Rev: April 27, 2011

Procedure for Collection of Whole Blood Specimens for Circulating Tumour Cell (CTC) Assessment Using the Wavesense and Veridex Platforms

1. MATERIALS AND SUPPLIES

Supplies:
CellSave™ tubes (Veridex)
Sodium heparin BD Vacutainer blood tubes
Labels
BD blood collection needle
Tourniquet
Alcohol swabs
Gauze pads
Medical tape
Non-latex gloves
Permanent marker

2. SPECIMEN LABELLING

The following labels were employed in a recent NCIC Clinical Trials Group trial, and serve as an example of good practices to be followed when labeling blood specimens slated for CTC analysis. The particular trial in question consisted of three samples per patient one each at baseline, 6 weeks, and 12 weeks. Adjust your labels according to your particular study.

Labels should be affixed to tubes prior to the collection of specimens and should be filled out using a permanent marker.

Baseline

- Use the following labels for all Baseline CellSave and sodium heparin (green top) tubes.

STUDY # **CTC-CellSave**
Initials: _ _ _ **BASELINE**
ID#: _ _ _ _ - _ _ _ _
Date: _ _-_ _-_ _
Order of Collection:_of 2

STUDY # **CTC-GreenTop**
Initials: _ _ _ **BASELINE**
ID#: _ _ _ _ - _ _ _ _
Date: _ _-_ _-_ _
Order of Collection:_of 2

Week 6

- Use the following labels for all Week CellSave and sodium heparin (green top) tubes.

STUDY # **CTC-CellSave**
Initials: _ _ _ **Week 6**
ID#: _ _ _ _ - _ _ _ _
Date: _ _-_ _-_ _
Order of Collection: _ of 2

STUDY # **CTC-GreenTop**
Initials: _ _ _ **Week 6**
ID#: _ _ _ _ - _ _ _ _
Date: _ _-_ _-_ _
Order of Collection: _ of 2

Week 12

- Use the following labels for all Week 12 CellSave and sodium heparin (green top) tubes.

STUDY # **CTC-CellSave** Initials: _ _ _ **Week 12** ID#: _ _ _ _ - _ _ _ _ Date: _ _._ _._ _ _ Order of Collection: _ of 2	**STUDY #** **CTC-GreenTop** Initials: _ _ _ **Week 12** ID#: _ _ _ _ - _ _ _ _ Date: _ _._ _._ _ _ Order of Collection: _ of 2

3. PROCEDURES

SAMPLES

- Ensure patients scheduled for blood collection have completed the necessary consent forms, and that the study has been granted ethics approval from the appropriate institution.

PREPARATIONS REQUIRED BEFORE STARTING PROCEDURE

- Prepare all the necessary tubes for collection of specimens required at a specific visit, as described above. Make sure that all collection tubes are labeled with required patient's information, visit and collection date as specified by the laboratory manager.
- Blood collection must be performed by personnel qualified by training to draw blood according to your institution's requirements and procedures for venipuncture technique.
- Protective non-latex gloves should be worn when performing venipuncture.

PROTOCOL

Drawing blood

- Apply the tourniquet to an exposed vein. Select appropriate site for venipuncture.
- Prepare the patient's arm using alcohol prep by scrubbing in an outward circular motion. Allow the area to air dry.
- Use a BD Vacutainer® Safety-Lok™ Blood Collection Set or similar phlebotomy set for sequential blood draws.
- Allow at least 10 seconds for a complete blood draw to take place.

Order of collection

- The CellSave tube must be drawn first using standard venipuncture into the 10mL tube - the tube must contain at least 8mL of blood.
- The 6 mL sodium heparin tube must contain at least 5ml of blood.
- Remove the needle from the patient and apply a gauze and adequate pressure to the site of venipuncture.
- Dispose of needles and supplies into the appropriate medical waste container.

Specimen processing

- Stretch provided strip of Parafilm (remove paper backing first) and wrap it multiple times around where the cap meets the glass of the CellSave tube to ensure the cap is fastened securely in place

- Gently invert both the CellSave and sodium heparin tubes 8 times to mix and prevent clotting
- Leave at room temperature, **do not refrigerate or freeze**
- Prepare for shipment according to the CTC Specimen Shipping SOP

Table 1. Summary Protocol

	Action
1	Label tubes with all required information
2	Ensure patient has signed appropriate consent forms
3	Collect at least 8mL of blood in a CellSave tube
4	Collect at least 5mL of blood in a sodium heparin tube
5	Remove and dispose of needle appropriately
6	Wrap tube's cap in Parafilm to ensure a good seal
7	Gently invert filled tubes 8 times
8	Store at room temperature until ready to ship

References

- Refer to the 3rd edition of the Public Health Agency of Canada's Laboratory Biosafety Guidelines,
- Refer to the Queen's University's Biohazards Safety Manual published by the Department of Environmental Health and Safety, when handling biohazardous materials such as blood and tumor samples