Wear protective clothing such as laboratory coats, disposable gloves and eye protection.

Human plasma used in the Positive and Negative Controls was tested by ELISA for Infectious Mononucleosis antibodies in whole blood, serum or plasma specimens. The results show that the specificity of the MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) is 97.8% relative to the slide agglutination test.

**EXPECTED VALUES**

Epstein-Barr virus (EBV) infection during adolescence or young adulthood causes Infectious Mononucleosis (IM), which is a viral illness. The infection occurs when the Epstein-Barr virus (EBV) infects the B lymphocytes of the immune system. The virus can be transmitted through saliva, so exposure can occur during casual social interactions such as kissing or sharing food and drinks. The incubation period for EBV infection is typically between 2 and 6 weeks after exposure.

**PRECAUTIONS**

- Avoid contact with a person who has signs and symptoms of Infectious Mononucleosis.
- Wash your hands frequently with soap and water, especially after contact with a person with Infectious Mononucleosis.
- Avoid close contact with family members or friends who are currently infected or who have signs and symptoms of Infectious Mononucleosis.
- Avoid sharing eating utensils, drinks, or personal items with someone who has signs and symptoms of Infectious Mononucleosis.

**CONTRAINDICATIONS**

- This test is not recommended for use in pregnant or breastfeeding women.
- This test is not recommended for use in children under 12 years of age.

**ADIPOSE CONTROL**

- Use the MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) in vitro diagnostic test kit to detect Infectious Mononucleosis antibodies in whole blood, serum or plasma specimens. This test should be used as the sole criteria for the diagnosis of Infectious Mononucleosis infection.

**INTRA-ASSAY PRECISION**

- Within-run precision has been determined by using 3 replicates of three specimens: a positive control, a negative control solution, and a negative control. The results show that the sensitivity of the MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) is 96.3% relative to the slide agglutination test.

**INTERPRETATION OF RESULTS**

- (Please refer to the illustration above)

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appears in the control line region (C) if the test is performed correctly. If the control line is not present, the test should be repeated or the equipment should be checked.

**REFERENCES**

3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the diagnosis of Infectious Mononucleosis infection.

**PACKAGE INSTRUCTIONS**

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch.

**STORAGE**

- The MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma specimens. This test is not intended for use in detecting IgG or IgM antibodies to IM heterophile antibodies.

**SHELF LIFE**

- The MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence or absence of IM heterophile antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Infectious Mononucleosis infection.

**SUMMARY**

- Infectious Mononucleosis (IM) is caused by the Epstein-Barr virus, which is a member of the herpesvirus family. Symptoms of IM include fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may occur. Diagnosis of IM is mainly made by positive results of Mononucleosis heterophile antibodies, which are present in IgM and IgG class. They are present in 80-90% of IM patients during the first week of clinical illness.1

- The MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes an extract of bovine erythrocytes to qualitatively and selectively detect Infectious Mononucleosis heterophile antibodies in whole blood, serum or plasma specimens.

**PRINCIPLE**

- The MONO Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma specimens. This test is not intended for use in detecting IgG or IgM antibodies to IM heterophile antibodies.

**MONO Rapid Test Cassette**

- The test utilizes an extract of bovine erythrocytes and bovine erythrocyte extract antigen-coated membrane.

**PREPARATION OF TEST SPECIMENS**

- Fingerstick Whole Blood specimens:
  - Add 1 drop of buffer (approximately 55 μL) to the specimen well (S) of the Test Cassette, and add 1 drop of buffer (approximately 55 μL) to the control line region (C) and another line should be in the test line region (T).
  - Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 μL) to the specimen well (S) of the Test Cassette, and add 1 drop of buffer (approximately 55 μL) then start the timer. See illustration below.

- Serum or Plasma specimens:
  - Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25 μL) to the specimen well (S) of the Test Cassette, and add 1 drop of buffer (approximately 55 μL), then start the timer. See illustration below.

**INTERPRETATION OF RESULTS**

- (Please refer to the illustration above)

- (Please refer to the illustration above)