
4. FILL AND WIPE CAPILLARY

AUTOCALIBRATION – DO NOT TOUCH UNIT

COOLED SPECIMEN:

1. PRE-HEAT 2 ml SAMPLE: **7 MIN**
2. PRE-HEAT EMPTY CAPILLARY: > 4 MIN
3. MIX SAMPLE
4. FILL AND WIPE CAPILLARY

AUTOCALIBRATION – DO NOT TOUCH UNIT

- Prepare the EXTENDED or COOLED semen sample for testing according to the instructions on the screen.
- Wait for a “beep” and the screen message “INSERT CAPILLARY INTO CHAMBER” to be displayed. Insert the capillary and testing will begin automatically after initial pre-heating.

EXTENDED SPECIMEN:

1. PRE-HEAT 2 ml SAMPLE: **4 MIN**
2. PRE-HEAT EMPTY CAPILLARY: > 4 MIN
3. MIX SAMPLE
4. FILL AND WIPE CAPILLARY

INSERT CAPILLARY INTO CHAMBER

COOLED SPECIMEN:

1. PRE-HEAT 2 ml SAMPLE: **7 MIN**
2. PRE-HEAT EMPTY CAPILLARY: > 4 MIN
3. MIX SAMPLE
4. FILL AND WIPE CAPILLARY

INSERT CAPILLARY INTO CHAMBER

PLEASE WAIT
 PRE-HEATING CAPILLARY

- A “beep” will sound and the screen below will display the semen analysis report:

SEMEN ANALYSIS REPORT: EXTENDED/COOLED SAMPLE

DATE: 01/04/09	TIME: 8:15
STALLION ID: 28	
SAMPLE #: 1	
SEMEN VOLUME: 20.0 ml	
COOLING TIME > 24h	YES (COOLED ONLY)



- Press **ENTER** to view the test results:

TEST RESULTS: EXTENDED/COOLED SAMPLE			
CONC.	67.5 M/ml	MSC	45.0 M/ml
MOTILITY	66.6 %	PMSC	27.2 M/ml
PROG. MOT.	40.3 %	VELOC.	66 mic/sec

- If Motility is $\leq 30\%$ and $\geq 10\%$ in the sample, the report will display only MSC and PMSC:

TEST RESULTS:	
MOTILITY $\leq 30\%$	
MSC	45.0 M/ml
PMSC	27.2 M/ml

- If Motility is $< 10\%$ in the sample, semen parameters cannot be accurately measured and the screen below will be displayed.

TEST RESULTS:	
MOTILITY $< 10\%$	
SEMEN PARAMETERS CANNOT BE MEASURED	

Frozen Samples

- Select: TEST NEW SAMPLE from the Main Menu.
- Select: **FROZEN** sample type and the screen below will be displayed:

ENTER SAMPLE DATA: FROZEN	
DATE: 01/04/09	TIME: 08:15
STALLION ID:	28
STRAW DATE:	10/03/09
SAMPLE #:	1
SEMEN VOLUME:	0.500 ml

Enter the following:

- **Stallion ID:** up to 8 digits
- **Straw Date:** according to the straw labeling
- **Sample #:** up to 10 digits
- **Semen Volume** (actual straw volume): up to 2 integers and 3 decimal points.

Press **ENTER** and the SAMPLE PREPARATION screen below will be displayed:

FROZEN SPECIMEN:	
1. PRE-HEAT THAWED SAMPLE:	4 MIN
2. PRE-HEAT EMPTY CAPILLARY:	> 4 MIN
3. MIX SAMPLE	
4. FILL CAPILLARY:	20 ul
5. WIPE TESTING CAPILLARY	
AUTOCALIBRATION – DO NOT TOUCH UNIT	

- Prepare the FROZEN semen sample for testing according to the instructions on the screen.
- Wait for a “beep” and the screen message “**INSERT CAPILLARY INTO CHAMBER**” to be displayed. Insert the capillary and testing will begin automatically after initial pre-heating.

