



QUATEST 3[®]

**DIRECTORATE OF STANDARDS, METROLOGY AND QUALITY
QUALITY ASSURANCE AND TESTING CENTER 3**

PROTOCOL FOR PROFICIENCY TESTING PROGRAMS OF QUATEST 3

Issue no. 4 – July 2017

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1. INTRODUCTION

1.1. About Quality Assurance and Testing Center 3

Quality Assurance & Testing Center 3 (in short – QUATEST 3) is a science – technology organization under the Directorate for Standards, Metrology and Quality (STAMEQ) - Ministry of Science and Technology (MOST), providing technical services in the field of standards, metrology, quality and productivity on request of the requirement of governmental management; and providing the relevant technical services to meet the requirements of organizations and individuals.

QUATEST 3's major fields of activities include:

- ▶ Inspection
- ▶ Certification
- ▶ Testing
- ▶ Calibration
- ▶ Providing proficiency testing (PT) programs
- ▶ Training and provide solution
- ▶ Barcode
- ▶ Instrumental service

1.2. About proficiency testing service

Proficiency testing (PT) is a powerful quality assurance tool enabling labs to compare their results with similar labs and monitor their performance. This activity has been defined in the section 5.9 - ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories.

Since 2005, QUATEST 3 has begun to provide PT program in microbiology for labs in Vietnam and ASEAN that is one of functions of the ASEAN Food Reference Laboratory.

Since 2013, QUATEST 3 has been accredited conforming to ISO/IEC 17043:2010 by A2LA - America. The scope of accreditation is detailed at the following link: <http://www.a2la.org/-scopepdf/3477-01.pdf>

Presently, beside the domestic labs, PT programs of QUATEST 3 are attracting more and more foreign labs.

1.3. Contact information

Proficiency Testing Department Quality Assurance and Testing Center 3

No. 7, Road 1, Bien Hoa Industrial Zone 1, Dong Nai

Tel: 084 251 383 6212 - Ext: 123 - Fax: 084 251 882 6917 - 383 6298

E-mail: ptprovider@quatest3.com.vn

Website: <http://www.quatest3.com.vn/>

2. POLICY

2.1. Confidentiality

All information supplied by a participant to QUATEST 3 shall be treated as confidential. The identity of participants in a PT program shall be confidential and known only by the minimum number of persons involved in the provision and evaluation of the program.

If any third parties require the PT results of one or some of participants to be directly provided by the PT provider, the participants shall be made aware of the arrangement in advance of participation. In exceptional circumstances, when a regulatory authority requires the PT results to be directly provided by QUATEST 3, the participants shall be notified of this action in writing.

2.2. Personnel

QUATEST 3 assures that all staffs relating to providing PT programs must have appropriate capacity, experiences and knowledge adequately.

These staffs must be trained, re-trained and assessed conforming to assigned tasks.

2.3. Subcontractor

QUATEST 3 commits to use subcontractors that have sufficient competence for the works requested. QUATEST 3 is responsible to the customers for all results from subcontractors.

