

TML/MSH Microbiology Department Policy & Procedure Manual	Policy # MI\STER\04\v02	Page 1 of 2
Section: Sterility Testing Manual	Subject Title: Radiopharmacy / Manufacturing Pharmacy (UHN G.D.)	
Issued by: LABORATORY MANAGER	Original Date: July 17, 2001	
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RADIOPHARMACY / MANUFACTURING PHARMACY (UHN GENERAL DIVISION)

I. Introduction

Sterility testing for UHN Radiopharmacy and Manufacturing Pharmacy products is performed to ensure proper safety of all products prior to use in patients.

II. Specimen Collection and Transport

Specimens must be collected transported in its original bottle/vial or bag.

III. Processing of Specimens

Inoculate 1 mL of specimen from bottle/vial into the broths listed below.

Inoculate 10 mL of specimen from bag into the broths listed below.

Read these cultures daily for 14 days.

Culture:

Media	Incubation	
Specimens in Bottles/Vials:		
Single strength Thioglycollate (TH14)	O ₂ ,	35°C x 14 days
Single Strength Soya Casein Digest Broth (SD14)	O ₂ ,	RT°C x 14 days
Specimens in Bags:		
Double strength Thioglycollate (ETH14)	O ₂ ,	35°C x 14 days
Double Strength Soya Casein Digest Broth (ESD14)	O ₂ ,	RT°C x 14 days

Note: If specimen contains Benzalkonium Chloride or any other disinfectant, inoculate 0.1 ml. of specimen on a Lethen agar plate to neutralize the disinfectant. Incubate Lethen plate for two days at 37°C and two days at room temperature. Discard after four days.

Keep original specimen at 4°C specimen refrigerator for 1 month.

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IV. Isolation and Identification

Gram stain and subculture all turbid Broths. All isolates are to be identified. Depending on results of gram stain, subculture broths onto Blood agar, MacConkey agar and any additional plates indicated.

Replant the original specimen onto a new set of media. Read the newly inoculated media for 14 days.

V. Sensitivity Testing

Not required.

VI. Reporting

Telephone all positive reports

Negative Report: "No Growth"
Positive Report: Report all isolates.