Strep A Liquid Control Set
Positive and Negative

QUIDEL

INTENDED USE
The 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 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 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 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 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.

PRINCIPLE OF THE TEST
The Strep A Liquid Control Set is designed to be used as qualitative control samples in accordance with the 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)
- Package Insert (1)

WARNINGS AND PRECAUTIONS
- For *in vitro* diagnostic use
- 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 tests.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STABILITY AND STORAGE

Store the Strep A Liquid Control Set at room temperature 59°F to 86°F (15°C to 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 RESULTS

Refer to the "Interpretation of Results" section in the applicable QuickVue Strep A Test Package Insert.

LIMITATIONS OF THE PROCEDURE

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

EXPECTED VALUES

The 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 (in the U.S.) or 858.552.1100, Monday through Friday, from 7:00 a.m. to 5:00 p.m., Pacific Time. If outside the U.S., contact your local distributor or technicalsupport@quidel.com.

REF 00354 – Strep A Liquid Control Set

IVD

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REF Catalogue number	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
 Consult instructions for use	IVD For *In Vitro* diagnostic use
 Contains sufficient for 65 determinations	CONT Contents/Contains
CONTROL + Positive control	CONTROL − Negative control