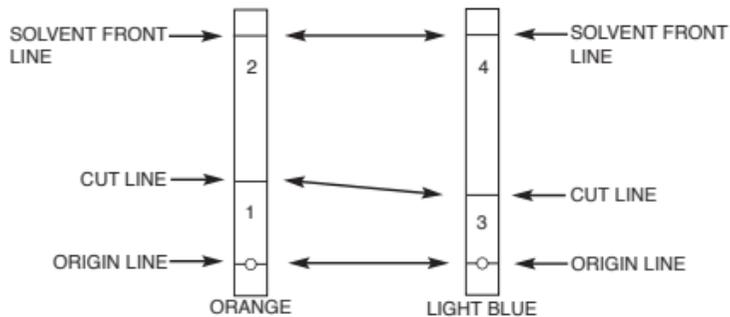


INTRODUCTION

Tec-Control is a miniaturized chromatography system for the radiochemical purity evaluation of specific radiopharmaceuticals.



Each orange (150-122) and each light blue-colored (150-125) chromatography strip has three distinct lines: an origin line, a cut line, and a solvent front line. For user convenience the back of each strip is marked with a soluble dye, located

close to the solvent front line, that will migrate with the solvent front. The technologist can easily see the solvent front via the movement of the dye. Use a 10ml Wheaton Serum Vial as a developing vial.

This test requires the technologist to "spot" approximately 10 microliters of the radiopharmaceutical sample onto the chromatography strip. This is easily accomplished using a 26G needle and syringe. One drop equals a volume of 0.01 cc (10ul or ten microliters).

NOTE: The 20% NACL and distilled H₂O solvents required to complete this procedure must be purchased separately.

NOTE: For each of the following procedures the strip should be placed on top or away from the well detector depending on count rate. If the strip is placed in the well, the dead time of the detector will give erroneous results.

TEST PROCEDURE FOR DETERMINATION OF FREE PERTECHNETATE IN Tc-99m DISOFENIN AND Tc-99m MEBROFENIN

1. Add 1cc of 20% NACL solvent to a developing vial.
2. Using the orange chromatography strip, spot one drop of the radiopharmaceutical onto the bottom line (origin) of the test strip.
3. Immediately place the test strip into the developing vial containing the solvent, and develop until the solvent front migrates to the top line (solvent front).

Immediately remove from solvent.

4. **Immediately cut strip** at the central line (cut line,) producing sections 1 and 2.

NOTE: Do not allow solvent front to migrate past the solvent front line.

5. Count background and calculate the net counts by subtracting the background counts from the number of counts registered for each strip section.

CALCULATION

% free pertechnetate

$$= \left[\frac{(\text{net cts sect. 2})}{(\text{net cts sect. 2}) + (\text{net cts sect. 1})} \right] \times 100$$

**TEST PROCEDURE FOR
DETERMINING HYDROLYZED
REDUCED Tc-99m DISOFENIN
AND Tc-99m MEBROFENIN
(*Performed after procedure above.)**

1. Add approximately 1cc of distilled H₂O solvent to a developing vial.
2. Select one light blue strip and spot one drop of the radiopharmaceutical on the bottom line (origin).
3. Immediately place the test strip in the developing vial containing the solvent and develop until the solvent front migrates to the top line (solvent front).
4. Remove the strip and cut strip at the middle line (cut line), producing sections 3 and 4.
5. Count background and calculate the net counts by subtracting the background counts from the number of counts registered for each strip section.

CALCULATIONS

% hydrolyzed reduced Tc-99m

$$= \left[\frac{(\text{net cts sect.3})}{(\text{net cts sect. 3}) + (\text{net cts sect.4})} \right] \times 100$$

% labeling of radiopharmaceutical

$$= 100 - \left[\begin{array}{c} \% \text{ free} \\ \text{pertechnetate} \end{array} \right] - \left[\begin{array}{c} \% \text{ hydrolyzed} \\ \text{reduced Tc-99m} \end{array} \right]$$

PREPARATION QUALITY

It is the decision of the nuclear medical clinician to determine the usability of the agent tested.

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**TEC-CONTROL
CHROMATOGRAPHY
STRIPS**

**For Disofenin (Hepatolite™) and
Mebrofenin (Cholotec™)**

OPERATION MANUAL
150-122 and 150-125

BIODEX

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