

Survey for Tumor Marker/Hormones (TMH12)

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Instructions for Use

Notes:

The usual precautions in the laboratory for potential hazardous samples apply for these samples. Human origin materials used for production were found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV.

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.esfeqa.eu

1. Intended Use

The samples are intended for use as quantitative control material for External Quality Assessment (EQA) in medical laboratories for the following analytes:

AFP, Aldosterone, AMH, Androstendione, CA 125, CA 15-3, CA 19-9, CEA, Calcitonin, Cortisol, C-Peptide, DHEA-S, Estradiol, Ferritin, Folate, FSH, hCG, Human Growth Hormone, IgE, IGF-1, Insulin, LH (Luteinizing Hormone), Progesterone, 17-OH-Progesterone, Prolactin, PSA free, PSA total, PTH, SHBG, T3 free, T3 total, T4 free, T4 total,

Testosterone, Thyreoglobulin, TSH, Vitamin B12, Vitamin D

2. Product Description

The samples are lyophilized material based on human plasma.

Sample 1: TMH12_2024_01_a
Sample 2: TMH12_2024_02_a
Sample 3: TMH12_2024_03_a
Sample 4: TMH12_2024_04_a
Sample 5: TMH12_2024_05_a
Sample 6: TMH12_2024_06_a

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 below.

After reconstitution, samples are stable in tightly recapped vials for 10 days at 2-8°C except for C-Peptide (stability 3 days) and PTH (1 day).

4. Sample Preparation and Analysis

Remove the screw cap from the vial and pipette exactly 3 ml of distilled or deionized water to the lyophilisate. Keep the control sample for about 30 minutes at rest in a light-protected place, then gently agitate the vial occasionally until the lyophilisate is completely dissolved.

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

5. Dates and Submission of Test Results

Testing Period Sample 1: 30/01/24 - 13/02/24
Testing Period Sample 2: 20/02/24 - 05/03/24
Testing Period Sample 3: 19/03/24 - 02/04/24
Testing Period Sample 4: 16/04/24 - 30/04/24
Testing Period Sample 5: 14/05/24 - 28/05/24
Testing Period Sample 6: 11/06/24 - 25/06/24

Please submit your results electronically to ESfEQA at <https://teqa.esfeqa.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 fax form provided on the ESfEQA website. In both cases indicate the instrument and method used for the analysis of the samples.

Quantitative results are generally reported with a value and a unit. The participant determines the number of digits for reporting. Results specified as e.g. '< below measuring range' or '< 0.02' are not valid. If the analyzer system displays such results, they shall be interpreted as following: For results within the measuring range and below the Limit of Quantification (LoQ) the obtained value should be reported. For results below the Limit of Detection (LoD), this limit should be reported. For samples that have analyte concentrations above the test range, the sample can be diluted (if recommended for particular applications) or the upper test range limit can be reported as result.

6. Deadline for Data Submission

Deadlines for data submission are (time zone GMT +1):

Sample 1: 13/02/24
Sample 2: 05/03/24
Sample 3: 02/04/24
Sample 4: 30/04/24
Sample 5: 28/05/24
Sample 6: 25/06/24

7. Reports and Certificates

The data will be evaluated by ESfEQA. The individual laboratory reports and certificates can be retrieved online at <https://teqa.esfeqa.eu>. The reports and certificates will be available within 10 days after the deadline of data submission.