FROZEN SPECIMEN:

1. PRE-HEAT THAWED SAMPLE: 4 MIN
2. PRE-HEAT EMPTY CAPILLARY: > 4 MIN
3. MIX SAMPLE
4. FILL CAPILLARY: 20 ul
5. WIPE TESTING CAPILLARY

INSERT CAPILLARY INTO CHAMBER

PLEASE WAIT
PRE-HEATING CAPILLARY

- Testing will begin automatically and will take about 45 seconds.
- A “beep” will sound when testing has completed and the screen below will display the semen analysis report:

SEMEN ANALYSIS REPORT: FROZEN SAMPLE

DATE: 01/04/09	TIME: 8:15
STALLION ID:	28
STRAW DATE:	10/03/09
SAMPLE #:	1
SEMEN VOLUME:	0.500 ml

- Press ENTER to view the test results:

TEST RESULTS: FROZEN SAMPLE

CONC.	NA M/ml	MSC	259.1 M/ml
MOTILITY	77.9 %	PMSC	183.9 M/ml
PROG. MOT.	55.3 %	VELOC.	32 mic/sec

- Sperm Concentration is not reported for FROZEN semen.
- If Motility is $\leq 30\%$ and $\geq 10\%$ in the FROZEN sample, only MSC and PMSC are reported.

TEST RESULTS:

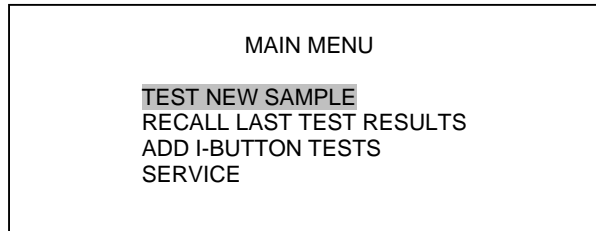
MOTILITY $\leq 30\%$

MSC	259.1 M/ml
PMSC	183.9 M/ml

- If Motility is $< 10\%$ in the FROZEN sample, semen parameters cannot be accurately measured and no test results will be reported.

MAIN MENU:

The MAIN MENU is displayed after each test is run:



- **TEST NEW SAMPLE:** Opens the screen for the sample type selection and further entering the sample data.
- **RECALL LAST TEST RESULTS:** Test results can be recalled for viewing.
- **ADD I-BUTTON TESTS:** Activates the screen for loading the I-Button tests.
- **SERVICE:** Provides access to the Service Data and Default Settings (Section 5 of the User Guide).

Section 5: SERVICE MENU

Select the **SERVICE MENU** and the following options are available:

- **SERVICE DATA**
- **DEFAULT SETTINGS**
- **SERVICE PERSONNEL**

SERVICE DATA: Select to view three service screens:

- **Service Data screen:** Service information for technical support is viewed from this screen.
- **Self-Test Data screen:** This screen provides information of the internal QC by displaying Self-Test and Internal Data.
- **Algorithm data screen:** This screen displays algorithm calculations.

DEFAULT SETTINGS: Select to set the system and sample defaults.

- **LOCAL TIME:** Enter local time.
- **DATE FORMAT:** Select the format DD/MM/YY or MM/DD/YY using the right/left arrows on the keypad.
- **DATE SETTING:** Enter current date.
- **RICH FRACTION COLLECTED YES/NO:** The default is NO for the entire ejaculate collected; If a rich ejaculate fraction is collected select YES.
- **AUTO PRINTING YES/NO:** Select YES/NO to automatically print test results after running a test using an external label printer connected to the system (recommended setting: YES).
- **# LABELS TO PRINT 1/2:** Select the number of labels required.
- **CONC STD:** Select "1" for Neubauer (default) or "2" for Nucleocounter

SERVICE PERSONNEL: For technical service (requires a password).

Section 6: ADD I-BUTTON TESTS

The QwikCheck GOLD Equine requires tests be “loaded” using an I-Button.

- Select **MAIN MENU > ADD I-BUTTON TESTS** and press **ENTER**.
- The QwikCheck GOLD Equine screen will instruct the user:

TO ADD TESTS:
HOLD NEW I-BUTTON AGAINST PORT
AND PRESS ENTER

PRESS ESC TO EXIT

- Hold the I-Button firmly in the port making sure it touches both the internal surface and the edges of the port.
- Continue to hold the I-Button in place until the **#TESTS ADDED** and the **TOTAL # OF TESTS REMAINING** are displayed on the screen.
- The user is informed when:
 - Less than 10 tests are available.
 - No more tests are available.