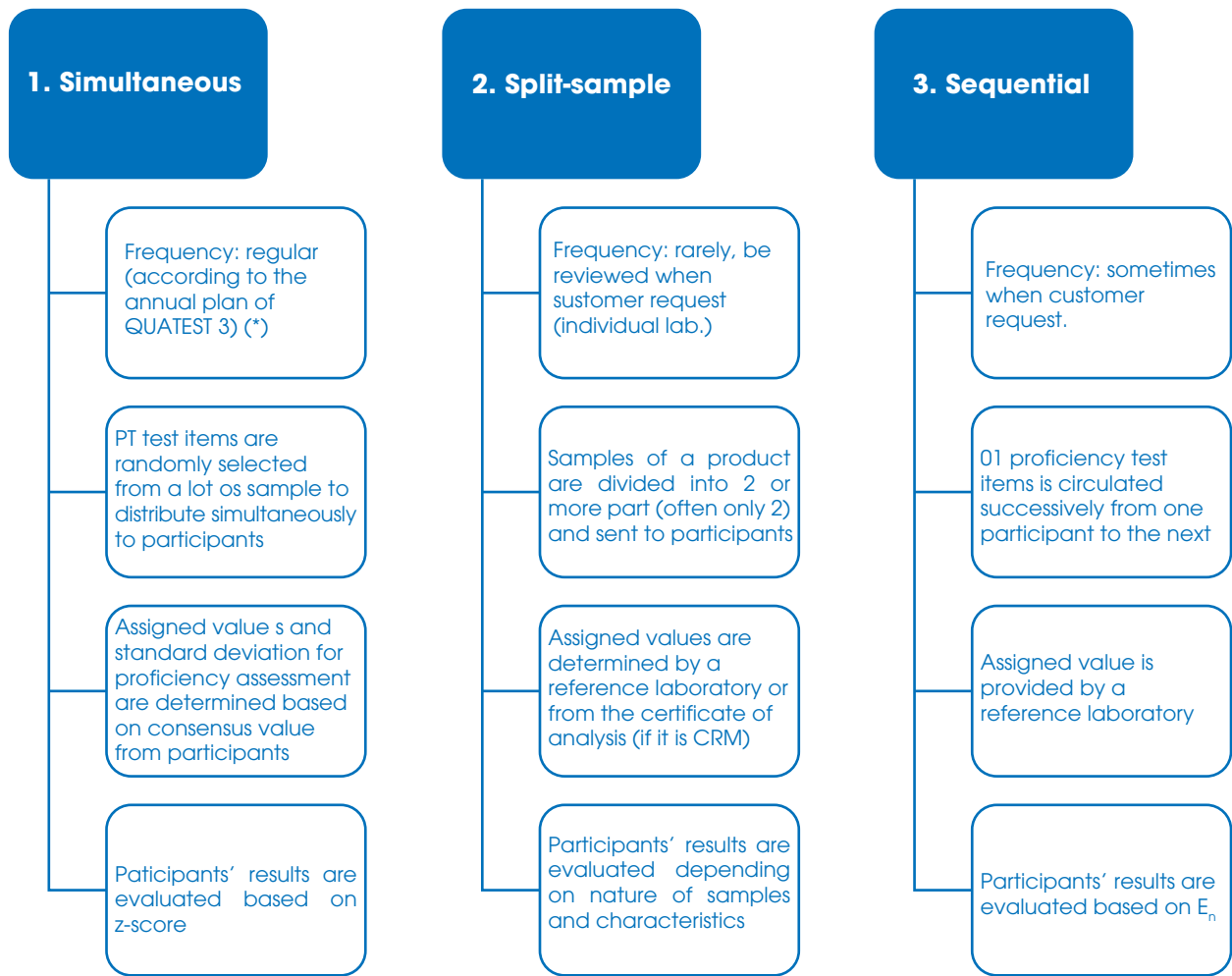
The PT Dept. is using subcontractors (internal or external) for the following works:

- ▶ Sample preparation (just for some PT programs)
- ▶ Homogeneity and stability check
- ▶ Sample delivery



3. DESIGN OF PT PROGRAM

QUATEST 3 is now applying the following PT schemes:



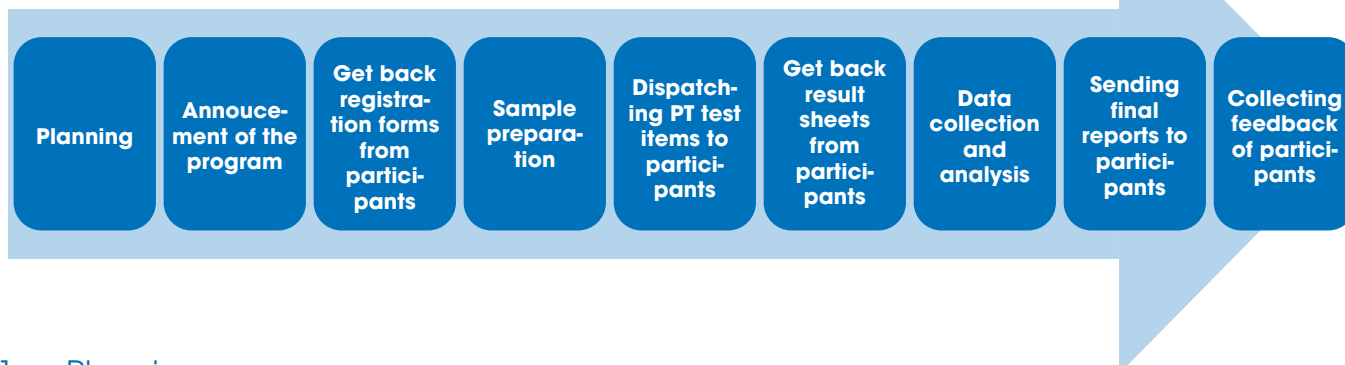
Scheme type 1 and type 2 is usually applied in area of chemical and microbiological testing. But scheme type 2 is rarely applied, so in this protocol, PT programs for testing area are considered being organized according to scheme type 1.

Scheme type 3 is usually applied in area of measurement. Accordingly, measurement comparison programs mentioned in this protocol are scheme type 3.

(*) This type of PT scheme is also be applied to organize PT programs requested by customers, in case that customer is an organization which can find more than 10 participating laboratories, such as: Department of Crop Production – Minister of Agriculture and Rural Development, Department of Food and Safety – Minister of Health, etc.



4. ORGANIZING PROFICIENCY TESTING PROGRAMS



4.1. Planning

Anually, at the 4th quarter, QUATEST 3 make schedule of PT programs for the next year. This schedule is both available in the website of QUATEST 3 and sent to concerned customers.

4.2. Announcement of programs – Get back registration forms

Please see the section 5.2.

4.3. Sample preparation

QUATEST 3 assures PT samples have been done sufficient homogeneity and stability check before being dispatched to participants to ensure that PT test items will not be changed significantly during the programs.

4.4. Dispatching samples to participants

QUATEST 3 shall control packaging and labeling processes to ensure conformity with the regulations on safety and transport related national and / or international areas.

Packaging must ensure that the sample remains in character throughout the process form transporting and storing in the laboratory to doing the test. Labels must include enough identify information and the storage conditions (temperature and other condition (if necessary)).

Before dispatching samples, PT provider will inform participants through email. If there are any changes in plan (time, characteristics, etc.), PT provider will update the schedule in the website as well as to inform participants through email.

The following documents will be enclosed with PT test items:

- ▶ Instructions to participants,
- ▶ Instructions for preparing sample (if any),
- ▶ Receipt form,
- ▶ Result sheet,
- ▶ Others (when necessary).

Participants please notice and follow the instructions.

4.5. Get back result sheets

QUATEST 3 receives test results by post, fax or email. Each program is assigned a due date of replies. For overdue participants' results, QUEST 3 will not take them in the statistical process.

For results being sent by post, QUEST 3 will base on stamps on envelopes for date of sending.

4.6. Data collection and analysis

The result sheets will be copied after give code for each participant. The original result sheets will be kept for reference while each copy will be cut into 2 parts (part of participants' information and part of results). These two parts will be given to different NP to keep participants' information confidential absolutely.

PT provider will contact participants to confirm about test results in cases of:

- ▶ Information, test results are blurred or not clear;
- ▶ It is suspected that there are mistakes in the unit or identification number of test methods;
- ▶ The number of significant digit or rounded number do not follow the defined regulations;
- ▶ The results are non-numerical for quantitative tests;
- ▶ The result is largely different from the others;
- ▶ Participants do not provide enough information as requested in the result sheets;
- ▶ One participant send more than one result sheet for one item.

After the deadline for resending test results, if PT provider still not receive the response of related participants, those results (not satisfy the request of PT provider) will be removed (for wrong unit and blurred results) or pre-process (for excess or lacking in significant digit number) before statistical process.

