

Royal for Quality System [RQS]

Protocol for Proficiency testing Schemes

Version 2, SEP 2026

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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 17043:2023
  - Conducting public workshops and seminars related to Total Quality Management (TQM)

1.2. Accreditation

- **RQS is a Seeking accredited proficiency testing provider from accredited bodies**
- **Accreditation Scope:** The Formal schedule of the accreditation can be obtained from accredited bodies website after complete the process of accreditation OR from RQS Web-site.

2. Organization of PT Scheme

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 17043-2023.

- RQS Maintain Advice committee which meet at least once a year or when necessary .the advice committee members 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

- RQS provide on-going PT scheme, where test material are distributed on a regular basis every year. RQS will add new activity bespoke closed PT scheme where the test materials are distributed at the time and request of a commissioning client.
- For ease of planning and timetabling, RQS advertiser the on-going scheme every 4 month.
- The outline process of conducting a single proficiency test as flows:
- Preparation test material including homogeneity testing.
- Dispatch of test material on the advertised date from RQS.
- RQS notify Participant within 2 days before sending PT items by Phone or Massage
    - Actions to be taken in the case of lost or damaged or unsuitable PT items:
    - In case of lose or damage of sample during transportation or in case of unsuitability of the PT items due to in-homogeneity, in-stability or contamination, the RQS shall compensate the participant with a new PT sample in the next scheme.
    - In case of damage of samples due miss handling participant (or not handling the sample as prescribed by RQS), Not compensation from RQS side.
- 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.
- Results subjected to stastical analysis by RQS.

- Distribution of final report to all participants. Generally the report issue within 15-21 days from closing date.

2.4 Management system

- The quality management system for RQS is accredited by EGAC according to the requirement of ISO/IEC 17043-2023.

2.5 Subcontractors

- RQS subcontract different laboratory to determine assigned value as well as 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.

2.7 Bespoke schemes

- There is possibility of producing bespoke PT schemes for customers for which the schedule PTs does not properly fulfill their purpose. Customers requiring a bespoke service should bear in mind the statistical and economic advantages of including as many participants as possible in a PT.

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 [https://pt-rqs-provider.de / 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 ISO13528/2022: 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.
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4.1 Criteria for Determining Assigned Value and Evaluation of Performance

1. **General Policy for Assigned Value** - per WI-RQS-02 Section 4 & Appendix 3,4,5,7 and ISO 13528:2022

Assigned value is derived from:

(a) **Consensus of participants** per Appendix 3 & Appendix 5 IN WI-RQS-02 [median / robust mean with MAD = 1.4826 × median|x_i - median| and kernel density h = 0.75σ_pt per ISO 13528:2022 6.5 & WI-RQS-02 Appendix 3, and limited number mean after IQR per IUPAC/CITAC 2010 Ex. B4] OR

(b) **Certified value of CRM** per WI-RQS-02 Appendix 7 IN WI-RQS-02 Model 1 and Section 4: x_pt = x_CRM per IUPAC/CITAC Guide 2010 Ex. B1/B2 and ISO 13528:2022 7.2.

An independent reference value obtained from accredited / reputable laboratory is analyzed in parallel and used solely for verification of metrological compatibility per ISO 13528:2022 Clause 7.8: Compatibility criterion $|x_{pt} - x_{ref}| / \sqrt{(u_{pt}^2 + u_{ref}^2)} \leq 2.0$. It is NOT used as the assigned value. If compatibility fails, the consensus is rejected and the round is cancelled / repeated, no expert lab value is used as replacement.

Consensus Values from Participants: Yes

Certified Reference Value and/or Reference Values: Yes

Consensus Values from Expert Laboratories: No (except for verification only per ISO 13528:2022 7.8)

2. **Quantitative Chemistry (Food & Feed, Water, Soil, Fertilizers, Pesticides, Petroleum Chemistry, Physical Tests, Paints, Plastic, Textiles Quantitative, Detergent, Environmental Air)**

Scenario - per number of participants	Assigned Value x_pt - per Scope	Uncertainty u(x_pt) and Sigma σ_pt - per WI-RQS-02 App3/5	Reference
General (N≥10)	1- Consensus of participants - General: median / robust mean with MAD = 1.4826 × median|x_i - median| and kernel density h=0.75σ_pt per ISO 13528:2022 & WI-RQS-02 Appendix 3	u(x_pt)=1.25×MAD/√n per WI-RQS-02 Appendix 3. Check u(x_pt) ≤0.3σ_pt per ISO 13528:2022 7.7.4. σ_pt = from precision experiment R/2.77 per 8.5, or prescribed fitness per 8.2, or general model Horwitz per 8.4 Eq.8, or European guide EEC	ISO 13528:2022 Cl.7.7, WI-RQS-02 App 3