Section 7: Troubleshooting

Failed Self-Test:

FAILED SELF-TEST
TURN OFF SWITCH ON REAR PANEL
CLEAN TESTING CHAMBER
THEN RESTART SYSTEM

IF SYSTEM FAILS AGAIN,
CALL TECHNICAL SUPPORT

- Check to see that there is no testing capillary in the measurement compartment.
- Remove the QwikCheck GOLD Equine from sources of electronic noise and/or vibration (centrifuge, etc.).
- Clean the measurement compartment (refer to Appendix IV).
- Reboot the QwikCheck GOLD Equine without a testing capillary in the chamber:
 - From the rear panel switch, turn the system **OFF** then back **ON**.
 - Press the front panel **ON/OFF** key to begin the system warming-up and Self-Test.
- Call for technical support if this message is displayed again. Prepare for technical support by printing a copy of the QwikCheck GOLD Equine Self-Test/Service Data:
 - Press **SERVICE** key. The **SERVICE MENU** will be displayed.
 - Press **PRINT** button and the Service Data will be printed by the label printer.

Electronic Noise:

ELECTRONIC NOISE
TURN OFF MAIN SWITCH ON REAR PANEL
REACTIVATE UNIT

IF PROBLEM PERSISTS,
CALL FOR TECHNICAL SUPPORT

- Check that there is no testing capillary in the measurement compartment.

- Remove QwikCheck GOLD Equine from sources of electronic noise and/or vibration (centrifuge, etc.).
- Clean the measurement compartment (refer to Appendix IV) and then:
 - Activate **MAIN MENU > TEST NEW SAMPLE** and re-run the test.
- If this message is displayed again, reboot the QwikCheck GOLD Equine:
 - Turn the system **OFF** then **ON** at the main switch on the rear panel.
 - Press the front panel **ON/OFF** key to begin the system warming-up and Self-Test.
 - From MAIN menu: Select **TEST NEW SAMPLE** and re-run.
 - Call technical support if this message is displayed again. Prepare for technical support by printing a copy of the Self-Test/Service parameters:
 - Press **SERVICE** key. The **SERVICE MENU** will be displayed.
 - Press **PRINT** button and the Service Data will be printed by the label printer.

Remove Capillary:

If the testing capillary has been left in the measurement chamber after testing a sample and prior to testing the next sample this screen will be displayed:

REMOVE CAPILLARY
FOLLOW ON-SCREEN INSTRUCTIONS



Appendix I: Semen Sample Preparation

EQUIPMENT REQUIRED:

- 10-ml plastic container
- Pipette
- QwikCheck GOLD Equine capillary
- On-board QwikCheck GOLD EQUINE Heater
- 20-micron Nylon Filter to filter samples with debris

RAW/EXTENDED/COOLED SEMEN SAMPLES:

SAMPLE PREPARATION

1. Place QwikCheck GOLD Equine empty capillaries and 10-ml plastic containers in the heating unit.
2. Distribute a 2-ml aliquot of semen into 10-ml container.
3. Close the plastic container and pre-heat the semen to 37°C (98.6°F) for 4 minutes (RAW/EXTENDED room temperature samples) or for 7 minutes (COOLED samples).
4. Gently but thoroughly mix the sample for 10 seconds.
5. The sample is now ready for testing.
6. Fill a pre-heated to 37°C (98.6°F) QwikCheck GOLD Equine testing capillary following the instructions in the Appendix II: Capillary Filling Instructions: Raw/Extended/Cooled Specimens.

FROZEN SEMEN SAMPLES:

SAMPLE PREPARATION

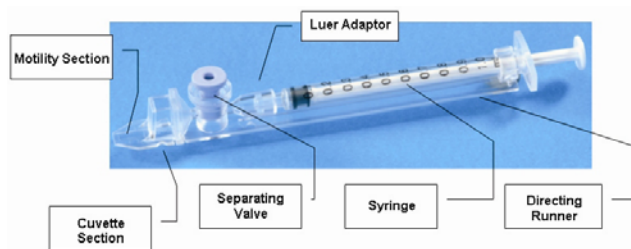
1. Thaw a frozen straw in a 37°C (98.6°F) water bath.
2. Expel the thawed sample into a pre-heated 10-ml plastic container.
3. Heat the sample to 37°C / 98.6°F for 4 minutes.
4. Gently but thoroughly mix the sample.
5. The sample is now ready for testing.
6. Fill a pre-heated to 37°C / 98.6°F QwikCheck GOLD Equine testing capillary with the semen sample following the instructions in the Appendix III: Capillary Filling Instructions: Frozen Specimens.

