



QuickVue In-Line Strep A Control Set

Positive and Negative

QUIDEL



INTENDED USE

The QuickVue In-Line Strep A Control Swabs are intended to be used as quality control samples representative of positive and negative test samples. These controls can be used to verify proper performance of the procedure and reagents of the QuickVue In-Line Strep A Test.

SUMMARY AND EXPLANATION

The QuickVue In-Line Strep A Positive Control Swab consists of heat-inactivated Group A Streptococcus dried onto the swab. The Negative Control Swab consists of heat-inactivated Group C Streptococcus dried onto the swab.

Group A Streptococci are organisms that typically cause illness such as tonsillitis, pharyngitis and scarlet fever. If untreated, these infections can lead to complications such as rheumatic fever.

When the Control Swabs are used in place of a patient throat swab specimen in the QuickVue In-Line Strep A Test, the results can be used as quality control samples representative of positive and negative test samples.

PRINCIPLE OF THE TEST

The QuickVue In-Line Strep A Control Swabs are designed to be used as qualitative control samples in accordance with the QuickVue In-Line Strep A Test Package Insert procedure.

REAGENTS AND MATERIALS SUPPLIED

- Strep A Positive Control Swabs (6): Contains heat-inactivated Group A Streptococcus.
- Strep A Negative Control Swabs (6): Contains heat-inactivated Group C Streptococcus.
- Package Insert (1)

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do assure proper drop delivery when dispensing the Controls, the dispensing bottle must be held vertically.
- Do not use contents beyond the expiration date printed on Foil Pouch.
- Use of Nitrile or Latex gloves is recommended when working with these controls.
- Dispose of used contents in accordance with Federal, State, and Local requirements.
- The Extraction Solution Bottle (included in the QuickVue In-Line Strep A Test kit) contains glass, break cautiously.
- The Extraction Solution Bottle contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- Testing should be performed in an area with adequate ventilation.
- Follow proper hand washing hygiene after handling these controls.
- The Control Swabs are designed for use only with the QuickVue In-Line Strep A Test.
- Controls contain heat-inactivated microorganisms. However, handle as if capable of transmitting infectious disease.

STABILITY AND STORAGE

Store the QuickVue In-Line Strep A Control Set at room temperature 59°F to 86°F (15°C to 30°C). Do not freeze. The contents can be used until the expiration date printed on the Foil Pouch.

QUALITY CONTROL

The QuickVue In-Line Strep A Control Set may be used to demonstrate that the test kit reagents and assay procedure perform properly. Please refer to the QuickVue In-Line Strep A Test Package Insert for quality control frequency recommendations.

TEST PROCEDURE

Refer to the QuickVue In-Line Strep A Package Insert.

INTERPRETATION OF RESULTS

Refer to the QuickVue In-Line Strep A Package Insert.

LIMITATIONS OF THE PROCEDURE

The QuickVue In-Line Strep A Control Swabs are qualitative reagents and are not to be used as quantitative calibrators. They should not be diluted or extracted with other reagents other than the QuickVue In-Line Strep A Test reagents, and have not been validated for use with other assays.

The QuickVue In-Line Strep A Control Swabs must be used at room temperature 59°F to 86°F (15°C to 30°C). Performance of the assay at other temperatures may yield invalid results.

EXPECTED VALUES

The QuickVue In-Line Strep A Control Swabs will produce examples of the color response to be expected for a negative and positive swab 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 Swab or a positive result with the Positive Control Swab indicates that the test was not performed properly or that the test reagents were not functioning properly.

If an inappropriate result is obtained for either the Positive or Negative Control Swab, either repeat the test or telephone Quidel Technical Support.

PHYSICIANS' OFFICE LABORATORY (POL) STUDY

An evaluation of the QuickVue Control Swabs was conducted at three Physicians' Offices using a panel of 180 coded control specimens. Testing was performed by physicians' office personnel with diverse educational backgrounds and work experience at different locations. The proficiency panel contained negative and positive specimens. Each specimen was tested in replicates of ten at each site over a period of 3 days.

One-hundred eighty (180) results were obtained: 87/87 positive results were correctly interpreted as positive; 85/85 negative results were correctly interpreted as negative; 8 results were correctly interpreted as invalid. No significant differences were observed within run (ten replicates), between runs (3 different assay days) or between sites (three POLs).

ASSISTANCE

If you have any questions regarding the use of this product, please call Quidel Technical Support at 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 00345 - QuickVue In-Line Strep A Control Set

IVD

 **Quidel Corporation**
10165 McKellar Court
San Diego, CA 92121 USA
quidel.com

0247605EN00 (09/15)

REF Catalogue number  CE mark of conformity

EC REP Authorized Representative in the European Community  Batch code

 Use by  Manufacturer

 Temperature limitation  Intended use

 Consult instructions for use  For *In Vitro* diagnostic use

 Contains sufficient for XX determinations  Contents/Contains

CONTROL + Positive Control  Negative Control