

Instructions for Use

SPEEDSTREAKS™

Cat. no. HS1R	1ul loop, Rigid-hard, Dark green	25 per bag, 1000 per box
Cat. no. HS1F	1ul loop, Flexible-soft, Light green	25 per bag, 1000 per box
Cat. no. HS10R	10ul loop, Rigid-hard, Dark blue	25 per bag, 1000 per box
Cat. no. HS10F	10ul loop, Flexible-soft, Light blue	25 per bag, 1000 per box
Cat. no. HSND	Needle, Rigid-hard, Violet	25 per bag, 1000 per box

SUMMARY

IFU

SpeedStreaksTM are Hardy Diagnostics line of disposable inoculating loops. The loops are available in several styles and are color coded for convenience. The 1ul and 10ul loops, each come in two different rigidities, rigid-hard, or flexible-soft, to fit a variety of streaking preferences. An inoculating needle is also available formed in the rigid-hard plastic.

The loops are manufactured using a process that smooths the edges, free of plastic burrs and will not gouge the agar surface. The loops are free from coatings and electrostatic charges that might interfere with wetting and transfer of the volume contained in the loop.

The 1ul and 10ul loops are calibrated and each box of 1000 loops comes shipped with a Certificate of Calibration that authenticates the accuracy of the loops. The loops are certified to deliver a volume within 20% of their stated volume. The loops are certified using the Colorimetric Evans Blue Dye Procedure.^(1,2)

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "<u>Guidelines for Isolation</u> <u>Precautions</u>" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections*.

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

CALIBRATION PROCEDURE

The following procedure is used by the manufacturer to certify each lot of loops produced. Twenty random samples are taken, and if one loop fails, the lot is held in quarantine for further investigation. The margin of error is +/-20%.

1.0 Preparation Stock Dye Solution

- 1.1. Add 0.75gm of Evans Blue Dye to 100ml deionized water.
- 1.2. Filter the solution through a 4 Whatman filter paper after it has dissolved.
- 1.3. Prepare the following dilutions of the dye stock: 1:500, 1:1000, 1:2000, and 1:4000.

Note: Stock solutions and dilutions can be kept for up to 6 months provided that they are stored in tightly closed dark bottles. (If the absorbance readings of the dilutions vary from their previous reading by more than 3%, fresh dilutions should be made.)

1.4. Create calibration curve by plotting the optical density (vertical scale) against the dye concentration (horizontal scale).

2.0 Calibration of the 1 u l loop

Using the 1ul loop transfer 10 loopfuls of the stock dye solution to 10ml of distilled water. The loop should be rinsed in deionized water after each transfer. The absorbance of this 10ml solution should be equivalent to that of the 1:1000 dilution on the calibration curve (+/- 20%). If the loop error is greater than the +/-20% margin, the loop is rejected.

3.0 Calibration of the 10ul loop

Using the 10ul loop transfer 10 loopfuls of the stock dye solution to 100ml of distilled water as described above. The absorbance of this solution should correlate to that of the 1:1000 dilution on the calibration curve (+/- 20%). If the loop error is greater than the +/-20% margin, the loop is rejected.

QUALITY CONTROL

User QC is not required for SpeedStreaksTM. Each lot is evaluated by the manufacturer, and a Certificate of Calibration is provided with each box of loops.



SpeedStreaksTM



1. Clarridge, J.E., M.T. Pezzlo and K.L. Vosti. 1987 *Cumitech 2A; Laboratory Diagnosis of Urinary Tract Infections*. ASM, Washington, D.C.

2. Isenberg, HD, ed. 1992. Calibration of Quantitative Loops; 12.17.10 - 12-17-12, *Clinical Microbiology Procedures Handbook*. ASM, Washington, D.C.

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Distribution Centers: California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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