The kit consists of reaction vials which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce Technetium Tc 99m Albumin Aggregated Injection for diagnostic use by intravenous injection.

Each 10 mg reaction vial contains 2.5 mg of albumin aggregated, 5 mg of human serum albumin, 0.06 mg (minimum) stannous chloride (maximum stannous

and stannic chloride 0.11 mg and 1.2 mg) and sodium hydroxide.
The contents are in a lyophilized form under an atmosphere of nitrogen. Sodium hydroxide or hydrochloric acid has been used for pH adjustment. No bacteriostatic preservative is present.

The human serum albumin was non-reactive when tested for Hepatitis-B Surface Antigen (HBsAg), antibodies to Human Immunodeficiency Virus (HIV-1/HIV-2), antibody to Hepatitis C virus (anti-HCV) and Antigen to Human Tumor Antigens (HIV-1). The albumin aggregated is sufficiently fragile for the capillary micro-occlusion to result in clot formation. In the event of these circumstances, standard red blood cell blood transfusions should be available for immediate use.

The intravenous administration of any particular materials such as albumin aggregated imposes a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients, the administration of albumin aggregated is possibly hazardous in acute pulmonary and other states of severely impaired pulmonary blood flow.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Contents of the vials are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are NOT to be administered directly to the patient.

The technetium Tc-99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Sodium stannous Tc-99m containing Technetium Tc-99m Albumin Aggregated Injection is physically unstable and consequently the particles settle with time. Failure to follow the labeling procedures will result in radioactive aggregation. If blood is drawn into the syringes, unnecessary delay prior to injection may result in clot formation in situ.

Do not use if clumping of the contents is observed.

Technetium Tc-99m Albumin Aggregated Injection, as well as other radiopharmaceuticals, must be handled with care. Once sodium pertechnetate Tc-99m is added to the vial, appropriate safety measures must be used to minimize radiation exposures to personnel. Care must also be taken to minimize the radiation exposure to patients in a manner consistent with proper patient management.

Radiopharmaceuticals should be used only by physicians who are qualified by training in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Radiocytotoxicity has not been established. Hypersensitivity reactions have not been reported (see ADVERSE REACTIONS). The intravenous administration of any particulate materials such as albumin aggregated to patients with pre-existing severe pulmonary hypertension, instances of hemodynamic or idiopathic reactions to preparations of Technetium Tc 99m Albumin Aggregated Injection have not been noted, the literature contains reports of deaths occurring after the administration of albumin aggregated to patients with a history of connective tissue disease. Instances of hypotension and hypotensive reactions to preparations of Technetium Tc 99m Albumin Aggregated Injection have been reported (see WARNINGS).
The number of particles available per dose of Technetium Tc 99m Albumin Aggregated Injection will vary depending on the physical decay of the technetium Tc-99m that has occurred. The number of particles in any dose and volume to be administered may be calculated as follows:

\[
V_r = \frac{D}{C} \times \frac{P_v}{F_r} \times N
\]

Where:
- \( V_r \) = volume of solution added to reconstituted vial
- \( D \) = desired dose to be administered in MBq (mCi)
- \( C \) = concentration at calibration time of sodium pertechnetate solution to be added to the reconstituted vial in MBq (mCi/mL)
- \( P_v \) = volume to be administered in mL
- \( F_r \) = fraction of technetium Tc-99m remaining after the time of calibration
- \( N \) = number of particles per vial. The number of particles per vial for each lot is shipped with the product.

Mix the contents of the syringe just before injection. If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to a clot formation. For optimum results and because of rapid lung clearance of the radiopharmaceutical, it is suggested that the patient be positioned under the imaging apparatus before administration. Strobe injection is recommended. Lung imaging may begin immediately after intravenous injection of the radiopharmaceutical.

Directions
- Place the vial in a suitable lead vial shield which has a fitted cap. Obtain the patient’s weight and calculate the number of particles per vial. The number of particles per vial for each lot is shipped with the product.
- Remove the protective disc from a reaction vial and swab the rubber septum of the radiopharmaceutical in the peritoneal cavity with no biological clearance. The estimated absorbed radiation doses1 to an average adult patient (70 kg) are shown in Table 5, which lists the maximum dose for pediatric patients from newborns to adults. The recommendations regarding number of particles to be administered are based on the absorbed radiation dose resulting from the intraperitoneal administration of the aggregated technetium Tc 99m albumin aggregate.

Table 6 – Maximum Tc 99m to be added Based on Vial Particle Number

<table>
<thead>
<tr>
<th>Particles per vial</th>
<th>Maximum Tc 99m to be added per vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 million to 4 million</td>
<td>3.7 GBq (100 mCi)</td>
</tr>
<tr>
<td>4 million to 8 million</td>
<td>4.44 GBq (120 mCi)</td>
</tr>
<tr>
<td>8 million to 16 million</td>
<td>8.85 GBq (245 mCi)</td>
</tr>
<tr>
<td>16 million to 32 million</td>
<td>17.7 GBq (500 mCi)</td>
</tr>
</tbody>
</table>

Calculate the amount of radioactivity/vial required to maintain the number particles per dose within a recommended range [for adults 200,000 to 6,850,000 (6.85 GBq to 17.7 GBq)].

Using a shielded syringe, add the Sodium Pertechnetate Tc 99m Injection to the reaction vial aseptically.

1. Place the cap on the vial shield and mix the contents of the shielded vial by repeated gentle inversion. Make sure that all the material is suspended. Avoid formation of foam. Using proper shielding, the vial should be visually inspected to ensure that the suspension is free of foreign matter before proceeding. Do not administer if foreign particulates are found in the preparation. The recommended dose for lung imaging are based on 1.85 MBq (50 μCi) per kilogram of body weight (except in the newborn where the maximum recommended dose of 18.5 MBq (500 μCi) is used) and are shown in Table 5, which lists the maximum dose for pediatric patients from newborns to adults. The recommendations regarding number of particles to be administered are based on the absorbed radiation dose resulting from the intraperitoneal administration of the aggregated technetium Tc 99m albumin aggregate.