



## Participant Instructions

### Q.2. WEEK 19: 04 & 05 MAY 2026 PT ROUND

#### Purpose

To provide detailed instructions for participants in compliance with the requirements of ISO/IEC 17043:2023, including participant instructions, scheme communication, impartiality, confidentiality, handling of complaints and appeals, and control of data and information management.

#### ISO/IEC 17043 Participant Information

This document forms part of the official instructions for participants in the JGK proficiency testing (PT) scheme(s) listed below. Participants shall follow these instructions and their routine laboratory procedures (SOPs) unless explicitly stated otherwise. Any scheme-specific updates (e.g., changes to timelines, reporting fields, or safety information) will be communicated by JGK via the official PT dispatch communication for the relevant round.

#### 1. Confidentiality and use of PT data

Participant identities and individual results are treated as confidential by JGK and are used for PT evaluation and scheme improvement. PT reports will present participant results using participant codes in a manner that does not disclose participant identity, except where disclosure is required by law/regulation or with the participant's authorization. Participants shall treat PT items and any pre-release PT information provided by JGK as controlled information and shall not share results with other participants prior to the closing date.

#### 2. Impartiality and technical integrity

To ensure an impartial evaluation, participants must test independently and must not discuss results with other participants before the closing date. If any testing is outsourced (in whole or in part) to an external laboratory or subcontractor, this must be declared on the result entry form (R.E.F) in the comments section, including the subcontractor's name and (where applicable) accreditation status.

#### 3. Participant responsibilities

- On receipt, check package condition, verify item identification codes, and store PT items as specified.
- Use routine methods and routine staff, equipment, calibrations, media, and quality controls as used for patient/field samples, unless otherwise specified.
- Record all results and observations contemporaneously, including deviations, issues, and corrective actions (if any).
- Submit complete results by the stated deadline using the supplied R.E.F. Late or incomplete submissions may be excluded from evaluation.
- Retain raw data, calculations, instrument printouts/screenshots, and QC evidence related to the PT for the period required by your laboratory's management system and/or regulator (minimum: until the final PT report is issued).

#### 4. Data and information management

Participants shall ensure PT data integrity and traceability by retaining original records and calculations, clearly identifying any transcriptions into the R.E.F, and authorizing results prior to submission. If corrections are required, the participant shall request the correction from JGK and provide an auditable explanation of the change. JGK will control result changes and will confirm whether the corrected result will be included in the evaluation (subject to the closing date). PT results and associated records shall be stored securely to prevent unauthorized access or alteration.

#### 5. Nonconforming work and PT item issues

If PT items are received damaged, compromised, out of temperature, or otherwise unsuitable, or if the participant becomes aware of a significant deviation from these instructions or routine procedure that could affect results, the participant shall inform JGK promptly with details. JGK will advise on whether replacement items are available and/or how the issue will be handled in the evaluation and report.

#### 6. Communication, enquiries, complaints, and appeals

Questions about the PT items or instructions should be directed to JGK as early as possible (before testing, where feasible). Complaints relating to the operation of the PT scheme should be submitted in writing to JGK with the scheme reference and participant code. Appeals relating to the evaluation outcome should be submitted in writing with supporting evidence. JGK will acknowledge receipt and will manage complaints and appeals in accordance with its documented processes, including communication of the outcome to the participant.

#### 7. Schedule and reporting

- **Receipt and storage:** Store PT items immediately on receipt as indicated in the scheme table.
- **Testing:** Perform testing within the timeframe indicated for each scheme and as soon as practicable after reconstitution (where applicable).
- **Result submission deadline:** **Wednesday, 26 May 2026** (unless otherwise communicated by JGK).
- **PT report:** A final PT report will be issued after the closing date and completion of statistical evaluation.

#### 8. Evaluation of results

JGK will evaluate participant performance using the scheme design and statistical methods described in the PT report (e.g., assigned value determination, standard deviation for proficiency, and performance scoring/ratings as applicable). Where qualitative outcomes are required (e.g., positive/negative categories), performance will be assessed against the expected outcome for each item. Participants will be informed in the report of any exclusions (e.g., late results, invalid units, missing fields) and the reasons for exclusion.

#### 9. Participant checklist before submission of results

- PT items received intact; labels and identification codes verified and recorded.
- Storage conditions met (temperature range and timeframe) and any excursions recorded.
- Testing performed using routine method/SOP and routine QC; deviations documented.
- All required fields completed in the R.E.F (method, units, replicate results, qualitative categories as applicable).
- Results reviewed and authorized internally before submission.
- R.E.F submitted by the closing date; a copy of the submitted file and supporting raw data retained.

