Addressing Current Measurement Challenges with the Health Assessment Measurements Quality Assurance Program (HAMQAP)

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HAMQAP Background

In 2017, the National Institute of Standards and Technology (NIST) established the Health Assessment Measurements Quality Assurance Program (HAMQAP) to identify, understand, and address community-wide measurement challenges. This program helps to improve measurement accuracy by providing an opportunity for laboratories to assess their in-house measurement performance and to demonstrate an effort to comply with applicable regulations. Standardization programs, proficiency testing, interlaboratory comparisons, and participation in quality assessment programs (QAPs), in conjunction with the use of reference materials (RMs), are all essential in order to improve the comparability and precision of data over time.

NIST has extensive experience in the coordination of QAPs[1] and the HAMQAP represents ongoing efforts previously supported via historical QA programs, such as the Dietary Supplements Laboratory QAP, Micronutrients Measurement QAP, Fatty Acids in Human Serum and Plasma QAP, and Vitamin D Metabolites QAP. HAMQAP exercises are focused on health assessment as a whole by providing a variety of sample matrices for both human dietary intake (e.g., foods, dietary supplements, and natural products) and human metabolism (e.g., urine, blood, serum, plasma, and human milk). HAMQAP participants receive information regarding the accuracy and precision of their results, as well as concordance within the community. Detailed study reports and certificates of completion are provided for participants, and workshops and webinars are held to discuss results as well as methodological advancements in the area of health assessment measurements.

Once the overall measurement performance within a community has been explored, accuracy and precision can be improved through use of reference materials. Reference materials can be used to validate methods, establish traceability, provide quality control when producing in-house reference materials, or produce scientific data that can be referred readily to a common base. HAMQAP, in conjunction with the NIST Standard Reference Materials (SRM) Program, supports development of well-characterized SRMs that are value assigned for chemical composition, by incorporation of candidate reference materials into HAMQAP studies while using existing RMs and SRMs for quality control. In collaboration with the National Institutes of Health Office of Dietary Supplements (NIH-ODS), NIST has produced numerous reference materials for chemical composition of foods, dietary supplements, and clinical samples, as well as botanical authenticity, by incorporating these materials into QAPs.

For more information about the HAMQAP, visit http://qa.nist.gov/hamqap, or email us at HAMQAP@nist.gov.

HAMQAP Goals

NIST & NIH-ODS

- Improve measurement accuracy, precision, and comparability
- Identify measurement challenges and encourage discussions to improve analytical methods
- Encourage use of sound measurement practices, including the use of and need for RMs