How to quickly observe samples for debris

- Place 10 µl of sample onto a standard slide, cover it with 22 mm x 22 mm coverslip and observe under the microscope for the presence of debris.
- If debris (big aggregates of epithelial cells) is observed, use a 20-micron nylon mesh to filter ~ 2 ml of sample (place the filter on a 10-ml plastic container and place the semen on the filter using a Pasteur pipette).

NOTE:
Semen containing a lot of debris should be filtered with a 20-micron mesh filter prior to testing.

Appendix II: Capillary Filling Instructions: Raw/Extended/Cooled Specimen



1. Push the syringe piston in fully. Place only the thin part of the capillary into the bottom of the sample (Figure 1).
2. Placing two fingers below the piston head pull the piston back slowly while keeping the tip of the capillary well below the sample level and below any surface bubbles (Figure 1). Continue to aspirate the sample until it appears in the Luer adaptor.
3. Hold the capillary in a vertical position and visually confirm that the sample has completely filled the thin section and the cuvette section and appears in the Luer adaptor (Figure 2).
4. Tap on the syringe to make sure there are no air bubbles in the sample.
5. Quickly and thoroughly wipe both the top and bottom of the outer surface of the capillary with a tissue (Figure 3).
6. Visually confirm that the capillary chambers are still full after wiping. If some of the sample has been depleted, a meniscus will be visible in the thin section of the capillary. If this is evident, push very slightly on the piston to re-fill the thin capillary section.
7. Slowly and carefully push-in the separating valve until it is level with the plastic. The capillary is now ready for testing (Figure 4).
8. Insert the capillary into the QwikCheck GOLD Equine (Figure 5)

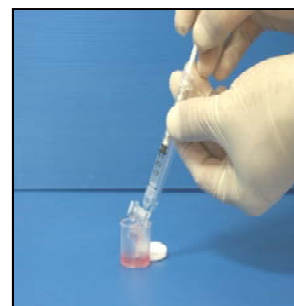


Figure 1

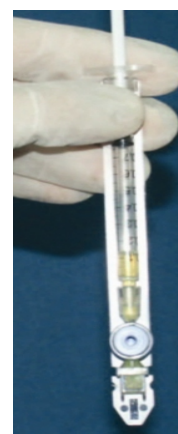


Figure 2



Figure 3



Figure 4



Figure 5

APPENDIX III: Capillary Filling Instructions: Frozen Specimens

Sample size, collection container and preparation:

1. For FROZEN Sample Testing, a minimum of 20 microliters is required to fill just the thin section of the testing capillary (Figure 1).
2. The semen sample must be **well mixed prior to aspiration**. Gently rotate the container to fully mix the specimen. **WARNING:** Do not shake nor use a pipette to aspirate and dispense specimen in order to mix, otherwise air bubbles will form.
3. **Carefully check that the specimen is free of air bubbles** before immersing the capillary into the specimen.

Filling the capillary:

1. **Push the syringe piston in fully**. Place only the thin part of the capillary into the bottom of the sample.
2. **Pull the piston back slowly** without withdrawing the capillary from the sample. **Fill only the (thin) capillary chamber** with 20 micro liters of semen. Aspirate the sample until it just appears in the cuvette part while keeping the tip of the capillary well below the sample level.
3. Visually inspect the capillary to ensure that the sample has completely filled the thin section (no meniscus).
4. Quickly and **thoroughly wipe the outer surface of the capillary** - It is important to remove all semen from the exterior of the capillary in order to prevent the QwikCheck GOLD Equine from becoming clogged.
5. Visually confirm that the thin chamber of the capillary is still full of semen after completing the cleaning process. If some of the sample is missing push-in the piston slightly until a drop appears on the capillary tip and then fill the capillary again from the sample container.
6. The separating valve must now be removed.
 - Use the jig supplied with the start-up kit to firmly **push-out the separating valve** from the underside of the capillary (Figure 1).
 - Completely detach the separating valve (Figure 2). The capillary is now ready to be inserted into the QwikCheck GOLD Equine system.
7. **PLEASE NOTE:** Test FROZEN samples as soon as the sample is aspirated into the capillary!



