Examination of the test

[Explanation of the test

3. The right section of the result window indicates the test results. If another color band appears in the right section of the result window, this band is the Test Band.

4. A negative result does not preclude the possibility of infection with H. pylori. Other clinically available tests are required if questionable results are obtained.

5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

6. The test procedure, precautions and interpretation of results for this test must be followed according to the instruction of the test kit.

7. The specimen is subjected to a strict quality control assessment, including testing for internal and external controls.

8. The performance characteristics of this test kit have been evaluated by the manufacturer, and the results are summarized in the following table.

9. The test kit is intended for use by trained medical professionals in laboratories that have the necessary equipment and personnel to perform the test.

10. The test kit is not intended for use in home or non-laboratory settings.

11. The test kit is not intended for use in pregnant women or lactating mothers.

12. The test kit is not intended for use in patients with known allergies to any of the components of the kit.

13. The test kit is not intended for use in patients with known or suspected immunodeficiency.

14. The test kit is not intended for use in patients with known or suspected systemic lupus erythematosus.

15. The test kit is not intended for use in patients with known or suspected multiple myeloma.

16. The test kit is not intended for use in patients with known or suspected Waldenström’s macroglobulinemia.

17. The test kit is not intended for use in patients with known or suspected myelodysplastic syndrome.

18. The test kit is not intended for use in patients with known or suspected chronic lymphocytic leukemia.

19. The test kit is not intended for use in patients with known or suspected chronic myelogenous leukemia.

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SD BIOLINE H. PYLORI AG Rapid Test Procedure

1. Assemble dropping cap on test device.
2. Add 3 drops (about 100 μL) of sample collection tube into the sample well (5) of test device.
3. Interpret test results at 10-15 minutes.

Interpretation of the Test:
- Invalid
- Positive
- Negative

5 minutes and leave to settle the tube for 5 minutes. Discard the swab while squeezing the swab against the wall of the tube.

Insert the swab into the sample collection tube and swirl the swab.

Take a portion of feces from a stool sample (about 5mg) from a stool sample. Insert a portion of feces into the swab.

Transfer assay diluent twice.

Up to the fill line.