

Survey for antibodies against *H. pylori* (HPYL)

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Instructions for Use

Notes:

The samples should be considered as potentially infectious. The usual precautions in the laboratory for potential hazardous samples apply for these samples. The blood donations used for production were found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. The samples should be used by trained personnel only



WARNING: Contains methylisothiazolones.
 H317 May cause allergic skin reaction.



This product contains human source material and should be considered as potentially infectious.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeda.eu

1. Intended Use

The samples are intended for use as qualitative control material for External Quality Assessment (EQA) in medical laboratories for antibodies against *H. pylori*. In addition participants may report their quantitative values for a statistical comparison:

anti-*H. pylori* IgA, IgG, and IgM
 anti-*H. pylori* total antibodies

2. Product Description

The liquid samples derive from defibrinated human plasma and are ready-to-use.

3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated on the sample labels.

4. Sample Preparation and Analysis

Allow the sample to equilibrate to room temperature for 15 minutes prior to testing. Directly before use, agitate the sample by gently inverting the vial several times.

All samples should be treated the same way as patient samples and analyzed in accordance with the instructions of the instrument and reagent manufacturer.

5. Dates and Submission of Test Results

Testing Periods: Please refer to the sample labels. Results can be submitted anytime within the testing period indicated on the sample labels.

Please submit your results electronically to ESfEQA at <https://teqa.esfeda.eu>.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance with registration in TEQA. Alternatively, though not preferred, use the result form provided on the ESfEQA website. In both cases indicate the instrument and method used for the analysis of the samples.

6. Deadline for Data Submission

The deadlines for submitting results are indicated on the sample labels (time zone GMT +1).

7. Reports and Certificates

The data will be evaluated by ESfEQA.

Please note that, in general, we will not issue a certificate of successful participation for the quantitative determination of anti-*H. pylori* antibodies since the target values are reagent-specific and a bias to the calculated consensus value does not necessarily represent a poor laboratory performance. The statistical Evaluation is for information purposes only.

The individual laboratory reports and certificates can be retrieved online at <https://teqa.esfeda.eu>.