Participants' results will be process statistically according to section 4.

4.7. Sending final reports to participants

The interim reports will be sent to participants within 2 – 4 weeks since the deadline of receiving results.

The final reports shall be sent to participants by post within 1 – 2 months since the issue of interim report.

4.8. Collecting feedback of participant

Questionnaire forms will be sent to participants in the end of year. After getting back questionnaire forms, PT provider will make the summary of feedbacks and have response to participants having special feedbacks.

5. STATISTICAL ANALYSIS

5.1. PT program for qualitative characteristics

Evaluation of PT results for qualitative characteristics is to compare the results of participants to assign value which is determined from results of reference labs or from samples with known value.

5.2. PT program for quantitative characteristics

5.2.1. Determining the assigned value and standard deviation for proficiency assessment

Normally, the assigned values of PT program for quantitative characteristics of QUATEST 3 are determined by robust analysis (*) (refer to ISO 13528:2005). To minimize the risk that the extreme outliers will affect the assigned value, QUATEST 3 will consider and remove these results before analysis base on the histogram. The uncertainty of assigned value from robust analysis will be determined as follows:

$$u_x = \frac{1,25 \cdot s^*}{\sqrt{p}}$$

Where p is the number of participants' results, not including removed extreme outlier (if any).

If $u_x > 0,3 \cdot \sigma$, z'-score is used to evaluate the performance of participants (see the section 5.2.2)..

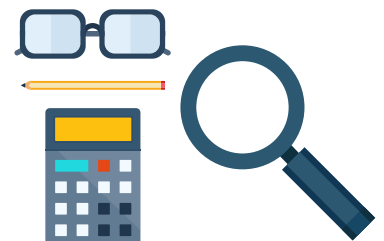
The standard deviation for proficiency assessment is normally determined from the participants' results: $\sigma = s^*$.

In some cases, the standard deviation could be determined from the history of QUATEST 3 or by Horwitz curve:

$$\sigma = \begin{cases} 0,22 \cdot c & \text{if } c < 1,2 \cdot 10^{-7} \\ 0,02 \cdot c^{0,8495} & \text{if } 1,2 \cdot 10^{-7} \leq c \leq 0,138 \\ 0,01 \cdot c^{0,5} & \text{if } c > 0,138 \end{cases}$$

Where c is the assigned value expressed as mass fraction, $c > 1 \mu\text{g/kg}$.

Note: (*) In some cases, QUATEST 3 could apply other appropriate method to determine the assigned value and the standard deviation for proficiency assessment. The statistical design will be stated clearly in the final report.



5.2.2. Evaluation

Base on z (z-score) or z' (z'-score):

$$z = \frac{x_i - X}{\sigma}$$
$$z' = \frac{x_i - X}{\sqrt{\sigma^2 + u_x^2}}$$

Where:

- x_i : The result of laboratory i
- X : The assigned value
- σ : Standard deviation for proficiency assessment
- u_x : The standard measurement uncertainty of assigned value.

Evaluation of z and z':

- ▶ $|z|; |z'| \leq 2.0$: Test result is "Satisfactory".
- ▶ $2.0 < |z|; |z'| < 3.0$: Test result is "Questionable". Participants should find out the cause of suspected results. If a laboratory attended two consecutive rounds with the same characteristics and have z-score in the range $2.0 < |z| < 3.0$, that laboratory should also consider for corrective action.
- ▶ $|z|; |z'| \geq 3.0$: Test result is "Unsatisfactory". Participants should consider for corrective action (if necessary).

5.3. Measurement interlaboratory comparison program

The results of interlaboratory comparison are evaluated through the standardized ratio E_n and E_n is calculated as follows:

$$E_n = \frac{x_i - X_{REF}}{\sqrt{U_{LAB,i}^2 + U_{REF}^2}}$$

Where:

- x_i : Result/ correction of participant i;
- X_{REF} : Assigned value (Result of the reference lab);
- $U_{LAB,i}$: The expanded measurement uncertainty of x_i ;
- U_{REF} : The expanded measurement uncertainty of X_{REF} .

