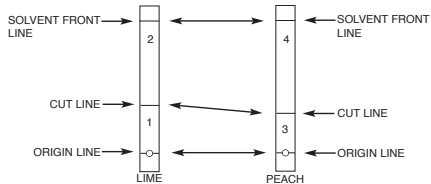


## INTRODUCTION

The two chromatography strips used in this procedure are designed to determine the radiochemical purity of Tc-99m labeled MAG3.



Each lime (150-951) or peach-colored (150-952) chromatography strip has three distinct lines: an origin line, a cut line, and a solvent front line. For user convenience, the back of each test strip is marked with a soluble dye that will migrate with the solvent front. The technologist can easily see the solvent front via the movement of the dye. Use two 10ml

Wheaton serum vials as developing vials. After cutting the strips at the cutting line, the strips are then divided into sections, each numbered one through four. Count each section with a gamma counter.

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 Acetone HPLC Grade (Sigma-Aldrich part # 27072-5), Chloroform 99.8% ACS Reagent (Sigma-Aldrich part # 31998-8) and Tetrahydrofuran 99+% ACS Reagent (Sigma-Aldrich part # 36058-9) solvents required to complete this procedure must be purchased separately. You will also need to purchase separately 0.9% NACL.*

*Tec-Control Solvent Vendor:  
Sigma-Aldrich Chemical Company  
800-888-9160 / [www.sigmaaldrich.com](http://www.sigmaaldrich.com)*

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

## TEST PROCEDURE

1. Add to a 10 ml Wheaton serum developing vial exactly 0.2 ml of the chloroform, 0.2 ml of the acetone, and 0.4 ml of the tetrahydrofuran. Swirl to mix.
2. Place approximately 0.8 ml of 0.9% NACL solvent in a 10 ml Wheaton vial.
3. Using a 26G needle and syringe, spot one drop of the radiopharmaceutical sample on the origin line of each chromatography strip (one lime-colored and one peach-colored strip).

4. Immediately place the color-coded strips into the two developing vials containing the solvent (lime-colored strip goes into the vial with the solution. The peach-colored strip goes into the 0.9% NACL) and develop until solvent front migrates to the solvent front line.
5. Remove the chromatography strips and cut strips at cut lines, producing sections one through section four.
6. Using a gamma counter or dose calibrator, count background and calculate the net counts by subtracting the background counts from the number of counts registered for each strip section.

**NOTE:** *The strips should be placed on top or away from the well detector depending on count rate. If the strips are placed in the well, the dead time of the detector will give erroneous results.*

## DATA ANALYSIS

The object of these tests is to determine the soluble Tc-99m impurities, including Tc-99m pertechnetate and the hydrolyzed-reduced Tc-99m.

## PREPARATION QUALITY

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

## CALCULATIONS

% Soluble Tc-99m Impurities (%TcS)

$$= \left[ \frac{\text{(net counts section 2)}}{\text{(net counts section 1) + (net counts section 2)}} \right] \times 100$$

% Reduced Hydrolyzed Tc-99m (%TcHR)

$$= \left[ \frac{\text{(net counts section 3)}}{\text{(net counts section 3) + (net counts section 4)}} \right] \times 100$$

% Final Radiochemical Purity (%RCP)

$$\%RCP = 100\% - \%TcS - \%TcHR$$

*Authorized European Community Representative:  
Emergo Europe  
Prinsessegracht 20  
2514 AP, The Hague  
The Netherlands*



# BIODEX

Biodex Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704

Tel: 800-224-6339 (Int'l 631-924-9000),

Fax: 631-924-9241 Email: info@biodex.com, www.biodex.com

## TEC-CONTROL CHROMATOGRAPHY STRIPS

For Tc-99m MERTIATIDE (MAG3™)

OPERATION MANUAL

150-951 and 150-952

# BIODEX

www.biodex.com

**1-800-224-6339**

Int'l 631-924-9000