

HealthLink Strep Quality Control Kit

Product No: 3137 Rev. No: 3

Section I: Intended Use

The HealthLink Strep QC kit contains dehydrated *Streptococcus pyogenes* (Group A) and dehydrated *Streptococcus agalactiae* (Group B) strains which are intended to be used for Quality Control of culture media.

Section II: Summary

A reliable source of stock microorganisms is essential. Microorganisms with known and predictable biochemical, physiological, serological and antimicrobial susceptibility characteristics and assay values are used in quality control. The *Streptococcus* strains in this kit meet all of these requirements.

Section III: Principle

HealthLink microorganisms are dehydrated using principles and procedures developed by HealthLink, which uses a suspending medium designed to preserve the organism in a crystalline matrix during dehydration. The microorganisms are equivalent to ATCC® strains used for quality control.

Section IV: Product Use

Each HealthLink organism contains one set of two vials. Each set is in a sealed laminated pouch along with an absorbent pad. Each set includes a vial with *Streptococcus agalactiae* (Group B) or dehydrated *Streptococcus pyogenes* (Group A) and one re-hydration medium used to re-hydrate the Microorganism paired with it. The absorbent pad is in the pouch to prevent the adverse accumulation of moisture. Instructions for using the product are follows:

1. Open microorganism vial and place cap upside-down on counter.
2. Pour vial labeled "TYL Broth" into microorganism vial and replace cap.
3. Let stand at room temperature until the pellet is completely dissolved.
4. Invert, mix well.
5. Open microorganism vial and place cap upside-down on counter.
6. Use sterile swab and dip into vial, then streak Strep Selective Agar as required for QC.
7. Store vial at 2-8 °C.

For Multiple uses:

1. Remove microorganism vial from refrigerator.
2. Let microorganism vial warm up to room temperature (do not incubate).
3. Invert, mix well.
4. Open microorganism vial and place cap upside-down on counter.
5. Use sterile swab and dip into vial, then streak Strep Selective Agar as required for QC.
6. Store vial at 2-8 °C.

NOTE:

HealthLink Strep Quality Control Kit

- If the microorganism is incubated it will decrease the longevity of the sample.
- Keep in mind that with each use there is a possibility that the vial could become contaminated. If your sample becomes contaminated with mold or another type of bacteria then discard the sample.
- If all specifications are met then the sample will last for approximately 6-8 weeks.

Section V: Expected Results

Streptococcus pyogenes (Group A):	Growth, Beta Hemolysis, with a zone of any size around the Bacitracin Differentiation Disc
Streptococcus agalactiae (Group B):	Growth, Alpha Hemolysis, with no inhibition zone around the Bacitracin Differentiation Disc

Section VI: Precautions and Limitations

This product is for in-vitro diagnostic use by trained, qualified personnel. Precautions must be taken against microbial hazards. Dispose of all specimens, containers and media by either sterilization or in appropriate biohazard containers.

For optimum results the HealthLink Strep QC kit must be stored, processed and used as outlined in Section IV. The HealthLink Strep QC kit should not be used if any of the following conditions apply:

- a) The pouch has been opened prior to receipt.
- b) There is visible moisture in the pouch.
- c) The expiration date on the label has passed.
- d) The performance specifications are not met.

Section VII: Storage

Store the HealthLink Strep QC Kit at 2-8 °C.

References:

1. Clinical Microbiology Procedure Handbook Vol. 1 and 2. 1st Ed. 1992 ASM, Washington D.C.
2. Quality Control for Commercially Prepared Microbiological Culture Media NCCLS Document m22-A.
3. Manual of Quality Control Procedures for Microbiology Laboratories, 3rd. Ed., 1981 CDC Atlanta GA.
4. Journal of Clinical Microbiology. 1981. 14:61-66

TECHNICAL SERVICE

HealthLink provides a toll free technical service line (800-638-2625) to assist with product usage. To have technical questions answered; please call between the hours of 9:00 am to 5:00 pm EST.

ATCC® is a registered trademark of American Type Culture Collection located in Manassas, VA.

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