REF **200013**

Status H. pylori Control Set

(Positive and Negative Controls)

Intended Use

Status Unassayed H. pylori Control Set is intended for in vitro diagnostic use only to estimate the precision and monitor the accuracy of H. pylori test procedures. The set contains external positive and negative serum controls for qualitative use.

Summary and Principle

Status Unassayed H. pylori Control Set uses a specially formulated matrix to provide satisfactory results with a large number of currently popular H. pylori test methods. Positive and negative controls are provided to facilitate monitoring in the expected clinical range.

Ingredients

Control set contains one vial x 2 ml each of a positive and negative control. **Status Unassayed H. pylori Control Set** is provided in liquid form for convenience and is made from human serum to which preservatives and stabilizers, biochemicals and chemicals are added.

Storage and Stability

The vials should be kept tightly closed after opening to avoid evaporation. Store vials upright at 2-8° C. Do not freeze. **The Status Unassayed H. pylori Controls** are stable until the date on the vial label.

Procedure

1. Allow **Status Unassayed H. pylori Controls** to reach room temperature. Gently invert the vial 5-10 times to assure complete mixing.
2. Remove the cap. Dispense 1 drop of control material into the device sample well. Replace the cap and store at 2-8° C.
3. Follow test procedure as directed in the H.pylori package insert for addition of developer solution and test time.

Expected Results

Each laboratory needs to establish expected results and deviations for each lot of **Status Unassayed H. pylori Controls** according to the established quality assurance procedure for that laboratory. Subsequent results are expected to fall within the limits established based on these statistical parameters.

Limitations

Status Unassayed H. pylori Controls should not be used beyond the expiration date printed on the label. They may not perform as expected if the handling or storage conditions recommended are not followed. **Status Unassayed H. pylori Controls** should not be used if there is evidence of microbial contamination or excessive turbidity. Satisfactory results may not be obtained if procedural directions for the reagents are not followed.

Precautions

Handle **Status Unassayed H. pylori Controls** as biohazards and in the same manner as patient specimens. The human serum used to make this product was tested by currently approved methods and found non-reactive for hepatitis B surface antigen (HbsAg), HIV1, HIV2 and HCV antibodies. Currently there is no test method that can assure that human blood used in this product will not transmit infectious agents. In accordance with Good Laboratory Practice, all human source material should be considered potentially infectious. This control set contains 0.1% sodium azide as a preservative.

Technical Assistance

For technical assistance and customer service, contact LifeSign at:
(800) 526-2125 X102 / X109

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