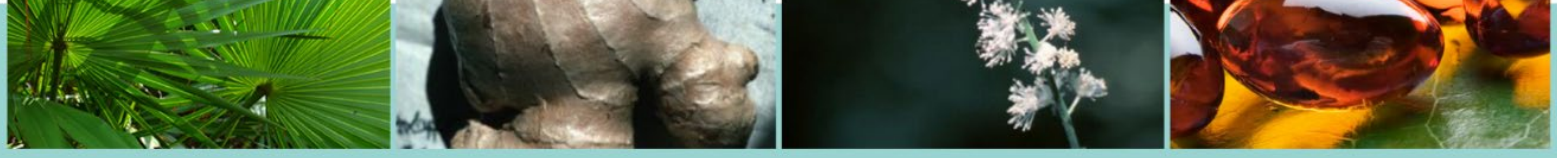

Dietary Supplement Laboratory Quality Assurance Program

Request for participation – Exercise 2 Now Open

National Institute of Standards and Technology
100 Bureau Drive, Stop 8392
Gaithersburg, Maryland 20899-8392
Email: QAPHUB@nist.gov
Website: https://qa-hub.nist.gov

April 11, 2023

Dear Colleagues,

Thank you for your interest and/or past participation in NIST Quality Assurance Programs (QAPs). A call for participants in Exercise 2 of the Dietary Supplement Laboratory Quality Assurance Program (DSQAP) is now open. DSQAP is designed to assist laboratories in the development and validation of new analytical methods, in improving the quality of their analytical measurements, and in supporting compliance with a number of federal regulations enforced by the US FDA, USDA, and other international bodies. Exercise 2 will offer opportunities for participants to measure mass fractions of toxic elements, fat-soluble vitamins, fatty acids, gingerols, and triterpenoids in dietary supplement ingredients and finished products. Laboratories may elect to participate in some or all studies (e.g., only toxic elements and fat-soluble vitamins) or report only selected analytes (e.g., arsenic and lead, but not cadmium and mercury), as applicable to the work done in their laboratories.

Participation in DSQAP is free of charge with the support of NIH-Office of Dietary Supplements (ODS), 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), 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. In no cases are participants paid to participate in DSQAP.

Instructions for sign up for new and existing NIST QAP participants are attached. Registration will open on April 11, 2023 and will close on May 5, 2023. Samples will be distributed in late June/early July 2023.

We hope that within this exercise you will find studies that are of interest and use to your laboratory. Future DSQAP studies may address additional areas such as authenticity and microbial contaminants, as needs are identified. If you have any suggestions for studies or would like more information regarding DSQAP and other NIST QAPs, please send your request to QAPHUB@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 DSQAP exercises.

Best regards,
DSQAP Team

Scan for more information on DSQAP, major accomplishments, and historical exercises.

Scan to navigate to the QAP HUB Webpage.

Dietary Supplement Laboratory Quality Assurance Program (DSQAP)

Exercise 2 – Studies

Toxic Elements:

Purpose

Arsenic, cadmium, lead, and mercury, sometimes called the "big four", are environmental contaminants that can be present in foods and dietary supplements. These contaminants can be incurred naturally through environmental exposure or through downstream processing of a product. The U.S. FDA has set goals to lower the intake of these toxic elements. As regulations strive for toxic element levels as low as possible in foods and supplements, laboratories are challenged to validate methods with lower LOQs.

Rationale

This study will be used by NIST to determine any community-wide analytical challenges and support improvement of quantitative measurements through testing of two reference materials with similar extraction challenges but with varying levels of toxic elements. This study will also assist the community with evaluating internal analytical challenges associated with toxic elements measurements in botanical supplementation matrices.

Design

Samples	Analytes
Eleuthero Extract and Ginger Extract	Arsenic, Cadmium, Lead, Mercury

Fat-Soluble Vitamins: β-carotene

Purpose

Carotenoids are responsible for the yellow and orange colors found in many fruits and vegetables and are a source of vitamin A. Vitamin A is essential to maintain normal human vision, for the function of the immune and reproductive systems, as well as the heart, lungs, kidneys, and other organs. β-carotene is converted to vitamin A within the body, and the cis-trans isomerization can affect the provitamin A activity. Accurate determination of the isomers is essential for understanding intake values, bioactivity, and correlation to health benefits.

