Strep A Liquid Control Set
(Positive and Negative)

Instructions for Professional Use

For *In Vitro* Diagnostic Use

INTENDED USE

The QuickVue Strep A Liquid Control Set is intended to be used as quality control samples representative of positive and negative test results and to verify proper performance of the procedure and reagents of the QuickVue Strep A test systems.

SUMMARY AND EXPLANATION

Group A *Streptococci* are organisms that typically cause illnesses such as tonsillitis, pharyngitis and scarlet fever. If untreated, these infections can lead to complications such as rheumatic fever. The QuickVue Strep A test is performed directly on throat swab-extracted antigens and is used to aid in the diagnosis of group A streptococcal infections.

The QuickVue Strep A Positive Liquid Control consists of heat-inactivated group A *Streptococcus*. The Negative Control consists of heat-inactivated group C *Streptococcus*.

When the Liquid Controls are used in place of a patient swab specimen in the QuickVue Strep A test, the results can be used as quality control samples representative of positive and negative test results to verify proper performance of the procedure and reagents of the test.

PRINCIPLES OF THE PROCEDURE

The QuickVue Strep A Liquid Control Set is designed to be used as qualitative control samples in accordance with the QuickVue Strep A test package insert procedure.

REAGENTS AND MATERIALS

Positive Control (1): Heat-inactivated group A *Streptococcus,* diluted in a buffer solution containing 0.02% sodium azide (2.5 mL).

Negative Control (1): Heat-inactivated group C *Streptococcus,* diluted in a buffer solution containing 0.02% sodium azide (2.5 mL).

WARNINGS AND PRECAUTIONS

- To assure proper drop delivery when dispensing the Controls, the dispensing bottle must be held vertically.
- The Controls contain heat-inactivated microorganisms. However, handle as if capable of transmitting infectious disease.
- Do not interchange the caps on the vials.
- The Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water.
- The Controls are designed for use with the QuickVue Strep A test.

STABILITY AND STORAGE

Store the QuickVue Strep A Liquid Control Set at room temperature 59–86°F (15–30°C). The contents are stable through the expiration date printed on the outer box. Do not freeze.

QUALITY CONTROL

If your laboratory elects to use optional external controls for the QuickVue Strep A test systems, please refer to the appropriate kit package insert for external quality control frequency recommendations.

TEST PROCEDURE

Holding the bottle vertically, place one free falling drop of Liquid Control (Positive or Negative) on a sterile plastic-shafted rayon swab. Run the test in accordance with the "Test Procedure" instructions in the QuickVue Strep A test package inserts.

INTERPRETATION OF THE RESULTS

Positive Control Result:
The appearance of any pink-to-purple Test Line next to the letter "T" AND a blue Control Line next to the letter "C" in the Result Window indicates that the sample contains detectable levels of group A *Streptococcus*. A positive result should occur when the QuickVue Strep A Liquid Positive Control is used as directed.

Negative Control Results:
The appearance of **only** a blue Control Line next to the letter "C" in the Result Window indicates that the sample does not contain detectable levels of group A *Streptococcus*. A negative result should occur when the QuickVue Strep A Liquid Negative Control is used as directed.

LIMITATIONS OF THE PROCEDURE

The Positive and Negative Controls in the QuickVue Strep A Liquid Control Set are qualitative reagents and are not to be used as quantitative calibrators. They should not be diluted or extracted with reagents other than the QuickVue Strep A test reagents.

The QuickVue Strep A Liquid Control Set must be at room temperature 59–86°F (15–30°C) for use. Performance of the assay at other temperatures may yield invalid results.

EXPECTED VALUES

The QuickVue Strep A Liquid Control Set will produce examples of the color response to be expected for a negative and positive specimen. The microorganisms used in the preparation of these controls are traceable to American Tissue Culture Collection (ATCC) catalog numbers 19615 (positive), and 12388 (negative).

The failure to obtain a negative result with the Negative Control or a positive result with the Positive Control indicates that the test was not performed properly or that the test reagents were not functioning properly.

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel's Technical Support number, (800) 874-1517 (toll-free in the U.S.A.) or (858) 552-1100, Monday through Friday, between 7:00 a.m. and 5:00 p.m. Pacific Time, U.S.A. If outside the United States, contact your local distributor or technicalsupport@quidel.com.

FOR INFORMATIONAL USE ONLY ■ FOR INFORMATIONAL USE ONLY

Not to be used for performing assay. Refer to most current package insert accompanying your test kit.

REF 00354 – Strep A Liquid Control Set

IVD

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QUIDEL®

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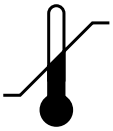
CONTROL + Positive control

CONTROL − Negative control



Temperature limitation

REF Catalogue number

Manufacturer

Use by

LOT Batch code

IVD For *In Vitro* diagnostic use