Participants

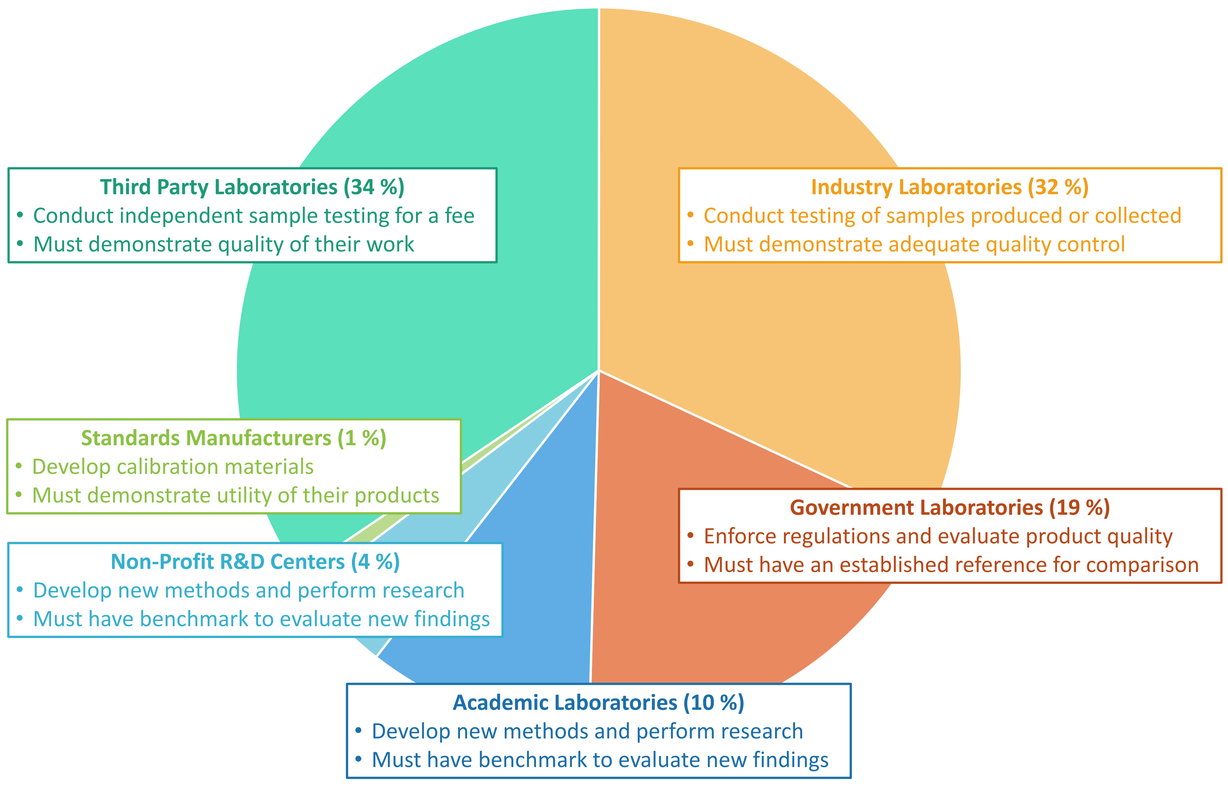
- Improve measurement processes
- Demonstrate accuracy and comparable performance to other laboratories
- Participate in complementary studies in dietary intake and human metabolism

The best way to know if a test is performing as expected is to utilize quality control materials (materials with known characteristics or quantities) throughout the testing process. In the absence of quality control materials, another approach is to participate in a proficiency testing or quality assurance program in which test results are compared to the results from other laboratories, and ideally to a known value (determined independently or through participant consensus). With participation, laboratories with outlying test results can improve performance by modifying protocols or changing the testing procedure altogether.

The goal of the HAMQAP is to assist laboratories in identifying those tests that give incorrect or inconsistent results and working with laboratories to improve their testing capabilities.

HAMQAP Participants

All laboratories participate on a voluntary basis and without compensation.



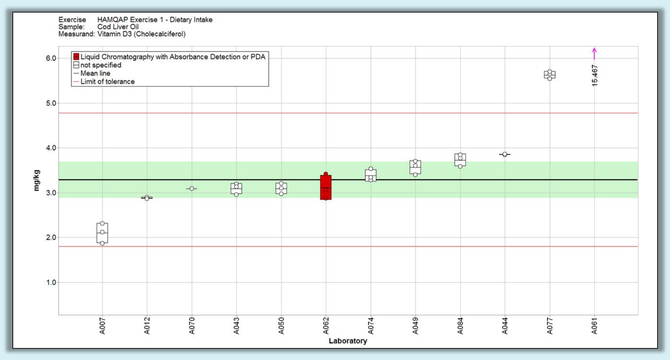
HAMQAP Exercise 1 Design

	Dietary Intake	Human Metabolites
Nutritional Elements	Iron Multivitamin, Cereal	Iron, Transferrins Human Serum
Toxic Elements	Arsenic, Arsenic Species Tobacco†, Kelp	Arsenic, Arsenic Species Human Urine
Water-Soluble Vitamins	Vitamin B_{12} Multivitamin, Cereal	Vitamin B_{12} Human Serum
Fat-Soluble Vitamins	Vitamin D, Vitamin D Metabolites Liver, Cod Liver Oil	Vitamin D, Vitamin D Metabolites Human Serum
Fatty Acids	Fatty Acids Solution, Fish Oil, Cod Liver Oil	Fatty Acids Solution, Human Plasma
Natural Products	Actein, 27-Deoxyactein Black Cohosh Rhizome, Leaves, Extract	Not offered
Contaminants	Mycotoxins Corn	~~VOC Metabolites~~* ~~Human Urine~~

