ISO 15189:2022-aligned method verification plan template

Clinical microbiology | All Things Microbiology

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Laboratory adaptation status: Draft - requires local review and approval.

How to use this template

This original working template is aligned to ISO 15189:2022 for medical laboratories. It does not reproduce the standard, confer ISO approval or establish accreditation. Check your controlled copy of the standard and applicable regulator or accreditation-body guidance. Non-medical, food or environmental testing may require a different framework, such as ISO/IEC 17025 and applicable ISO 16140 guidance; assess that scope separately.

Type in the blank cells in the Word version. Print the PDF for a paper working copy. Duplicate study-design, acceptance-criteria and result tables for every applicable characteristic, method and specimen or organism group. Retain enough blank rows for the complete record and link to controlled raw data where a separate study workbook is used.

Complete and approve the plan before study testing. Define the intended use, clinical risks, study size and method-specific acceptance criteria locally. Sample counts, acceptance limits, allowed errors and confidence requirements are deliberately blank; there is no universal sample number or pass threshold in this template.

Use this plan for an unmodified, established method within its intended scope. Laboratory-developed, modified or out-of-scope methods require an appropriate validation programme. Select applicable studies and record a reason for each characteristic marked not applicable.

Use coded specimens and isolates in study records. Keep patient identifiers in the laboratory's approved records system. Completing the template does not authorise clinical use: an authorised person must review the evidence and approve the supported scope.

1. Document control and responsibilities

Complete the laboratory entries and maintain this plan as a controlled record.

Field	Laboratory entry
Laboratory / department / site	
Document ID / version / effective date	
Method / examination name	
Manufacturer / platform / software version / IFU revision	
SOP ID / version	
Planned study dates	
Study lead / technical reviewer / authorising person	
Raw-data location / retention period	
Change history / superseded plan	

Approval table:

Role	Name	Approval / signature	Date	Comments / conditions
Prepared by				
Technical / quality review				
Plan authorised before testing				

2. Intended use, scope, and verification-or-validation decision

Scope field	Laboratory entry
Clinical purpose and decisions supported	
Method type: culture / identification / AST / qualitative NAAT / quantitative examination / other	
Analytes / organisms / organism groups / antimicrobial agents	
Specimen types / matrices / transport and storage conditions	
Patient population / setting / inclusion and exclusion scope	
Reported result, units, interpretation / clinical decision limits	
Claimed range / detection capability / relevant manufacturer claims	
Local operators, equipment, environment, workflow	
Scope exclusions and limitations	

Record the scope decision before approving the study.

Decision question	Yes / No / N/A	Evidence and implications
Is this an established, previously validated method used without modification?		
Are all local specimens, populations, intended uses and conditions within its established scope?		
Are documented performance claims available and suitable for the laboratory’s intended use?		

Decision question	Yes / No / N/A	Evidence and implications
Is the method laboratory-developed, modified, or being used outside its established scope?		
Are any unresolved scope or performance questions present?		

Route selected: [ ] Verification of an unmodified established method within its scope [ ] Validation required [ ] Technical review needed before proceeding.

Decision rationale / authoriser / date: _____

For laboratory-developed, modified, or out-of-scope methods, complete an appropriate validation plan before clinical implementation. This verification template does not establish the full validation programme. Do not treat a change of specimen matrix, extraction method, algorithm, threshold, or intended use as automatically covered by a manufacturer’s original validation.

3. Prerequisites and clinical risk review

Prerequisite	Evidence reference	Ready / Not ready / N/A	Gap, owner and due date
Controlled instructions and method SOP			
Equipment qualification, maintenance and relevant calibration			
Staff training / competency / authorisation			
Reagent, medium, control and reference-material suitability			
Comparator suitability and independent evidence			
Biosafety, contamination prevention and waste procedures			
Specimen suitability, consent / ethical arrangements where applicable			
Result calculation, reporting and LIMS interface checks			
QC and validity rules for study runs			

Risk table:

Failure mode / affected result	Potential clinical harm	Likelihood / impact and rationale	Study element / control that addresses the risk	Residual risk / reviewer

Failure mode / affected result	Potential clinical harm	Likelihood / impact and rationale	Study element / control that addresses the risk	Residual risk / reviewer

Risk prompts include missed pathogen, false-positive contamination, misidentification, incorrect susceptibility category, near-threshold classification, quantitative bias, invalid results, delays and transcription errors. Use the laboratory's documented risk scale and rationale.

4. Performance characteristics to verify

Do not force every characteristic onto every method. Require an applicable/not-applicable decision with a rationale.

