

GastroClear Sample Collection and Serum Processing requirement

- COMPANY will handle the blood collection, serum processing and storage of samples as per the procedures described below.
- COMPANY is responsible to keep record of all chain of custody including identity of personnel collecting the blood, sample processing, and shall make such record available when requested.

Blood Collection Tubes

- Gold Top BD Vacutainer **SSTI Tubes** (BD Catalog # 367986);
- Red Top BD Vacutainer Serum Tubes (BD Catalog # 367815)

Blood Collection Procedure

1. Using aseptic technique, obtain venous blood by using 21G to 22G needle.
NOTE:
 - i. Do not apply the tourniquet for longer than 1 min as this may lead to hemolysis.
 - ii. Needles finer than 23G are not recommended as it may lead to hemolysis as well.
2. Fill the Red Top BD Vacutainer serum tube with 1 ml of blood and discard the serum tube.
3. Fill the **Gold Top BD SSTI or another Red Top** Tube to 5 ml. Be sure to draw blood until it reaches the fill line to ensure the correct blood-clot activator ratio.
4. Invert the Gold Top BD SST or Red Top Tube **5 times** right after blood collection. Be sure that the sample tube is NOT being shaken vigorously, as this can lead to a hemolyzed sample.
5. Label the sample tube with **at least 2 patient identifiers** (Name and Identification Number or Date of Birth).
6. Record the **date and the time** of blood draw on the TRF if possible.
7. Place the Gold Top BD SST or Red Top Tubes in a tube rack in **upright position**, in room temperature, for **at least 30 mins** for the sample to clot.
8. WARNING:
 - i. A minimum of 30 mins is required for the clotting. As blood cells are able to secrete miRNA, it is important not to allow clot formation beyond 90 mins to minimize contamination of circulating cell free miRNA by secreted blood cell miRNA.
9. After clotting for 30 mins, place the **sample and the ORF into a biohazard** zip lock bag and send it to the lab immediately for processing (refer to Serum Processing Protocol). If the lab is not immediately reachable in the same building, transport the sample at ambient temperature with ice gel packs in a Styrofoam box.
 - i. Transport time **cannot exceed 3.5 hrs** (excluding 30 mins clotting time). Do not freeze.
 - ii. Avoid direct contact of gel packs with blood tubes during transportation.
 - iii. Clinic staff to indicate date and time of transfer to lab on ORF if possible.