NOTE: Assay item discussed and all references to the company have been removed and replaced with XX.

Package Inserts: new cardiac product—produced for a medical diagnostic company	
Verbiage from package insert (510K submission for FDA approval) *12th grade+ comprehension level*	**Same information for clinical sites collecting data for a CLIA waiver study** (Users are health care workers who deliver cardiac care in an outpatient setting but do not have a laboratory science background.) *7th grade comprehension level*
Principle The test contains a monoclonal and a polyclonal antibody against epitopes of the XX molecule, one gold-labeled, the other biotinylated. The antibodies form a sandwich complex with XX in the blood sample. Following removal of erythrocytes from the sample, plasma passes through the detection zone in which the gold-labeled XX sandwich complexes accumulate and appear as a reddish-purple line (the signal line). Excess gold-labeled antibodies accumulate along the control line, signaling that the test is valid. The intensity of the signal line increases in proportion to the XX concentration. The optical system of [instrument] detects the two lines and measures the intensity of the signal line. Integrated system software converts the signal intensity to a quantitative reading and displays it in the window.	**Principle** XX is present in the blood in minute amounts. Something large must be attached to it to make it detectable. This test uses "tags" to make XX easily measurable. The process first filters RBCs out of the plasma. Then the plasma migrates to the test reaction zone. Two types of antibodies are present in that zone. Each antibody can attach to a specific, different spot on the XX molecule. One antibody is tagged with gold; the other is tagged with biotin. When both antibodies attach to XX, they form a "sandwich"—a compound large enough to be measured. This sandwich appears on the test strip as a reddish-purple line, called the signal line. More gold on the signal line means a higher concentration of XX in the specimen. The test purposely supplies more gold-labeled antibodies than are ever needed. This excess migrates to another spot on the test strip to form a second line. This is called the control line. It lets you know that the test is valid. Optics in the [instrument] detect the two lines and measure the signal line's intensity. System software converts the signal to a numeric reading. Then the result displays in the window.