Characteristic	Applicable / N/A and rationale	Source of claim or requirement	Planned study ID
Agreement with suitable comparator / reference			
Repeatability / reproducibility appropriate to the result type			
Detection / recovery capability or relevant analytical sensitivity			
Specificity / selectivity / cross-reactivity where relevant			
Reportable range / linearity / quantitation where relevant			
Bias / trueness where relevant and reference suitable			
Interference / carry-over / contamination where relevant			
Specimen stability / handling conditions where relevant			

Characteristic	Applicable / N/A and rationale	Source of claim or requirement	Planned study ID
Invalid, indeterminate, no-identification or no-result handling			
Turnaround / reporting / interpretive rules where relevant			
Measurement uncertainty evaluation or relevant information, where applicable			

For a qualitative result, assess repeatability or result consistency as appropriate; do not require a numerical CV. For a quantitative method, plan suitable precision/bias/range studies and assess measurement uncertainty where applicable. A laboratory should explain any claimed characteristic that it will not test locally and identify the evidence supporting that decision.

5. Study design and justified sample sizes

Repeat the following table for each study ID. Keep the study design separate from its results.

Design field	Laboratory entry
Study ID / characteristic / objective	
Intended clinical claim being verified	
Specimen / isolate / reference material sources	
Independent samples / isolates planned, by required category or stratum	
Replicates / runs / days / operators / instruments / reagent lots	
Challenge groups: positives, negatives, low-level or near-cut-off material, relevant organisms / resistance phenotypes	

Design field	Laboratory entry
Inclusion / exclusion criteria and handling of unsuitable samples	
Comparator / reference method, qualification and limitations	
Pairing, masking, order of testing and independent interpretation	
Handling / storage / freeze-thaw conditions	
Statistical approach, denominator, confidence interval method if used	
Sample size rationale: clinical risk, desired certainty, performance claim, available guidance and feasibility	
Limits of the design / additional evidence or work needed	
Data form / raw record references	

A specimen-stratum table is useful:

Group / matrix / organism or antimicrobial	Independent samples planned	Replicates per sample	Selection rationale / source	Clinical risk addressed

The study must distinguish independent patient samples / isolates from technical replicates. Repeated testing of one isolate does not create additional independent clinical samples. Include clinically important uncommon groups and near-decision-limit material when relevant. A convenience panel alone may not support the proposed scope; record any coverage limits. Control material may support precision or detection studies but does not automatically establish patient-sample agreement.

6. Pre-agreed acceptance criteria and decision rules

This table is completed and approved before testing. Values are deliberately blank.

Study ID / characteristic / group	Metric and exact denominator	Acceptance limit / allowed error	Source / rationale	Confidence or uncertainty requirement, if applicable	Decision / escalation rule

Rule to define before testing	Laboratory entry
Run validity / QC failure rule	
Invalid / indeterminate / no-result handling and reporting	
Repeats and allowed reason for repeat testing	
Discordance investigation / independent resolution process	
Predetermined exclusion rule and excluded-result reporting	
Criteria for an inconclusive study / insufficient evidence	
Handling of failed criteria and required additional work	
Control of plan amendments: reason, approval, date and impact	

Retain original results when repeats or discrepancy investigations occur. Report original paired agreement separately from resolved findings; do not replace an unfavourable pair with a resolved result or remove it without a documented pre-agreed reason. Changing criteria after seeing results requires a controlled amendment and transparent justification, rather than a retrospective pass threshold.

7. Method-specific planning prompts

Use only the applicable row(s); these are prompts, not mandatory numerical thresholds.

Method	What to specify in the plan
Culture / organism recovery	Specimen matrices, media and atmosphere, incubation conditions, target and non-target organisms, mixed growth where relevant, recovery/identity endpoints, clinically important low-level challenges, comparator limitations, and interpretation/reporting rules.
Identification	Claimed taxonomic/reporting level, representative species or groups, difficult/near-neighbour organisms, database/software version, correct identification versus misidentification versus no-identification, and an appropriate independent reference for discordance.
AST	Organism–antimicrobial combinations, reference method, local specimen/organism scope, applicable CLSI or EUCAST document and edition, breakpoint/version and category definitions, QC rules, quantitative MIC or zone results where relevant, categorical agreement and relevant error definitions/denominators.
Qualitative NAAT	Target(s), specimen matrices, extraction and internal controls, positive/negative agreement with a suitable comparator, low-level detection near the claimed limit, repeatability, inhibitors, cross-reactivity and contamination/carry-over where relevant, invalid/indeterminate outcomes, and cut-off interpretation.
Quantitative examination	Measurand and units, traceability/reference material, relevant range and decision levels, repeatability/intermediate precision, bias or suitable comparison, range/linearity and quantitation claims where applicable, interference/carry-over, uncertainty and reporting.

