

National Institute of Standards and Technology
Health Assessment Measurements Quality Assurance Program
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Dear Colleagues,

Thank you for your interest and/or past participation in NIST Quality Assurance Programs (QAPs). Exercise 7 of the Health Assessment Measurement Quality Assurance Program (HAMQAP) will be open for sign up on **March 22, 2021**. HAMQAP is designed to help natural product, food, and clinical laboratories demonstrate measurement competence as well as to learn about the measurement capabilities of the community and help improve measurement capabilities through education. Exercise 7 will be comprised of the studies listed below. A brief description of each study is provided to describe the rationale for conducting the study and how the intake and metabolism studies relate, as appropriate. Participants may elect to sign up for some or all studies, as applicable to the work done in their laboratories. Laboratories may elect to participate in specific sample sets (e.g., dietary intake versus human metabolites), and may also elect to report selected analytes (e.g., only reporting total arsenic, but not individual species). *Laboratories participating in human metabolites studies must have proper facilities (e.g., biosafety level 2 laboratory or equivalent) and training prior to conducting work with human fluids.*

HAMQAP Exercise 7 is supported by the National Institutes of Health, Office of Dietary Supplements (NIH-ODS). As a result, participation in HAMQAP is free of charge; although participants will be required to pay for the cost of sample shipment by providing NIST with a shipping account number using UPS, FedEx (including TNT Express), or DHL. International participants must provide an import shipping account number, if applicable. Participants are responsible for all incurred shipping charges, including those that may result from shipments being returned to NIST because of customs clearance issues. Under no circumstances are participants paid to participate in HAMQAP.

Instructions for sign up for new and existing participants are attached. **The call for participation will close on April 16, 2021, and samples will be distributed in July 2021.**

We hope that within this exercise you will find studies that are of interest and use to your laboratory. If you have any suggestions for studies or would like more information regarding HAMQAP and our other QAPs, please send your request to hamqap@nist.gov or visit <https://qa.nist.gov/>.

Please let us know if you have questions. We look forward to your participation in this and future HAMQAP exercises.

Best regards,
HAMQAP Team

HAMQAP EXERCISE 7 STUDY DESCRIPTIONS

Nutritional Elements

Consumers expect labeling information to be accurate on the food and dietary supplement products they purchase in order to make informed choices. In the U.S., accurate measurements of nutrients are needed to ensure compliance with the Food and Drug Administration regulations on the levels claimed on Nutrition Facts and Supplement Facts labels. Certain foods are often fortified with trace minerals, and these nutrients are also increasingly found in nutritionally fortified waters. Appropriate levels of trace minerals are essential for the body to function properly, and deficiencies or excess consumption can lead to potential health risks. Testing of these minerals in nutritionally supplemented water can help ensure accurate product labeling while testing in biological samples such as serum can be used to determine health status and nutrient deficiencies for individuals or within a population.

Dietary Intake Study

Analytes: Zn, Mg, and Ca
Matrices: Nutritionally Fortified Water

Human Metabolism Study

Analytes: Zn, Mg, and Ca
Matrices: Human and Animal Serum

Toxic Elements

Plant uptake of toxic elements from the air, water, or soil may result in contamination of certain foods and dietary supplements. Furthermore, the processing of plant materials may also increase the mass fractions of these toxic elements in consumer products. Consumption of such contaminated foods can cause illness, impairment or, at high doses, death. Testing of these environmental toxins in foods and supplements can help ensure product safety while testing in biological samples such as serum can identify exposure and risk.

Dietary Intake Study

Analytes: As, Cd, Pb, and Hg
Matrices: Black Cohosh Extract and
Ashwagandha Extract

Human Metabolism Study

Analytes: As, Cd, Pb, and Hg
Matrices: Human and Animal Serum

Water-Soluble Vitamins

Vitamin B₂ (riboflavin) and vitamin B₆ are water-soluble vitamins, present in some foods both naturally and through fortification, and available as dietary supplements. Vitamin B₂ has major roles in energy production; cellular function, growth, and development; and metabolism of fats, drugs, and steroids. Vitamin B₆ is important for a wide variety of functions in the body, particularly in protein and amino acid metabolism. Vitamin B₆ vitamers are also involved in the biosynthesis of neurotransmitters, in maintaining normal levels of homocysteine in the blood, in gluconeogenesis and glycogenolysis, in immune functions, and in hemoglobin formation. Testing of these vitamins in foods and supplements can help ensure accurate dietary intake estimates and product labeling; while testing for vitamins, metabolites, and related compounds in biological samples such as serum can be used to determine health status and nutrient deficiencies for individuals or within a population.

