1. State **test procedure**:

 a. Appropriate hand hygiene protocol must be followed. See test procedure for details.

b. Take solvent vial by cap and shake well. Make sure all liquid in vial has dropped to the bottom. Open vial and place in vertical position.

 c. **Specimen collection: No speculum exam required**

 1.) Patient must lie flat on her back.

 2.) Remove sterile swab from package. Hold swab in middle of stick. Maintain sterility of polyester tip.

 3.) Insert polyester tip into vagina until the fingers contact the skin no more than 2-3 inches deep.

 4.) Leave the swab in the vagina for 1 minute.

 d. Place swab in vial with solvent and rotate for 1 minute. Discard swab.

 e. Tear open foil pouch at notches and remove AmniSure test strip.

 f. Place the white end of the test strip (marked with arrows) into the vial with solvent.

 g. **Incubate for 10 minutes.**

2. **Interpret results**:

 a. Read results by placing strip on a clean, dry, flat surface.

 b. One line: negative, no membrane rupture

 c. Two lines: positive, membranes are ruptured

 d. No lines: invalid test. Repeat test with a new specimen and test kit.

 e. A strong leakage may be detected prior to the complete 10-minute incubation period. A test may be called positive in less than 10 minutes ONLY if 2 lines appear.

 f. The test is valid even if the lines are faint or uneven.

3. **Record results**, including internal control documentation. (**Control line must be present and documented for the test to be valid.)**

4. **Limits of the test**:

 a. A significant presence of blood on the swab can cause malfunction. The test functions properly with only trace amounts of blood on the swab.

 b. Do not use this test earlier than 6 hours after the removal of any disinfectant solutions or medications from the vagina.

 c. Placenta previa or/and performing digital exams prior to sample collection can lead to inaccurate results.

 d. The performance of this test has not been established in the presence of meconium, anti-fungal creams or suppositories, K-Y Jelly, Monistat, Baby powder (starch or talc). Replens, or Baby Oil.

 e. Vaginal infections, sperm or urine DO NOT interfere with the test.

 f. A false negative result may occur if a sample is taken 12 hours or later after a rupture.

5. Test storage and stability: Store at room temperature.

 a. Test is stable until the “Use By” date on the foil pouch. Test strip must be used within 6 hours after removal from the foil pouch.

6. Controls

 a. Internal control (top line on test strip) must be present and documented with each patient test.

**Please review the lab procedures in the BDHS organization-wide Policies and Procedures manual. This manual may be found in SharePoint under the Policies and Procedures tab, Organization Wide Procedures, Laboratory. You will be asked to locate these procedures by an inspector.**

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