Evaluation:

- $|E_n| \leq 1,0$: Satisfactory;
- $|E_n| > 1,0$: Unsatisfactory.

If $|E_n| > 1,0$: Participants must find out the root cause for necessary corrective or preventive actions.

6. ADDITIONAL INFORMATION AND HOW TO REGISTER

6.1. Regular PT programs

QUATEST 3 now usually organizes PT programs in following areas:

- ▶ Milk and milk product: microbiological and chemical characteristics (nutritions)
- ▶ Other food: microbiological and chemical characteristics (nutritions, antibiotics residues, toxins, heavy metals, etc.)
- ▶ Fertilizers: chemical characteristics (compositions, macro and micro-nutrients, heavy metals, etc)
- ▶ Feeding stuffs: chemical characteristics (nutritions, antibiotics, toxins, heavy metals, etc.)
- ▶ Cement, diesel oil, lubricant, steel, etc.: chemical and physical characteristics.

Beside, QUATEST 3 also provide customized PT programs.

6.2. How to register

6.2.1. Search for information

Laboratories that have demand of PT programs can find information by:

- ▶ Contact directly to PT Dept. – QUATEST 3 (Please see section 1.3 for detail)
- ▶ Website of QUATEST 3;
- ▶ Invitation letter from QUATEST 3;
- ▶ Information from authorities (such as Department of Crop Production, Department of Food and Safety, etc.)

6.2.2. Registration

- ▶ Participant can get Registration forms by following method:
 - ▶ Downloading from website of QUATEST 3,
 - ▶ Being enclosed with invitation letters,
 - ▶ Sending request to QUATEST 3.
- ▶ Return Registration forms to PT provider through email, fax or by post.
- ▶ It is required that there is stamp of your company on the form
- ▶ Deadline of registration: Depending on each program.
- ▶ Base on Registration forms, QUATEST 3 will make list of participants.

Note:

- ▶ Subcontractors that are used to check homogeneity and stability are allowed to participate in the PT programs of QUATEST 3 in case that the assigned value is determined from participants' results.
- ▶ Within 2 working days since sending registration forms, participants will receive confirmation from PT provider. If not, please contact us by phone.

6.2.3. Fee

Fee of PT program vary depending on each program and be announced in the website or in the invitation letter at the beginning.

Participants are requested to make payment since receiving the PT test items till before the issuance of final report.

6.2.4. Requirements for participants

Participants are requested to read the following items and regulations carefully before registering each PT program provided by QUATEST 3.

- ▶ Participants must provide exact contact information and contact person in registration forms. PT provider will only contact that person. If there are any changes in contact persons, please inform to PT provider in writing (email or fax) with your company stamp.
- ▶ In case that participants would like to change or cancel the PT program:
 - ▶ To change delivery address after the PT sample(s) have been delivered: it will be charged at full shipping fee;
 - ▶ To cancel registration after deadline but the PT sample(s) have not been delivered: it will be charged at 20 % of the total fee/program;
 - ▶ To cancel registration after the PT sample(s) have been delivered: it will be charged at 50 % of the total fee/program.
- ▶ Participants must commit to prevent dishonest results, avoiding collusion and falsification of results. If PT provider discover any dishonest results, collusion and falsification of results, those results will be removed.
- ▶ If there is any change in final reports after sending to participants, PT provider will have notifications in writing. Otherwise, PT provider does not take responsibility for any other difference from original final reports.

6.3. Use of PT results

The participating laboratories have to see the results received from the PT program as basic source of information that show the quality and capacity of laboratories. All results in one final report (assigned value, standard deviation for proficiency testing assessment ...) are only valuable for that program and just for reference for any other cases.

Where results of one laboratory are not consistent and compatible with the results of reference or with other laboratories, that laboratory should investigate the cause and appropriate corrective action, timely.

If there are any questions about PT results or need technical consultation, participants can contact PT provider by contact information in the final report.