Scenario - per number of participants	Assigned Value x_pt - per Scope	Uncertainty u(x_pt) and Sigma σ_pt - per WI-RQS-02 App3/5	Reference
		315/93 expanded/2 per WI-RQS-02 Section 4	
Limited number (Np<30, N<10 after removal)*	2- Consensus of participants - Limited number: mean after IQR outlier removal per Appendix 5 per IUPAC/CITAC Guide 2010 Ex. B4. Q1=25th, Q3=75th, IQR=Q3-Q1, Limits=Q1±1.5×IQR	u(x_pt)= s/√n of remaining OR u_cert = s × √[(Np-N)/(Np×N)]** per WI-RQS-02 App5 Ex B4. Example 4. If N*<10 or u>0.3σ_pt cancel round per Appendix 6. σ_pt = Horwitz σ_R=0.02c^0.8495 per 8.4 or European guide: σ=expanded uncertainty/2	IUPAC/CITAC 2010 Ex B4, WI-RQS-02 App5,
CRM / Reference material	3- Certified value of CRM: x_pt = x_CRM per IUPAC/CITAC Guide 2010 Ex. B1/B2 per WI-RQS-02 Section 4	u(x_pt)= u_CRM from certificate per ISO 17034. σ_pt not from participants - from Horwitz or method reproducibility R/2.77	ISO 13528:2022 Cl.7.2, WI-RQS-02 Sec4
Independent verification (all schemes)	Independent reference value from accredited lab analyzed in parallel, used solely for verification per ISO 13528:2022 Cl.7.8: $\|x_pt - x_ref\| \leq 2\sqrt{(u_pt^2+u_ref^2)}$. NOT used as assigned value.	If compatibility fails, consensus rejected and round cancelled/repeated per RFQ Table 11 and WI-RQS-02 App 4.0	ISO 13528:2022 Cl.7.8, WI-RQS-02 App4

3. Food / Water Microbiology - Qualitative and Quantitative

Sub-discipline	Assigned Value	Evaluation	Sigma
Food/Feed (Qualitative): Salmonella spp, Listeria spp, Vibrio spp, Staph aureus, Coliform, E.coli, Yeast/Mold, Bacillus cereus, Campylobacter, Clostridium perfringens, Enterobacteriaceae, Shigella, Hepatitis A, Norovirus, Enterococcus faecalis, E.coli O157, GMO 35s/Nos, Yersinia, Cronobacter	Qualitative Microbiology - Assigned value per WI-RQS-02 & ISO 13528:2022 Cl.8: x_pt = expected result [Present/Absent or Identity] from reference culture / spiked strain or modal value of participants.	Performance assessed as Correct/Incorrect / False positive/False negative. No z-score.	NA - Qualitative
Food/Feed (Quantitative): Staph aureus, Coliform, Listeria, E.coli, Yeast/Mold, APC, Bacillus cereus, Clostridium, Enterobacteriaceae, aerobic spore forming, Enterococcus, Sulfite reducing, Thermophilic, Lactic acid bacteria	Quantitative Microbiology - Assigned value per WI-RQS-02: x_pt = median / robust mean per IUPAC 2006.	z-score on log10: z=(log10 x - log10 x_pt)/σ_pt	σ _pt=R/2.77 where R from ISO 4833-1:2013/Amd1:2022 / ISO 16266 / ISO 11731 etc. Limited number: IUPAC/CITAC 2010 Ex. B4
Water (Qualitative): E.coli, faecal coliforms, total coliforms, Pseudomonas, Legionella, Salmonella spp, yeast/mold	Same as Food qualitative: expected result from reference culture / spiked strain per WI-RQS-02 & ISO 13528 Cl.8	Correct/Incorrect, FP/FN	NA
Water (Quantitative): E.coli, faecal coliforms, total coliforms, faecal streptococci, plate count 35C/22C, TPC 28C, Pseudomonas, sulphite reducing anaerobes, Legionella, Shigella, yeast/mold, C.perfringens	Same as Food quantitative: median / robust mean	z-score log10	R/2.77