AST details to include only if relevant:

AST metric / rule	Exact local definition and denominator / approved criterion
Essential agreement for MIC results	
Categorical agreement	
Very major error / false-susceptible result: numerator and reference-resistant denominator	

AST metric / rule	Exact local definition and denominator / approved criterion
Major error / false-resistant result: numerator and reference-susceptible denominator	
Other category discrepancies and applicable treatment of intermediate / increased-exposure categories	
Treatment of off-scale MICs, technical uncertainty and unreportable combinations	
Organism–drug-specific and overall summaries, including sparse denominators	

AST is not one homogeneous pooled claim. Report organism–drug groups and clinically important resistance categories where appropriate. A percentage with few reference-resistant isolates can conceal serious uncertainty; show the counts. CLSI and EUCAST category definitions cannot be mixed. EUCAST “I” means susceptible, increased exposure; it should not be casually relabelled as a generic intermediate category. State the chosen version because breakpoints change. Do not apply essential agreement to disc zone diameters as if they were MIC dilution results.

For NAAT and other qualitative comparisons, use positive / negative percentage agreement when the comparator is not a sufficiently established clinical reference. Do not rename comparator agreement as diagnostic sensitivity or specificity without a suitable clinical reference standard and study design. Cycle-threshold precision alone does not establish qualitative detection performance.

8. Execution record, deviations, and analysis

Raw-data record (repeat rows as needed):

Coded sample / isolate ID and group	Date / run / operator	Lot / instrument	Candidate original result	Comparator original result	QC / validity	Repeat / resolution reference	Deviation / comment

Separate disagreement/deviation record:

Record ID / original finding	Investigation / evidence	Resolution and clinical significance	Corrective action / owner / due date	Closure / reviewer

Results summary:

Study ID / characteristic / group	Planned / tested / excluded counts and reasons	Estimate / count / uncertainty or CI if specified	Approved criterion	Met / Not met / Inconclusive	Evidence reference / reviewer

Show invalid, indeterminate, no-identification and no-result counts separately with their denominators. Do not silently remove these from an agreement analysis. Keep traceable coded IDs; do not put identifiable patient information in publicly shared template copies.

9. Technical conclusion and authorisation for intended use

Review field	Laboratory entry
Verified claims and supported scope	
Failed / inconclusive claims, limitations and unresolved questions	
Deviations and their effect on interpretation	
Additional study / corrective action required	
Clinical risk review and any scope restrictions	
SOP / reporting / training / QC changes needed	
Overall decision: verified within stated scope / not verified / inconclusive	
Authorised clinical scope and exclusions, if authorised	
Implementation date / responsible person	

Review and release table:

Role	Name	Decision / signature	Date	Conditions / evidence references
Technical review				
Quality review				
Authorisation for stated intended use				

A completed form is not itself clinical authorisation. The authorised person must review the evidence and decide whether the defined scope is supported. Failed or unresolved criteria cannot be hidden behind a generic “pass”.

10. Implementation, ongoing assurance and change review

Implementation / monitoring item	Requirement / evidence	Owner	Due / review date	Status
Controlled SOP and interpretation / reporting rules				
Staff competency and authorisation				
QC plan and action rules				
EQA / interlaboratory comparison or suitable alternative, where applicable				
LIMS result mapping, calculations, flags and audit trail				
Reagent / medium / control lot acceptance arrangements				
Review of invalids, discordance and clinically important errors				
Planned review and triggers for re-verification / validation assessment				

Change triggers should include changes in method, intended use, specimen type, instrument, critical software/database/algorithm, significant reagent changes, clinical decision limits or AST breakpoints, relocation/conditions, and persistent QC/EQA or performance concerns. Assess the effect of a change and document the needed work; not every lot change automatically requires a complete new method verification.

11. References and local guidance

Keep the laboratory's applicable editions controlled rather than assuming a universal numeric acceptance criterion.

Reference / controlled edition	Relevant use / location
ISO 15189:2022 — Medical laboratories — Requirements for quality and competence	Primary alignment; verification, validation and validity of results. Official catalogue: https://www.iso.org/standard/76677.html
Manufacturer IFU / performance claims / revision	
Laboratory SOP / verification policy / risk policy	
Applicable national regulator / accreditation body guidance	
Applicable CLSI / EUCAST method, QC and breakpoint documents and editions	
ISO 20776 series, if applicable to AST study design	
Applicable method-specific verification / statistics guidance	