Rationale

This study will be used by NIST to determine any community-wide analytical challenges and support improvement of β-carotene measurements through appropriate reference materials and educational resources. This study will also assist the community with evaluating internal analytical challenges associated with calibration and sample preparation effects on fat-soluble vitamin isomer quantitation.

Design

Samples	Analytes
Saw Palmetto and Multivitamin Tablets	Total β-carotene, *Trans*-β-carotene, 9-*Cis*-β-carotene

Botanicals I: Gingerols

Purpose

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.

Rationale

This study is a continuation of efforts initiated through HAMQAP Exercise 7 to gather multi-laboratory validation data for the AOAC Official First Action Method of Analysis 2018.04. **Previous participation is neither a requirement nor a restriction**. Participants will be strongly encouraged to use the AOAC method for the DSQAP measurements and copy of the method will be provided to participants in the study.

Design

Samples	Analytes
Ginger Rhizome, Extract, and Ginger Containing Supplements	10-gingerol, 10-shogaol, 8-gingerol, 8-shogaol, 6-gingerol, 6-paradol, 6-shogaol, zingerone

Fatty Acids: Fish Oil

Purpose

Fatty acids (FAs) are important in several functions in the body and are components of cell membranes. The polyunsaturated omega-3 and omega-6 FAs can be found in foods, such as fish and flaxseed, and in dietary supplements, such as fish oil. Some studies suggest that the relative intakes of omega-3 and omega-6 FAs may have important implications for the pathogenesis of chronic diseases such as cardiovascular disease and cancer, but an optimal ratio has not yet been defined. Standardization of FA measurements is essential to accurate product label information and dietary intake survey interpretations and will lead to a better understanding of omega-3 and omega-6 fatty acid intake and their impact on inflammation and disease. This in turn can advance clinical research that investigates how manipulating the FA intakes may yield positive health outcomes.

Rationale

Participation in this DSQAP study provides opportunities for laboratories to evaluate their current inhouse method performance and will also be used by NIST to determine any community-wide analytical challenges and support measurement improvements through appropriate reference materials and educational resources.

Design

Samples	Analytes *
3 Fish Oils	α-linolenic acid (ALA), arachidonic acid, EPA, DPA, and DHA

** Optional: Results for additional FAs can be returned and Z Scores will be calculated if > 10 laboratories return data*

Botanicals II: Black Cohosh

Purpose

Black cohosh (*Actaea racemosa*), a member of the buttercup family, is a perennial plant native to North America. Black cohosh has a long history of medicinal uses such as the treatment of musculoskeletal pain, fever, cough, pneumonia, and the support of women's reproductive health. Today, black cohosh is most commonly used for menopausal symptoms. Preparations of black cohosh are usually made from the roots and rhizomes and are sold as dietary supplements in many forms including powdered whole herb, liquid extracts, and dried extracts in pill form. The chemical composition of the various supplement preparations vary considerably, in part because the compounds in black cohosh that may be responsible for any relief of menopausal symptoms are not known. Substances in black cohosh that may account for its activity include triterpene glycosides and aromatic acid derivatives. Products containing black cohosh extract are frequently standardized to provide at least 1 mg triterpene glycosides per daily dose.

Rationale

Reference materials and appropriate analytical techniques are essential in understanding the marker compounds in black cohosh and the connection to health outcomes. Participation in this DSQAP study provides opportunities for laboratories to evaluate their current inhouse method performance and will also be used by NIST to determine any community-wide analytical challenges and support measurement improvements through appropriate reference materials and educational resources. NIST is currently working on the development of a suite of black cohosh (*Actaea racemose*) reference materials, including leaves, rhizome, extract, and solid oral dosage form.

Design

Samples	Analytes
Black cohosh Rhizome and Extract	triterpene glycosides

Registration

Log into your account https://qa-hub.nist.gov and click on *Enroll to upcoming exercises* in the top right corner.

If you need help with enrollment or creating an account on HUB, please find instructions at https://www.nist.gov/document/qaphub-registration-instructions or email us at QAPHUB@nist.gov

Scan QR code to navigate to the QAP Registration Instructions

Scan QR code to navigate to the QAP HUB Webpage.