FOR EXPORT ONLY. NOT FOR SALE IN USA

MiOXSYS®

External Control Solutions Package Insert 100336
External Control Solutions for use with MiOXSYS System
Catalog #100279

Intended Use
The MiOXSYS External Control Solutions Kit contains High (positive) and Low (negative) Control Solutions and is intended to provide for quality control testing on the MiOXSYS System using the MiOXSYS Analyzer and the MiOXSYS Sensor. These external controls are intended to provide the user with a method of detecting issues that may result in erroneous test results.

Controls should be employed:

- For first use of the analyzer or for training purposes.
- If the analyzer's function is suspect.
- If the sensor is suspect.
- If test results are not within the expected range.
- As part of scheduled metrology quality control checks.
- To comply with a laboratory's internal quality control and accreditation requirements.
- When a new user is performing the test.
- When a new sensor lot is being employed.
- When the storage and handling of sensors deviate from the conditions specified by the manufacturer (room temperature 5-30°C [41-86°F]).

Summary and Explanation of the Test
The MiOXSYS External Control Solutions are reagents that are not built into the test system, but are tested in the same manner as patient specimens. Quality control testing is performed to detect factors that may contribute to erroneous test results.

1. Good Laboratory Practices recommend the use of external quality control checks. Users should follow the appropriate federal, state, and local guidelines concerning the running of external controls.
2. The MiOXSYS External Control Solutions contain known sORP values and are used to confirm that the MiOXSYS Sensor and MiOXSYS Analyzer are functioning properly together.
3. Two levels, Low Control and High Control, are provided. The Low Control produces a value representative of a negative result and the High Control produces a value representative of a positive result.
4. A separate MiOXSYS Sensor must be used for each quality control test.
5. When unacceptable quality control values are obtained, all test results should be considered invalid.

Materials and Equipment

Materials Provided

CONTROL + 25 Glass Vials of High Control Solution: potassium phosphate monobasic, sodium phosphate dibasic, high purity water, and proprietary preservative.

CONTROL - 25 Glass Vials of Low Control Solution: potassium chloride, sodium hydroxide, high purity water, and proprietary preservative.

Materials or Equipment Provided Separately
1. MiOXSYS Sensors (10 Sensors per box).
2. MiOXSYS Analyzer.
3. MiOXSYS Analyzer Calibration Verification Key (CVK) and Calibration Verification Card.

Materials or Equipment Needed but Not Provided
1. Disposable powder-free latex gloves or equivalent.

Warnings and Precautions
1. All reagents are for *in vitro* diagnostic use only.
2. MiOXSYS Sensors must be used with the MiOXSYS Analyzer.
3. Performance characteristics of the MiOXSYS System have been established only on human semen samples.
4. External Control Solutions must be kept at room temperature 20-28°C (68-82°F)). **Do not freeze**.
5. Proper sample collection, storage and transport of human specimens are essential for accurate results.
6. High and Low Control Solutions are to be used to evaluate the performance of the MiOXSYS System and are not to be used in the testing of patient samples.
7. Universal precautions must be followed when handling specimens and MiOXSYS System materials and equipment.
8. Wear disposable gloves while handling specimens and thoroughly wash hands after specimen handling.
9. Follow Biosafety Level 2 and Good Laboratory Practices prior to and during testing. Treat all specimens and used MiOXSYS Sensors as capable of transmitting infectious diseases. Do not eat, drink or smoke in areas where specimens or sensors are handled.
10. Quality Control Programs for CLIA Moderately Complex Testing Laboratories should be employed.
11. Each MiOXSYS Sensor is sealed in an airtight pouch and is intended for single use only. The protective pouch should remain sealed until use.
12. Dispose of used MiOXSYS Sensors immediately after processing pursuant to the proper disposal of biological fluids guidelines.
13. Do not eat, drink or smoke in areas where specimens, sensors or External Control Solutions are handled.

Hazards and Precautionary Statements
There are no known hazards associated with this product.

Shelf Life and Storage
The expiration date of the External Control Solutions is indicated on the label. Store the External Control Solutions at room temperature 20-28°C (68-82°F)).