Dietary Intake Study

Analytes: Vitamins B₂ and B₆
Matrices: Multivitamin, Protein Powder

Human Metabolism Study

Analytes: Vitamin B₂ and B₆, Homocysteine
Matrices: Human Serum

Fat-Soluble Vitamins

Vitamin K is a family of fat-soluble vitamins found in some foods and available as a dietary supplement. Vitamin K has important functions in homeostasis and bone metabolism. The naturally occurring compounds include phylloquinone (vitamin K₁) and menaquinones (vitamin K₂), each having multiple forms. Food sources of phylloquinone include vegetables, especially green leafy vegetables, vegetable oils, and some fruits. Meat, dairy foods, and eggs contain low levels of phylloquinone but modest amounts of menaquinones. Fermented foods, such as natto, cheeses, and sauerkraut, can contain high amounts of menaquinones, varying in levels depending on the bacteria present and the fermentation conditions. Vitamin K deficiency has been linked to osteoporosis and coronary heart disease. The population groups most likely to have inadequate vitamin K are newborns not treated with vitamin K at birth and people with malabsorption disorders. There have been no findings on adverse effects of excessive vitamin K intake, though some anticoagulant medications (notably Warfarin (Coumadin®)) antagonize vitamin K activity and certain other medications can reduce vitamin K levels (e.g., antibiotics, bile acid sequestrants). It is important that testing labs use fit-for-purpose methods and standards that can support reliable and accurate measurements for nutritional labeling and diagnostic and clinical testing.

Dietary Intake Study

Analytes: Vitamin K
Matrices: Multivitamin, Kelp

Human Metabolism Study

Analytes: Vitamin K
Matrices: Human Serum

Botanicals

Ginger (*Zingiber officinale*) is a flowering plant native to Asia and its rhizomes are commonly used in culinary dishes. Additionally, ginger has been used medicinally for many centuries to quell nausea and vomiting. Gingerols, the major phytochemical constituents of ginger, have been suggested to have anticancer, anti-inflammatory, anti-fungal, antioxidant, neuroprotective, and gastroprotective properties. Raw ginger contains high levels of gingerols, and processed ginger may also contain shogaols and zingerone formed from gingerols during heating and drying steps. Accurate determination of these compounds in foods or supplements is critical to ensure quality or facilitate standardization for clinical investigations of health effects. Participants in this study are strongly encouraged to use AOAC Official *First Action* Method of Analysis 2018.14. The data collected from this method will be used to evaluate method reproducibility and assist in the multi-laboratory validation of the method. A copy of the method will be provided to participants in the study and is available upon request.

Dietary Intake Study

Analytes: Gingerols
Matrices: Ginger Rhizome, Ginger-Containing Dietary Supplements

Protein Source Identification

The accurate measurement of protein and amino acid content is a necessity for analytical characterization and verification of foods and dietary supplements. However, commonly used methods may not distinguish between proteins, peptides, amino acids, and other non-protein, nitrogen containing compounds. The need for specific detection of certain proteins is further exemplified by increased food allergen concerns. Given these considerations, the use of accurate and reliable measurements that can distinguish between protein, amino acids, and adulterants, as well as differentiate between protein from different sources (e.g., soy versus milk), is becoming a crucial component of manufacturing and QC/QA practices. Participants in this study are strongly encouraged to use AOAC Official *First Action* Method of Analysis 2017.11. The data collected from this method will be used to evaluate method reproducibility and assist in the multi-laboratory validation of the method. A copy of the method will be provided to participants in the study.

Dietary Intake Study

Analytes: Protein Source
Matrices: Protein Supplements

Registration Instructions

For New Participants

To participate, first request an account by navigating to <https://qa.nist.gov/hamqap> and clicking *Request new account*. Once your account request is approved, you will receive an automated email with login information. Please modify this password immediately upon logging in to the system and confirm or update your contact information on the *My account* page. If you have additional users that you wish to grant access to your laboratory sign-up and participation information (e.g., QC manager, additional analysts), you may also create secondary accounts on the *My account* page. To add your laboratory to the HAMQAP *List of Participants* page, check the box on the *My account* page. *All participants are required to provide shipping account information (e.g., FedEx, UPS, DHL), to which the cost of sample shipment will be charged. Your account will not be approved until a valid shipping account is provided.* Next, log in to your account at <https://qa.nist.gov/hamqap>. Click *Register for Exercise* on the left menu and select the blue *Details* button next to HAMQAP Exercise 7 – Dietary Intake and/or HAMQAP Exercise 7 – Human Metabolites. Once you have selected the studies of interest, click the blue button for *Participate in this exercise*. Your participation request will be approved by a program administrator, and you will receive an automated confirmation email. Study selections can be modified at any time up until the closure of the registration period.

For Existing Participants (DSQAP and/or HAMQAP)

Log in to your account at <https://qa.nist.gov/hamqap>. *Participants in the DSQAP should use existing login credentials, as DSQAP account information was transferred to the HAMQAP site.* Click *Register for Exercise* on the left menu and select the blue *Details* button next to HAMQAP Exercise 7 – Dietary Intake and/or HAMQAP Exercise 7 – Human Metabolites. Once you have selected the studies of interest, click the blue button for *Participate in this exercise*. Your participation request will be approved by a program administrator, and you will receive an automated confirmation email. Study selections can be modified at any time up until the closure of the registration period. *All participants are required to provide shipping account information (e.g., FedEx, UPS, DHL), to which the cost of sample shipment will be charged. Your registration for the exercise will not be accepted until a valid shipping account is provided.* Additional users (e.g., QC manager, additional analysts) can be granted access to your laboratory sign up and participation information on the *My account* page at any time. Your laboratory may be added to the HAMQAP *List of Participants* page at any time by checking the box on the *My account* page.