† Study on tobacco was not funded by the NIH-ODS
* Cancelled due to low enrollment

HAMQAP Exercise 1: Lessons Learned

Vitamin D and Metabolites: Community Comparison



Cod Liver Oil

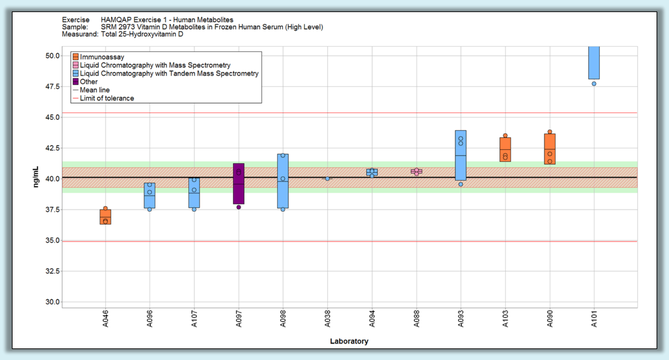
Consensus:
3.29 mg/kg vitamin D_3
22 % RSD_R

Laboratories perform well for vitamin D in fortified foods and supplements. Few laboratories reported results for vitamin D metabolites in intake samples, but more participation is expected as requirements for vitamin D declaration on food labels change.

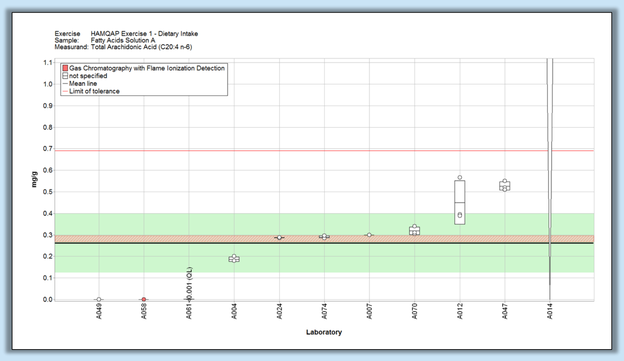
Human Serum

NIST Value: 40.1 ng/mL total 25OHD
Consensus: 40.1 ng/mL total 25OHD
6 % RSD_R

Laboratories perform well in the determination of 25OHD in serum, as expected given the existence of numerous interlaboratory programs and reference materials with values assigned for vitamin D metabolites in human serum.



Fatty Acids: Community Comparison



Fatty Acids Solution

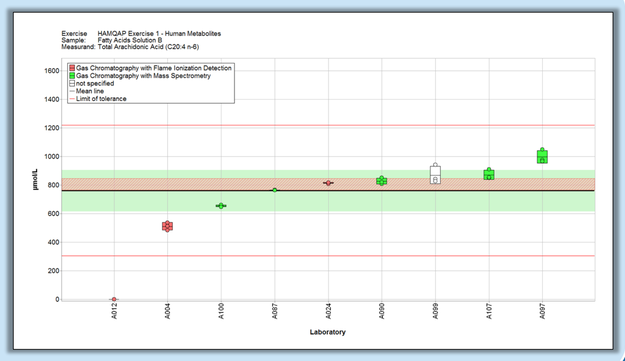
NIST Value: 0.282 mg/g Total ARA
Consensus: 0.262 mg/g Total ARA
76 % RSD_R

Food and supplement laboratories had difficulty measuring fatty acids at low levels in a solution. Laboratories must extend the linear range of their analytical method when the concentration in a sample is different than expected.

Fatty Acids Solution

NIST Value: 806 µmol/L Total ARA
Consensus: 761 µmol/L Total ARA
29 % RSD_R

Clinical laboratories perform well in the determination of low levels of fatty acids, as would be expected in human serum samples. Sample preparation steps for fatty acids in serum are simpler than those for foods and supplements, which may also reduce within- and between-laboratory variability.



References

[1]Sander, LC et al.; Anal Bioanal Chem.; 2013 May; 405(13):4437-41. doi: 10.1007/s00216-013-6864-7.

Acknowledgements

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