1. Principle: Immunoassay for the qualitative detection of IgG to Helicobacter pylori.

2. Can only be used for patients 18 years of age or older.

3. Test must be run using a Whole Blood sample in order to be considered waived.

a. Specimen should be collected via fingerstick using the heparinized capillary tubes provided in the kit.

b. Gloves must be worn for the entire duration of testing and appropriate hand hygiene must be followed. See test procedure for details.

c. Perform test immediately after sample has been collected.

4. Procedure:

a. Is it an H.Pylori or is it an HCG cartridge in your hand?

b. LABEL the test cartridge with patient identifier!

c. Collect approximately 50µl of blood from a well performed fingerstick.

d. Add one full capillary tube of blood to the sample (S) well

e. Next add 1 drop Sample Buffer to the Sample well

f. Start a timer for 10 minutes

g. Test can NOT be interpreted after 15 minutes

5. Interpretation of Results

a. The internal Control (C) line must be present or the test is invalid

b. Two distinct lines in the test window indicate a positive result

c. One distinct line (the internal control line) in the test window indicates a negative result

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

1/2014 DDe