Stability for MiOXSYS Sensors has been established at 15-30°C (59-86°F). MiOXSYS Sensors must be disposed of after the expiration date indicated on the labeling.

Quality Control Test Procedure
MiOXSYS External Control Solutions, MiOXSYS Analyzer and MiOXSYS Sensors must be at room temperature 20-28°C (68-82°F)before use. A new MiOXSYS Sensor must be used for each control to be tested.
NOTE: Ensure that the MiOXSYS Analyzer is powered on and properly calibrated prior to testing the Quality Control Solutions. Refer to the MiOXSYS Analyzer User Manual for further information regarding instrument set-up and operation.

A. Sensor Insertion
1. Unseal an individual MiOXSYS Sensor.
2. Holding sensor at front side edges, insert the MiOXSYS Sensor face-up and with the sensor electrodes facing the MiOXSYS Analyzer. Align the socket insertion end with the sensor socket on the MiOXSYS Analyzer. Make sure the sensor is fully inserted before continuing the quality control procedure.
3. Once the MiOXSYS Sensor is inserted properly, "Waiting for sample" will appear on the display screen and a 2-minute sample detection countdown timer will begin.

B. Control Application
1. Using a new high control solution vial, ensure that the control solution is located at the body of the vial. Invert, if necessary.
2. Holding the body of the vial firmly, snap the top portion of vial at the scored or neck location with hand and discard into a sharps container.
3. 30ul of the control solution is required for each test and the sample must be applied using an aerosol resistant micropipette tip.

C. Control Run
1. When the control reaches the Reference Cell of the sensor, the testing automatically begins. Proper functioning of the test is indicated by a blinking blue testing LED light.
2. Once the test is initiated, the display screen will show "Processing sample" and the time remaining for the analysis.
3. **IMPORTANT NOTE:** Do not press any buttons or remove the sensor while control testing is in progress.
4. If an error occurs during control testing, an error code will appear on the display screen and the red alert LED light will illuminate. Please make a note of the error reading for your records. Follow the instructions on the screen to clear the error.

D. Control Test Results
1. Audible beeps indicate completion of the control test.
2. Control test results will appear on the display screen in the following order:
   1.)Date 2.) Time 3.) sORP (in millivolts or mV)
   NOTE: Record the date, time, and sORP value in your records prior to removing the sensor from the analyzer.
3. Remove the sensor from the sensor socket after the quality control data is recorded.
4. Once the used MiOXSYS Sensor is removed, repeat procedure for the Low Control Solution.
5. Once control testing is complete, the MiOXSYS Analyzer can be switched "OFF" by pushing and holding the power button down.

NOTE: If the MiOXSYS Analyzer is "ON" but inactive, the MiOXSYS Analyzer will automatically turn "OFF." A 15-second timeout warning appears on the display screen with a warning beep emitted every second. The timeout clock can be reset by pressing any button.

Interpretation of Results
The MiOXSYS Analyzer measures sORP and reports value in millivolts. Valid test result interpretation range should be as follows:

External High Control Range: 91 mV – 117 mV

External Low Control Range: 33 mV – 70 mV

If either one of the control values are out of expected ranges, repeat procedure using both the High Control Solution and the Low Control Solution.

In the event either one of the control values remain out of its respective range, please contact Aytu BioScience Technical Support at 1 855 298 8246 (US) or your local distributor for further assistance and prior to performing specimen analysis.

Limitations of the Quality Control Procedure
The External Control Solutions consist of aqueous solution matrixes. Although specimen matrix interference has not been observed with the MiOXSYS System, the aqueous matrix of the controls cannot account for specimen matrix effects. To evaluate controls in the sample matrix, refer to the Clinical and Laboratory Standards Institute guideline EP14-A2, Evaluation of Matrix Effects: Approved Guideline—second edition, January 2005.

Glossary of Symbols

 Manufacturer

 Date of Manufacture

 Read Usage Instruction

 In vitro Diagnostic Medical Device

 This product meets the requirements of 98/79/EC of in vitro diagnostic medical devices

 Underwriters Laboratory

 Catalogue Number

 Serial Number

 Use By

 Positive Control

 Negative Control

 Re-use not Allowed

 Caution, Consult Document

 Authorized representative for European Community

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