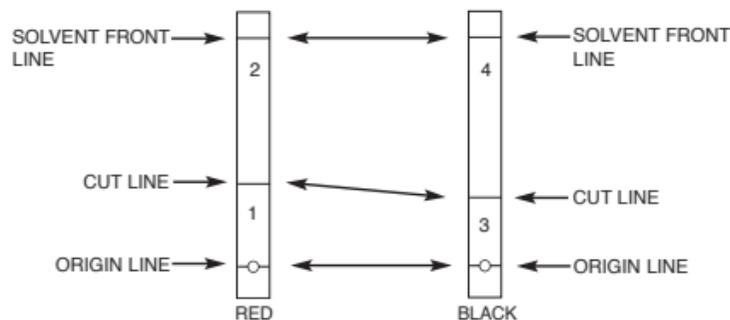


INTRODUCTION

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



Each red (150-001) and each black (150-005) chromatography strip have 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 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 (10µl or ten microliters).

NOTE: The Acetone HPLC grade solvent (Sigma-Aldrich part # 27972-5) and distilled H₂O required to complete this procedure must be purchased separately.

Tec-Control Solvent Vendor:
Sigma-Aldrich Chemical Company
800-558-9160 www.sigmaaldrich.com

Customers outside the USA should visit the Sigma-Aldrich web site to locate a regional office.

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.

NOTE: Black strip development time will take less than 1 minute.

NOTE: Red strip development time will take less than 1 minute.

DETERMINATION OF FREE PERTECHNETATE IN Tc-99m LABELED MAA, SULFUR COLLOID, STANNOUS CHLORIDE, ALBUMIN COLLOID AND GLUCOHEPTONATE

1. Add 1cc of acetone solvent to a developing vial.
2. Using a red chromatography strip, spot approximately 10 microliters of the test sample onto the bottom line (origin) of the test strip.
3. Immediately place the test strip into the developing vial containing acetone, and develop until the solvent front migrates to top line (solvent front).
4. Remove strip from the vial and allow to dry.
5. Cut strip at central line (cut line), producing sections 1 and 2.
6. Using a gamma counter, count background and calculate the net counts by subtracting the background counts from the number of counts registered for each strip section.

CALCULATION

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

DETERMINING FREE PERTECHNETATE, HYDROLYZED REDUCED Tc-99m, AND % LABELING IN Tc-99m LABELED DTPA, DIPHOSPHONATE, PYROPHOSPHATE AND MDP

1. Add 1cc of acetone solvent to a developing vial.
2. Using a red chromatography strip, spot approximately 10 microliters of the test sample onto the bottom line (origin) of the test strip.
3. Immediately place the test strip into the developing vial containing acetone, and develop until the solvent front migrates to top line (solvent front).
4. Remove strip from the vial and allow to dry.
5. Cut strip at central line (cut line), producing sections 1 and 2.
6. Using a gamma counter, 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

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

- In a clean developing vial place approximately 1cc of distilled H₂O solvent
- Select one strip of the black chromatography paper and spot approximately 10 microliters of the test compound onto the bottom line (origin). For MDP, prespot the black strip with 10 microliter of unlabeled MDP (See note below).
- Immediately place the test strip into the developing vial containing distilled H₂O and develop until the solvent front migrates to top line (solvent front).
- Remove the strip from the vial and allow to dry.
- Cut strip at center line (cut line) into sections 3 and 4.
- Using a gamma counter, count background and calculate the net counts by subtracting the background counts from the number of counts registered for each strip section.

NOTE: Prepare "cold" MDP by adding 1 ml saline to MDP vial. Solution can be used until used up. Either unlabeled vial can be used for MDP.

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 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.

Authorized European Community Representative:

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Prinsessegracht 20
2514 AP, The Hague
The Netherlands*



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TEC-CONTROL CHROMATOGRAPHY STRIPS

For Free Pertechnetate, Hydrolyzed Reduced Tc-99m, % Labeling in Tc-99m Labeled DTPA, Disphosphonate, Pyrophosphate, MDP, Free Pertechnetate in Tc-99m Labeled MAA, Sulfur Collid, Stannous Chloride, and Albumin Colloid and Glucoheptonate

OPERATION MANUAL

150-001 and 150-005

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