Figure 1

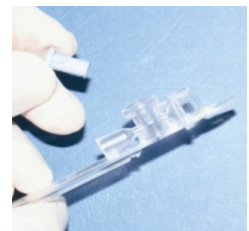


Figure 2

APPENDIX IV: Cleaning the Capillary/Slide Compartment

When to clean:

Daily or after every 10-15 tests
If the system fails **SELF-TEST**

Cleaning kit components:

- Blue Dot capillaries (Fig. 1)
- Sponge-tipped drying capillaries (Fig. 2)
- Cleaning brush -wooden-handled (Fig. 4)
- Cleaning fluid

CLEANING: STEP 1

1. **TURN OFF** the QwikCheck GOLD Equine device.
2. Use a **BLUE DOT** fibrous material capillary (Fig. 1).
3. Moisten with ONE drop of cleaning fluid, shaking off excess fluid.
4. Insert into the measurement compartment - fibrous material facing up. Move back and forth a few times. Repeat with the material facing down.
5. Use a sponge-tipped drying capillary to dry the same compartment (Fig. 2-3).

CLEANING: STEP II

1. Insert the brush (bristle-side down – Fig. 4) into the measurement chamber of the QwikCheck GOLD Equine device (Fig. 5).
2. Pull the brush out of the chamber while sweeping or "dusting off" the lens (you will feel a step or shelf at the back and top of the chamber – this is the top of the lens).
3. Switch QwikCheck GOLD Equine system ON and observe Self-Test results. The analyzer should now PASS the Self-Test. If not, repeat cleaning procedure with the brush.

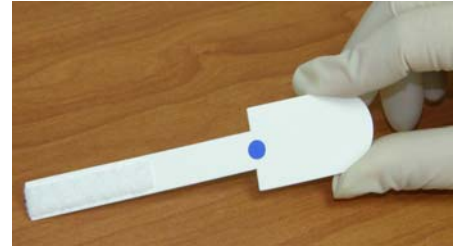


Figure 1

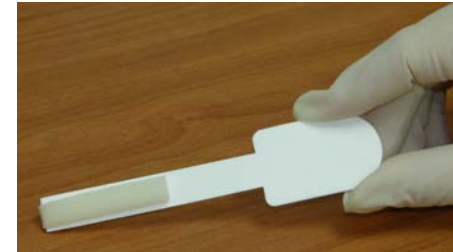


Figure 2



Figure 3



Figure 4



Figure 5

Appendix V: Capillary Washing Instructions



FOR ANIMAL SYSTEMS ONLY!!

Both testing capillaries and 10ml sample collection cups can be washed and re-used up to 10 times by following this EASY procedure:

Testing Capillary



Reposition the blue valve with the jig



Remove the plunger



Reassemble the capillary

Step 1 After running a test:

- Use the white capillary jig to re-position the blue capillary valve
- Expel semen by pumping the plunger a couple of times
- Soak the testing capillary in tap water until ready to wash

Step 2 Set-up: Fill with 1 liter/2 quarts of solution as follows:

- Bowl #1: Tap water (marked "TAP WATER")
- Bowl #2: Distilled water (marked "DISTILLED WATER")
- Bowl #3: Isopropyl Alcohol 70-100%

Step 3: Remove all liquid from the testing capillary:

- Pump the syringe plunger a couple of times to expel all remaining liquids.

Step 4: Capillary Washing – Follow this order:

- **Bowl #1 Tap Water:** Completely fill each capillary with tap water. Expel the solution into a hazardous waste container. **Repeat 2 times** then go to Bowl 2.
- **Bowl #2 Distilled Water:** Completely fill each capillary with distilled water. Expel the solution into a hazardous waste container. **Repeat 2 times** then go to Bowl 3.
- **Bowl #3 Isopropyl Alcohol:** Completely fill each capillary with isopropyl alcohol and expel the solution into a hazardous waste container. **Repeat 2 times.**
- After final washing, remove the plunger from the syringe.

Step 5: Drying the Capillaries:

- Place the capillaries on a flat surface to dry overnight or use the silica bead desiccator described in the Appendix section or place in a low heat oven for a few hours to dry.

Step 6: Final Preparation/Inspection:

- Replace the plunger into the syringe.
- Inspect the capillary and throw away if cracked, broken or semen remains.
- Note the number of washings by making a dot on the capillary with a water proof marker after each washing cycle.

Sample collection cups

Washing – Please refer to Step 4 Capillary Washing and follow the same process for washing in the solutions in bowls #1; #2 and #3. Turn upside down on absorbent paper to dry overnight.

Appendix VI: Capillary Drying Instructions

For Animal Applications ONLY!

A simple desiccator can be made to dry the washed QwikCheck™ QC testing capillaries using the silica gel beads provided in the QwikCheck™ QC start-up kit. The testing capillaries will dry in approximately 12-24 hours.