**Table 1: Scheme-specific participant information**

Information	JGKPT01 – AST (Clinical Pathogens)	JGKPT03 – Brucella Ab (RBT only)	JGKPT04 – Brucella Ab (RBT & CFT)	JGKPT05 – Brucella Ab (MRT)	JGKPT06 – Brucella Culture & ID	JGKPT35-38 – <i>T. foetus</i> & <i>C.</i> <i>foetus</i>
<b>Sample type and identification</b>	ATB01/C–ATB02/C Clindamycin 2 µg x 6 discs; Oxoid Erythromycin 30 µg x 6 discs; Oxoid Cefpodoxime 10 µg x 6 discs; Oxoid	RBT01 – RBT06	RBT/CFT01 – RBT/CFT06	MRT01 – MRT04	CAC01 – CAC03	SW01 – SW05
<b>Sample format</b>	Freeze-dried / Commercial discs	Freeze-dried	Freeze-dried	Liquid	Freeze-dried	Broth
<b>Sample volume</b>	ATB01/C: 0.5 ml ATB02/C: 0.8 ml	RBT01: 1 ml RBT02: 0.3 ml RBT03: 0.5 ml RBT04: 0.5 ml RBT05: 1 ml RBT06: 0.3 ml	RBT/CFT01: 1 ml RBT/CFT02: 0.5 ml RBT/CFT03: 0.5 ml RBT/CFT04: 0.5 ml RBT/CFT05: 1 ml RBT/CFT06: 0.5 ml	MRT01: 4 ml MRT02: 4 ml MRT03: 4 ml MRT04: 4 ml	CAC01: 0.8 ml CAC02: 0.8 ml CAC03: 0.8 ml	SW01: 3 ml SW02: 3 ml SW03: 3 ml SW04: 3 ml SW05: 3 ml
<b>Storage on receipt</b>	2 – 8 °C	2 – 8 °C	2 – 8 °C	2 – 8 °C	2 – 8 °C	2 – 8 °C
<b>Sample reconstitution</b> (see volume above)	Diluent to use: <b>Normal saline</b> (sterile)	Diluent to be used: sterile distilled/ de- ionized water	Diluent to be used: sterile distilled/ de- ionized water	N/A	Diluent to use: <b>Normal saline</b> (sterile)	N/A
<b>Required testing timeframe</b>	Start within 24 h of receipt	Immediately after reconstitution	Immediately after reconstitution	Immediately upon receipt	Immediately after reconstitution	Immediately upon receipt
<b>Approved test methods</b>	Lab-validated Disc diffusion technique (Kirby-Bauer)	Lab-validated Rose Bengal Test	Lab-validated Complement Fixation Test	Lab-validated Milk Ring Test	Lab-validated Conventional or Molecular agent ID technique	Lab-validated Conventional or Molecular agent ID technique
<b>Test replicates per sample</b>	3 results per drug- organism AST	1 result per sample	2 results per sample	1 result per sample	1 result per sample	1 result per sample
<b>Unit of measurement for results</b>	Zone Ø in mm. AST categorical interpretation: Sensitive (S) / Intermediate (I) / Resistance (R)	Categorical: Positive (+, ++, +++ ) / Negative	Quantitative: CFT IU/ml. Scale: use 50% haemolysis (++) at 1/220 serum dilution as equivalent to 1000 IU/ml.	Categorical: Positive (weak, strong) / Negative	Categorical: Detected / Not detected  Brucella strain: Field / Vaccine	Categorical: Presence / Absence of <i>T. foetus</i> / <i>C. fetus</i>
<b>Result entry form to use</b>	R.E.F 01-02 – Rev. 24 / 01 Feb, 2026	R.E.F 03 – Rev. 23 / 01 Feb, 2026	R.E.F 04 – Rev. 23 / 01 Feb, 2026	R.E.F 05 – Rev. 23 / 01 Feb, 2026	R.E.F 06 – Rev. 23 / 01 Feb, 2026	R.E.F 35-38 – Rev. 23 / 01 Feb, 2026

## 10. Additional Information

### 10.1 Treatment of proficiency test items

PT items shall not receive special treatment. PT items shall be handled, tested, and reported in the same manner as routine samples normally processed by the laboratory, unless explicitly stated otherwise in these instructions.

### 10.2 Handling, biosafety, and waste management

Laboratories shall apply their routine biosafety, decontamination, and waste-management procedures when handling PT items. Work surfaces shall be disinfected using suitable disinfectants, and laboratory utensils, unused materials, and waste shall be treated and disposed of in accordance with the laboratory's approved standard operating procedures.

### **10.3 Specific testing environment requirements**

For JGKPT06 (**Brucella culture**), all handling and testing activities shall be conducted in a Class II biological safety cabinet (or higher).

### **10.4 Recording of results**

Participants shall use only the applicable Excel PT R.E.Fs supplied by JGK to record and submit results. All requested information shall be completed accurately, including method details, units of measurement, and comments on any deviations or issues encountered. Results shall be reported exactly as generated by the laboratory's routine method, without additional rounding beyond normal reporting practice.

### **10.5 Submission and follow-up**

Completed R.E.Fs shall be submitted in accordance with the closing date and time communicated in the relevant Dispatch Notice. Results submitted after the closing date may be excluded from evaluation. Any errors identified after submission shall be communicated to JGK immediately; corrections are accepted only up to the stated closing date and time.

### **10.6 Enquiries and correspondence**

All correspondence with JGK shall clearly reference the applicable scheme code, PT item identification, and participant code. Contact details are provided in the Dispatch Notice.

### **10.7 Return of PT items**

Return of PT items is not required.