4. Pharmaceuticals Microbiology and Biological Assays

Sub-discipline	Assigned Value	Evaluation	Sigma & Reference
Solid and Liquid Pharma (Micro): Sterility Test, Somatic cell count, APC, Bacterial Endotoxin, Potency Gentamycin biological assay, Mycoplasma, etc.	Qualitative: x_pt = expected result [Present/Absent, Sterile/Non-sterile, Detected/Not detected, Identity] from reference strain / spiked sample / reference culture per Ph.Eur. 2.6.1 Sterility, 2.6.7 Mycoplasma per WI-RQS-02 & ISO 13528 Cl.8 Quantitative / Biological Assay: x_pt = median / robust mean per IUPAC 2006 on log10 transformed counts where applicable per WI-RQS-02 Appendix 6 & ISO 13528 Cl.7	Qualitative: Correct/Incorrect, FP/FN. No z-score Quantitative: z-score	σ_pt=R/2.77 where R from ISO 4833-1 plate count, ISO 21527 yeast/mould, ISO 13366 somatic cell count, Ph.Eur. 2.6.14 / USP <85> Endotoxin, Ph.Eur. 2.7.8 / USP <81> antibiotic potency, Ph.Eur. 2.6.12 bile-tolerant GNB. u_xpt=1.25×MAD/√n. Limited per IUPAC/CITAC 2010 Ex.B4 after >2s removal.
Serum, Vaccine, Virology: ND virus, FMD antibody, Virus titre tissue culture/egg, Sheep/goat pox, Brucella, Rift valley fever, Equine Influenza, BVD, AI, IB, IBD, Avian Leucosis, etc.	Qualitative: x_pt = expected result [Present/Absent, Identity, Genotype] from reference strain / spiked material / reference standard or modal value per WI-RQS-02 & ISO 13528 Cl.8. Performance = Correct/Incorrect, FP/FN. No z-score Quantitative Biological: x_pt = robust mean / median of log10 transformed titres / potencies / % per IUPAC 2006	Qualitative: Correct/Incorrect Quantitative: z-score	σ_pt=R/2.77 where R from OIE Terrestrial Manual / Ph.Eur. 2.7.5, 2.7.24, 2.7.27, 5.2.7 / OECD TG 473,487 or from method validation reproducibility. u_xpt=1.25×MAD/√n. Limited per IUPAC/CITAC 2010 Ex.B4. Data >2s from median removed.
DNA Extract Pharma: WSSV, DNA/RNA integrity Gel	Qualitative Molecular: x_pt = expected result [Detected/Not detected,	Qualitative: Correct/Incorrect, FP/FN, No z-score	σ_pt=R/2.77 where R from ISO 20395:2019 for nucleic acid

electrophoresis, Nucleic acid quantification, fertility genes, Whole Genome Sequence	Intact/Degraded, Genotype/Haplotype, Identity] from reference material / reference sequence / spiked extract or modal value per OIE Manual Crustacean Ch.2.2.5 for WSSV, ISO 20395, ISO 20813 per WI-RQS-02 & ISO 13528 Cl.8 Quantitative Molecular: x_pt = median / robust mean per IUPAC 2006	Quantitative: z-score	quantification / method validation reproducibility. u_xpt=1.25×MAD/√n. Limited per IUPAC/CITAC 2010 Ex.B4. If CRM available x_pt=x_CRM
Plant Pathology DNA Extract: F. oxysporum, Monilinia, Phytophthora, Phytoplasma, TYLCV, Cercospora, Sporisorium, Phoma, Ralstonia, Fusarium solani, Rhizoctonia, Pythium, etc. + Potato viruses PVY, PVX, PLRV	Qualitative Molecular: x_pt = expected result [Detected/Not detected, Present/Absent, Identity to species level, Sequence/Genotype] from reference strain / reference sequence / spiked DNA extract or modal value per EPPO PM 7/21, PM 7/128, PM 7/40 for viruses, IPPC ISPM 27 per WI-RQS-02 & ISO 13528 Cl.8	Correct/Incorrect, FP/FN, Identity correct/incorrect. No z-score, No σ_pt	NA - Qualitative per RFQ Table 23

