Royal for Quality System [RQS]

Protocol for Medical Proficiency testing Schemes

Version 1, Nov 2019

Contents

1. INTRODUCTION

1.1. RQS

- Royal for Quality system is foundation [Private sector] and not part of any organization. Established on 2017 to provide PT Provider in Egypt and related area in Arab country.
- **Services provided by RQS**
  - PT Scheme according to ISO/IEC 17043:2010
  - Conducting public workshops and seminars related to Total Quality Management (TQM)

1.2. Accreditation

- **RQS is a EGAC accredited proficiency testing provider No.717002A**
- **Accreditation Scope:** The Formal schedule of the accreditation can be obtained from EGAC website after complete the process of accreditation OR from RQS Web-site.

2. Organization of PT Scheme

External quality assessment (EQA) programs, such as **RQS® – (MED) EQAs**, are valuable tools for clinical laboratories to assess the performance of their test systems in a variety of different clinical examinations.

Program cycles extend for a predefined period of one year with samples typically tested every 3 month. Your laboratory receives a report for each sample that provides you with an individual performance analysis of your submitted results.

For quantitative programs, statistical processes from ISO 13528, "Statistical methods for use in proficiency testing by inter-laboratory comparisons," are used to calculate a robust estimate of the consensus mean and standard deviation, which are used to assess acceptable performance.

At the end of each program cycle, each participating laboratory is provided a report that summarizes overall performance in the cycle and provides statistics for each batch.

2.1. Administration

- All PT Scheme provided by RQS are administrated in keeping with international agreed principles in particular those set out within IUPAC international Harmonized protocol for proficiency test as well as technical and management requirement of ISO/IEC 17043-2010.

- RQS Maintain Advice committee which meets at least once a year or when necessary .the advice committee member's comment upon the relevant programme of PT planned by RQS and discus any scientific issues. Advice committee member are available to advice RQS staff at any point during the year.

2.2. Confidentiality

- All information held by RQS about participants. Including z-score, is confidential and will not be disclosed to anyone unless explicitly agreed by the participant for a particular purpose. To preserve this confidentiality participants receive reports giving all the result all the results for that pt but without identifying individual laboratories. The laboratory code numbers used in report are assigned in order of receipt of results from participants. Participants will be assigned the same code number in different pts only by chance.
- To avoid any conflict of interest /breach of confidentiality, if any of various analytical testing teams elsewhere within RQS wished to participate in a PT they will be treated in exactly the same manner as any other participant. They will not have access to details of any other participants.
- All PT report issued by RQS are copyright RQS. Anyone wishing to use data from within RQS reports for their own publication should first seek permission from RQS.

2.3. Typical Timetable

(1) RQS provide on-going PT scheme, where test material are distributed on a regular basis every year. The Scheme is planned in the form of annual cycle for each sample consists of number of sub-samples dispatched in a regular frequency every 3 months.

(2) **Participants are required to complete the whole annual cycle to get the final evaluation.**

(3) For ease of planning and timetabling, RQS advertiser the on-going scheme every year.

(4) The outline process of conducting a single proficiency test as flows:

- Preparation test material including homogeneity testing.
- Dispatch of scheduled test material on the advertised date from RQS.
- Participate analyses test material and report results by given date. Generally, the closing date is 2-3 weeks from the dispatch date; through for certain analysis where the analyte/matrix combinations potentially are unstable a much shorter timescale may be set.
- Your laboratory receives a report for each sample that provides you with an individual performance analysis of your submitted results after each sub sample.
- At the end of each program cycle, each participating laboratory is provided a report that summarizes overall performance in the cycle and provides statistics for each batch.

2.4 Management system

- The quality management system for RQS is accredited by EGAC according to the requirement of ISO/IEC 17043-2010.

2.5 Subcontractors

- RQS subcontract different laboratory to determine homogeny and stability study.
- RQS maintains a list of approved subcontracting laboratory and regularly reviews the service received.