Materials/Equipment Required

- 1 kg of blue Silica gel beads
- 1 large airtight plastic box/jar container.
- Plastic netting to hold capillaries above the silica beads
- 50 washed capillaries

Drying Instructions

Step 1: Assemble the desiccator:

- Pour all of the Silica gel beads provided into the desiccation container.
- Put plastic net over the silica beads.
- Place 50 washed capillaries on the net.

Step 2: Close the desiccator:

- Tightly close the cover of the desiccator

Step 3: Capillary Drying :

- After 12-24 hours see if the capillaries are dry (without opening the cover).
- If the capillaries appear dry, open the desiccator and check closely to see if all of the water has evaporated from the capillaries.
- If they are still wet, check again in 2 hours.
- When dry, remove capillaries from the desiccator and tightly close the desiccator to preserve the silica beads.

Step 4: Capillary re-assembly

- Slide the plunger back into the syringe.
- Check the capillary for cracks, broken parts or remaining semen.
- Throw away capillaries that are damaged or contaminated.
- Mark the capillary with a dot after each washing-drying cycle.
- The capillaries are ready for use.

Step 5: Silica gel re-activation

- When the BLUE silica gel beads turn PURPLE/PINK they need to be dried.
 - Heat for 3 – 4 hours at 130 degrees C.
 - Mix the beads 3-4 times during the drying.
 - When the color of the beads turns BLUE, place the beads into the desiccator and close tightly.



Silica Gel Beads



Capillaries Drying



Appendix VII: Glossary of Terms

	Parameter	QwikCheck GOLD Equine Terms	Definition
Sample Data	Serial number	SN	Serial Number of the QwikCheck GOLD Equine
	Date & time	DATE/TIME	The date and time the test was performed
	Stallion ID	STALLION ID	The identifying number of the stallion being tested
	Straw date	STRAW DATE	The date and time the frozen semen straw was produced
	Sample number	SAMPLE #	The number assigned to the semen sample
Test Results	Semen volume	SEMEN VOLUME	Raw, extended, cooled or frozen semen volume expressed in ml
	Sperm Concentration	CONC.	Sperm concentration expressed in millions/ml
	Motility	MOTILITY	Percent of motile spermatozoa
	Progressive Motility	PROG. MOT.	Percent of progressively motile spermatozoa
	Motile Sperm Concentration	MSC	Motile sperm concentration expressed in millions/ml
	Progressively Motile Sperm Concentration	PMSC	Progressively motile sperm concentration expressed in millions/ml
Velocity	VELOC.	The average velocity of the motile spermatozoa in the sample, in microns per second	

Appendix VIII: QwikCheck GOLD Equine System Specifications

Dimensions: 29 X 24 X 20 cm (length X width X height); Weight: 4.15 kg

AC power supply: 100 to 250 VAC, 50/60 Hz, 10 VA

Measurement Compartment

- **Sources of radiant energy** - two 880 nm LEDs for motility and spectrophotometry channels
- **Detector system** - 2 photo detectors - Motility and Optical Density

Display

- Operational backlight LCD (16 lines x 40 characters)

Printer

- External label printer
- Thermostatic label paper with ~30 characters per line (Brother)

Keypad

- **Operational keys:** ON/OFF, TEST, PRINT, SERVICE, DELETE, ENTER, four cursor buttons, ESC, numeric buttons (0-9)

Front Panel

- LCD operational display
- Measurement compartment
- Multi-button keypad

Rear/Side Panel

- Power connector with fuse-holder (fuse 250V, 1A)
- RS232 cable outlet
- I-Button port (side panel)

Specimen Testing Supplies

- **Measurement capillary:** Disposable, multi-use plastic, positive displacement testing capillary (purchase from manufacturer).
- **I-Button:** Required to run tests (purchase from manufacturer)

Operating System

- **Control:** Keypad
- **Analysis Time:** 45 seconds
- **Software:** Resides on flash memory and drives all man-machine interface functions, runs algorithms for test measurements and operational screens. System can be upgraded from a PC CD-ROM.
- **Sample Testing Temperature:** 37°C (98.6°F).
- **Motility channel input signal:** Analog, up to 5V.
- **Spectrophotometer channel input signal:** Modulated (1 kHz) analog, up to 5V.