5. Textiles and Petroleum Ordinal / Qualitative Ratings

Sub-discipline	Assigned Value	Evaluation
Textiles: Colour Fastness to Crocking, Thickness, Mass per unit area, Breaking Force, Formaldehyde, pH, Fiber Analysis, Perspiration, Saliva, Washing, Dry Cleaning, Hot Pressing, Flammability, Absorbency, Azo, Metals, Phthalates, etc.	Quantitative: same as chemistry general (median/robust mean) Qualitative/Ordinal: x_pt = modal value / median grade [1-5 Grey Scale] for Colour Fastness per ISO 105 series [X12 Crocking, E04 Perspiration, E03 Water, C06 Washing, D01 Dry cleaning, X11 Hot pressing, 105-E12 Saliva] or expected result [Present/Absent, Identity] for Fiber Analysis per ISO 1833 etc. per WI-RQS-02 & ISO 13528 Cl.8 & Cl.10.3	Quantitative: z-score |z|≤2 Satisfactory per WI-RQS-02 Qualitative: Correct/Incorrect or grade comparison
Petroleum Chemistry & Physical: pH, Reserve Alkalinity, Total	Quantitative: same as chemistry general	Quantitative: z-score Qualitative: Correct grade /

Sulfur, Salts, Water content, Ash, Volatile matter, Viscosity, Flash point, Density, Distillation, Copper corrosion, Foaming, ASTM Color, etc.	Ordinal/Qualitative Rating: x_pt = mode / median grade of participant results or reference grade from CRM / reference library. Applicable to Colour Fastness 1-5 Grey Scale, Copper Corrosion 1a-4c per ASTM D130, ASTM Colour 0.5-8.0 per D1500, Foaming per ASTM D892 per RFQ Table 29	Incorrect

6. Performance Evaluation Criteria

Type - per ISO 13528	Statistic - per ISO 13528	Criteria - per ISO 13528
Quantitative Chemistry, Physical, Textiles Quantitative, Environmental	z-score: $Z = (x - X)/\sigma_pt$ per WI-RQS-02 Sec 4.3.1	$\|z\| \leq 2$ Satisfactory, $2 < \|z\| < 3$ Warning, $\|z\| \geq 3$ Action per WI-RQS-02 4.3.3. Single action or warnings in 2 successive rounds = anomaly
Quantitative with u(x_pt) not negligible per Appendix 2	z-prime per ISO 13528 9.3: $z' = (x - x_pt)/\sqrt{(\sigma_pt^2 + u(x_pt)^2)}$ if $u > 0.3\sigma_pt$ per 7.7.4	Same criteria using z'
EQA Medical PT Schemes per WI-RQS-02 Sec 4.4	z-score per Annex 4,5,6. Corrected: Z score value per ISO 13528 9.1, percentile rank optional for information only - not per ISO 13528	Final cycle satisfactory if all 4 sub cycles satisfactory per WI-RQS-02 Sec 4.4
Qualitative / Ordinal / Molecular per RFQ	Correct/Incorrect, FP/FN, Identity	Correct=Satisfactory, Incorrect=Unsatisfactory. No z-score, No σ_pt

4.2 Measurement Uncertainty Reporting and Use per-7.2.2.3.g

Per WI-RQS-02, QP-PR-05, F-RQS-01, F-QA-32, F-RQS-02, F-RQS-08, F-RQS-03:
Participants shall report expanded measurement uncertainty U with coverage factor k and coverage probability per ISO/IEC 17043:2023 7.1.2.1 and F-RQS-02 Instruction: 'Record Results with measurement uncertainty (expanded U, k, coverage probability), recovery, LOQ per ISO 17043:2023, method details'.

Use of participant MU:

1) Primary evaluation via z-score independent of participant U: $z = (x - x_pt)/\sigma_pt$

2) If $u(x_pt) > 0.3\ \sigma_pt$, use z-prime: $z' = (x - x_pt)/\sqrt{(\sigma_pt^2 + u(x_pt)^2)}$ per Appendix 2
3) Optional En score for information: $En = (x - x_pt)/\sqrt{(U_lab^2 + U_ref^2)}$ where U_ref = expanded uncertainty of assigned value. En evaluated as $|En| \leq 1$ satisfactory.
4) For EQA schemes, $bias\% = (x - x_pt)/x_pt \times 100$ calculated per final report parameters.
Reporting MU required per result form, otherwise result considered incomplete. Documented in F-RQS-08 and F-RQS-03 clause i) participant results including MU.

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

- **Phone: +201002226326**
- **E-mail**: fouadeltahan@yahoo.co.uk**,** RQS_pt@yahoo.com
- **Web-site**: https://pt-rqs-provider.de.
- **Direct contact with RQS manager**: **Dr. Fouad EL-Tahan**_ *GIZA-Harm-El matbaa –Omar Abd El Aziz street -Cairo building No.8 -101*

REFERENCES

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Participant

Organization Name:

Title:

Date:

Signature:

RQS Reprehensive: Prof. Fouad El Tahan

Title: **General Manager of RQS**

Date:

Signature:



End of Protocol for Proficiency testing Schemes

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