2.6 Agents

- No agents for RQS until now.

3. Participation in Scheme

3.1 Test material Preparation and Homogeneity

- Test material are prepared by RQS according to own working instruction WI-RQS-01. The homogeneity and stability testing done by subcontracted laboratory.

3.2 Dispatch and Receipt test Material

- RQS test material sent either by private car Door to door service or courier where time limitation are imposed. such time limitation usually arise when an analyte /matrix combination is temperature sensitive or stable for only limited period of times.

3.3 Analysis of Test Material

- It is responsibility of participant to read the instruction provided hard copy or electronically and follow them exactly to conducting the actual analysis of test material. RQS cannot be held responsible for any problems arising from failure to comply with these instructions.

3.4 Follow Up Services

- After a PT has been completed and values for analyte concentrations assigned ,suplus PT Materials may be available to purchase for use as quality control (QC) materials or reference material (RM). These materials are not certified reference materials (CRM).
- RQS test materials may be the only source of a suitable quality control material.
- If a participant wishes to obtain advice on any aspect of their performance, they should contact RQS by email [RQS_PT@yahoo.com / fouadeltahan@yahoo.co.uk].

4. Performance Assessment

- The statistical model used by RQS is set fully within both the International Harmonized protocol & ISO 13528, Statistical methods for use in proficiency testing for Inter laboratory comparison.
- For limited number of participants RQS statistical model is set according to ISO13528/2015: cases for a limited number of participants.

- RQS –PT is to check the accuracy of results submitted by the participant laboratories. This check is achieved typically by comparing participants' results to some estimate of the true value.
- If the results submitted are quantitative then this comparison will be in the form of numerical score.
- The comparison for qualitative results will be against the answer anticipated by formulation or by taking account of the consensus of participants' results.

5. Customer Complaint Procedure

If there is a concern with any aspect of your participation in the EQAS Program [Concerns related to the program, results submitted, reports] you are encouraged to contact RQS through one of the following means so that immediate action can be taken.

6. Detailed information for the application on the PT rounds:

- **Phone: +201002226326**
- **E-mail**: fouadeltahan@yahoo.co.uk**,** RQS_pt@yahoo.com
- **Web-site**: WWW.RQS.ORG.
- **Direct contact with RQS manager**: **Dr. Fouad EL-Tahan_** *GIZA-Harm-El matbaa –Omar Abd El Aziz street -Cairo building No.8 -101*

REFERENCES

1- Heisterkamp S.H., Hoekstra J.A., van Strijp-Lockefeer N.G.W.M., Havelaar A.H., Mooijman K.A., in ’t Veld P.H. and Notermans S.H.W. (1993).

2- Statistical analysis of certification trials for microbiological reference materials. EUR 15008 EN. Commission of European Communities, Community Bureau of Reference, Brussels, Luxembourg.

3- RQS® , 2010, Protocol for Proficiency Testing Schemes, Part Common Principles, Revision 2010, Issued October 2010.

4- RQS® , 2010, Protocol for Proficiency Testing Schemes, Part Food Chemistry PT schemes, Revision 2010, Issued October 2010.

5- Thompson, M., Ellison, S.L.R., and Wood, R., 2006, The International Harmonised Protocol for the Proficiency Testing of Analytical Chemistry Laboratories, Pure Applied Chemistry, 78(1), 145-196.

6- BS ISO 13528:2015, Statistical methods for use in proficiency testing by inter-laboratory comparisons.

7- Fearn, T. And Thomposon, M., 2001, A New Test for Sufficient Homogeneity, Analyst, 126, 1414-1417.

8- ISO/IEC 17043:2010,Conformity assessment-General requirments for proficiency test.

Participant

Organization Name:

Title:

Date:

Signature:

RQS Reprehensive: Prof. Fouad El Tahan

Title: **General Manager of RQS**

Date: **April 2019**

Signature:

End of Protocol for Proficiency testing Schemes

RQS_pt@yahoo.com