Quality Control

- **Internal:** Electronic Self-Test

Operational Temperature and Humidity

- System is operational at 15-40°C.
- **NOTE:** QwikCheck GOLD Equine operates in a wide range of ambient temperatures however the system is calibrated to measure semen samples at 37°C (98.6°F).
- System is fully operational at up to 80% humidity and 31°C.



Maintenance Schedule

- Cleaning daily and after every 10-15 tests (refer to User Guide – "Cleaning Instructions").

Manufacturer Recommendations

- Operate the QwikCheck GOLD Equine system away from devices that may cause electronic noise (cell phones) or other devices causing vibrations such as centrifuges.
- Turn system **OFF** at the rear-panel when not in use for extended period of time.
- Semen is considered a biologically hazardous material and is subject to individual laboratory protocols for handling such materials.

Factory Default Settings:

Date format: DD/MM/YY

Time/Date: Manufacturer's local time/date

Auto printing: YES

Appendix IX: QwikCheck GOLD Equine Product Performance Data

Performance Data Summary:

The performance of the QwikCheck GOLD Equine Sperm Analyzer is summarized in the text, tables and graphs below. All values concerning sperm concentration measurements are expressed as 10^6 sperm cells per milliliter (M/ml). Motility values are expressed as a percent (%). Unless otherwise noted, all testing was performed using raw, extended, cooled and frozen equine semen samples. Manufacturers claims are generally lower than actual performance data. Please also note that Sensitivity & Specificity are clinical screening parameters that demonstrate the accuracy of device. Sensitivity & Specificity results are based on the cutoffs established by Society of Theriogenology. Each QwikCheck GOLD Equine device is biologically calibrated against two reference systems at MES A-Tech laboratory.

Abbreviations:

CONC: Sperm Concentration
 CV: Coefficient of Variation
 M/ml: Million per milliliter

Table 1. Dynamic Range

Sample Type	Concentration M/ml	% Motility	% Progressive Motility
Raw	0-500	0-100	0-100
Extended	0-150	0-100	0-100
Cooled	0-150	0-100	0-100
Frozen	0-1000	0-100	0-100

Sensitivity, specificity, precision and correlation to manual method established in the in-house and field clinical trials using equine semen samples

Clinical claims:

Sensitivity

- Concentration: 90%
- Motility: 90%
- Prog. Motility: 90%

Specificity

- Concentration: 90%
- Motility: 90%
- Prog. Motility: 80%

Precision (Intra-device CVs)

- Conc.: 3%
- Motility: 3%
- Prog. Motility: 7%

Precision (Inter-device CVs)

- Conc.: 10%
- Motility: 10%
- Prog. Motility: 10%

Accuracy (regression coefficients of the dilution trend line)

- Conc.: 0.9
- MSC: 0.9

Table 2. Sensitivity/Specificity

QwikCheck GOLD Equine vs. Microscope	Sensitivity %	Specificity %	% False Positive	% False Negative
Sperm Concentration	96.4	100.0	0	2.2
Motility	95.0	96.3	2.1	2.1
Progressive Motility	100.0	90.0	4.3	0

Table 3. Precision: QwikCheck GOLD Equine intra- and inter-device variability

Semen Parameters	Intra-device CV, %	Inter-device CV, %
Sperm Concentration	2.0	7.0
Motility	0.3	7.2
Prog. Motility	5.6	8.6

Correlation to Manual Method

- Concentration: 0.9
- Motility: 0.9
- Prog. Motility: 0.8

Notes:

- Sensitivity and specificity claims are lower than actual values noted (Table 2).
- Precision CV claims are higher (lower precision) than actual values noted (Table 3).
- Correlation to Manual Method claims are less than actual correlations noted (Table 4).

Method comparison:

The QwikCheck GOLD Equine system was compared to the microscope based on WHO'99 manual guidelines. The QwikCheck GOLD Equine automated readings for sperm concentration, motility and progressive motility were compared to microscopic results. The manual sperm concentration measurements were performed using a cell counting chamber according to the manufacturer's instructions. A microscope and standard slide were used to manually assess motility. The protocols were based on WHO'99 manual and MES guidelines. The clinical trials were conducted at the Medisoos vet clinic. A total of 201 raw, extended, cooled and frozen semen samples were analyzed.

Accuracy: Dilution plots.

The accuracy of the QwikCheck GOLD Equine system was assessed by diluting equine semen and analyzing the resulting sperm concentrations. Raw stallion semen was gradually diluted with commercial extender. Dilutions provided varying motile and total sperm concentrations. Semen samples were tested using the QwikCheck GOLD Equine device and the results were plotted. Linear trend lines were established for Concentration and MSC vs. expected values.

