

## Second Generation FIT Positive/Negative Control Set

Pursuant to GLP recommendations CLIA 88 Waived device controls do not require a package insert. This guide will assist with both the internal controls and the controls you have purchased for FOB / FIT Testing.

1. **Internal Controls:** There are two internal control features in the FOB test. A colored control band will always appear at the control position (C) if the test has been performed correctly and if the device is working properly. This is considered an internal positive procedural control. A clear background in the result window is considered an internal negative procedural control. If the test has been performed correctly and the Pinnacle FOB / FIT test is working properly, the background in the result window will be clear, providing a distinct result.
2. **External Controls:** Good Laboratory Practice (GLP) recommends (but does not require) the usage of external controls. The positive and negative controls (denoted on the vials) are supplied for this reason.
  1. Allow the test and the controls to equilibrate to room temperature (15 to 30 degrees Centigrade) prior to testing.
  2. To begin testing, open the sealed pouches of two (2) FOB / FIT test by tearing the pouch. Remove the test kit from the pouch for immediate use.
  3. Squeeze 3 drops of the positive control (denoted by "Positive FOB Control and an expiration date and lot number, in two separate vials in a protective bag) onto a cassette well (marked "S"). Repeat the same procedure on a separate cassette using the negative control.
  4. The results should be read and catalogued at five minutes, noting the test should not be interpreted after ten (10) minutes.
  5. Interpret results the same way you would interpret a patient sample.