Analytical Specificity:

- To achieve analytical specificity a specific wave length of light which is maximally absorbed by sperm cells and minimally absorbed by other cells, debris and seminal plasma is used.
- Low noise and high electronic resolution hardware components and compensation circuits ensure analytical specificity optimization.

Limitations of method:

Samples were assessed in duplicate on automated QwikCheck GOLD Equine systems and manually using a microscope. Statistical counting errors and intra-operator variability (subjectivity) may have affected the results of the study.

Table 4: Correlation to Manual Method

Semen Parameters	Correlation coefficients
Sperm Concentration, M/ml	0.996
Motility, %	0.956
Progressive Motility, %	0.892

Fig. 1. Method comparison: Regression plot of QwikCheck GOLD Equine Sperm Concentration in Raw equine semen vs. manual results

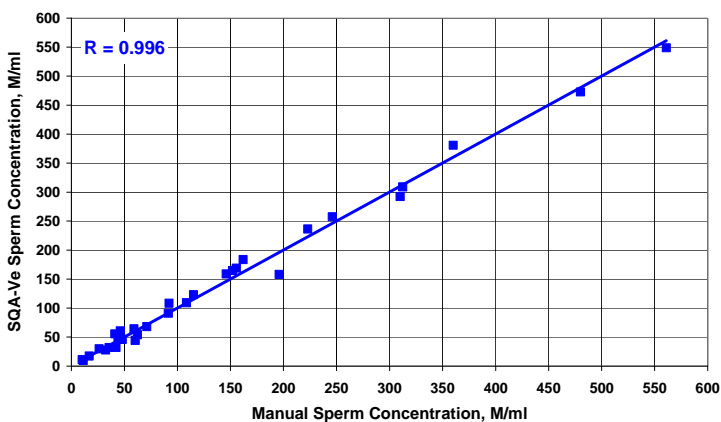
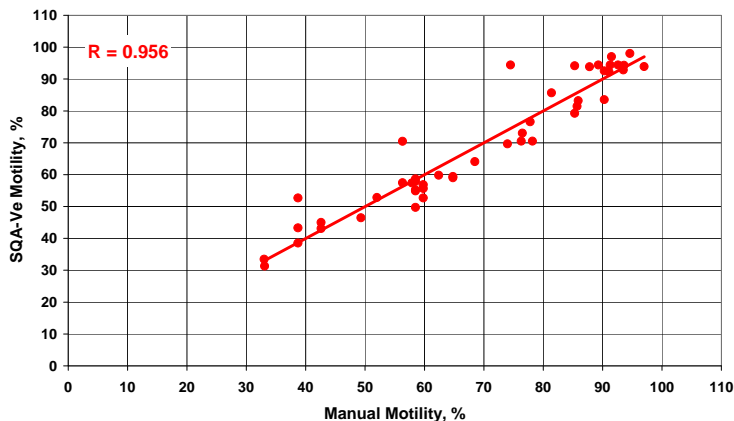


Fig. 2. Method comparison: Regression plot of QwikCheck GOLD Equine Motility in Raw equine semen vs. manual results



Performance parameters:

- Sensitivity and specificity were calculated using ROC analysis. Cutoffs normally used for sperm concentration and motility were used for the calculation of sensitivity, specificity, false positive and false negative parameters (Table 2).
- Precision of the QwikCheck GOLD Equine device was estimated by calculation of the intra-device and inter-device coefficients of variation (CV) of duplicate measurements (Table 3). CV is calculated according to the formula:

$$CV = SD / MEAN \times 100$$
 The lower CV, the higher precision of the method.
- Correlation to manual method was established by calculating correlation coefficients (Table 4, Fig. 1-2).
- The accuracy of the QwikCheck GOLD Equine system was determined by the regression coefficients of the dilution trendlines (Fig. 3).

Conclusions:

- The QwikCheck GOLD Equine Sperm Analyzer demonstrated high levels of sensitivity, specificity and correlation to the manual method.
- The QwikCheck GOLD Equine system is precise and accurate with low coefficients of variation for all semen parameters assessed (<10%).
- The QwikCheck GOLD Equine device can be used for semen quality assessment and QC of equine semen samples.

Fig. 3. Regression plot of QwikCheck GOLD Equine Conc. & MSC in Extended equine semen vs. expected values

