FIND

# VERIFICATION & VALIDATION

Olga Ordeig and Michelle Zaharik

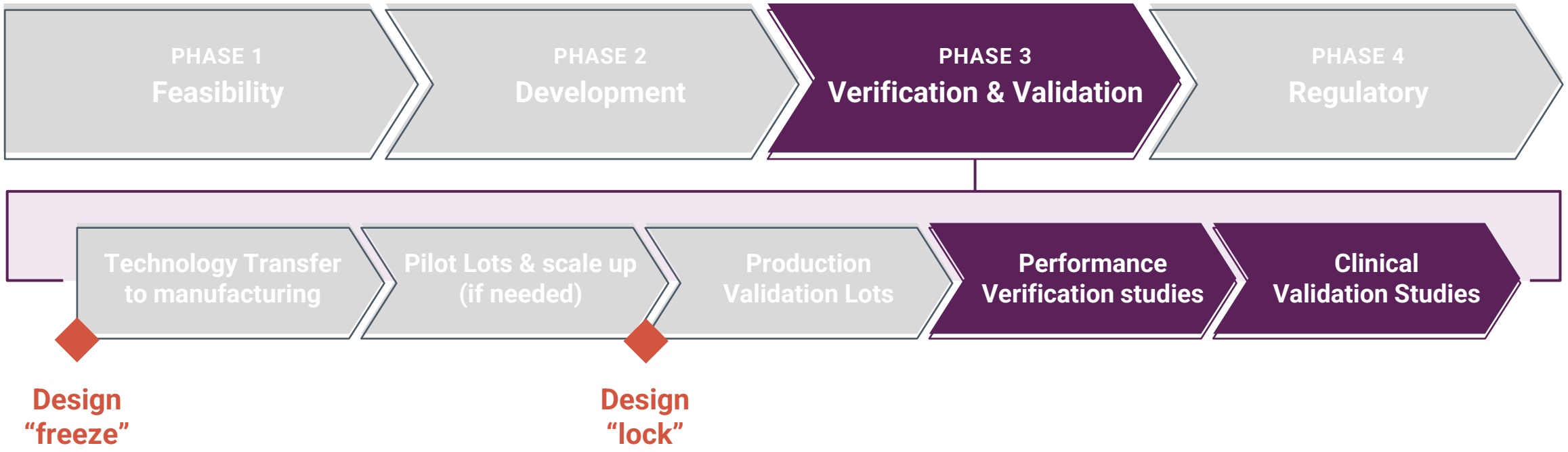
# TOPICS

1. Verification vs Validation studies
2. Verification:
   - Analytical Performance Testing – the use of standards and guidelines
   - Test stability and storage conditions
3. Move from Verification to Validation
4. Validation:
   - Design Clinical Performance evaluations
   - Do’s and Don’ts

# PRODUCT DEVELOPMENT: VERIFICATION AND VALIDATION PHASE

## Verification and Validation phase:

It is initiated with the technology transfer from R&D to manufacturing. Once the performance of the test is confirmed in the manufacturer's hands, the design is locked ("design lock") and validation lots are produced. The final Performance Verificati on and Clinical Validation studies are done in strict compliance with applicable regulatory requirements.



# VERIFICATION VS VALIDATION

## VERIFICATION
### Analytical Performance & other Evidences

**Ensures that the IVD test is built correctly and meets its design specifications.**

**Some common type of experiments conducted during IVD verification are:**

- Analytical Performance Testing (e.g. LoD, precision, linear range)
- Test stability and storage conditions
- Cross-reactivity studies
- Interference testing
- Specificity and Selectivity
- Instrument Performance Testing

## VALIDATION
### Clinical Performance

**Assesses whether the IVD test meets its intended purpose in real-world condition.**

**Some common type of experiments conducted during validation are:**

- Clinical accuracy testing
- Clinical Sensitivity and Specificity studies
- Clinical Precision and Reproducibility
- Clinical correlation studies
- Sample matrix studies

# VERIFICATION

# VERIFICATION – ANALYTICAL PERFORMANCE PLANNING

| | |
|---|---|
| **Performance Parameters** | Clearly define the parameters to be assessed. |
| **Reference Materials and Controls** | Specify the reference materials and controls to be used in the testing. |
| **Sample Types** | Define the samples types that will be used in the testing. |
| **Experimental Design** | Outline the experimental design. |
| **Testing Procedures** | Provide step-by-step instruction for conducing the tests. |
| **Data Analysis** | Describe the methods for data analysis, including statistical approaches. |

## REMEMBER

Follow Standards and Guidelines.

**If ANY design change has occurred, RE-VERIFY!**

## IMPORTANT

When more than one lot is required, each lot must be of different productions containing different lots of critical reagents

# CLSI GUIDELINES

The **Clinical and Laboratory Standards Institute** (CLSI) provides consensus-based guidelines and standards for clinical and laboratory testing procedures.

**ALWAYS CHECK**

Product regulatory requirements, as different regions may have specific standards and guidelines to be followed.

- CLSI guidelines relevant for IVD:
  - **EP05:** Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition
  - **EP06:** Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition
  - **EP07:** Interference Testing in Clinical Chemistry, 3rd Edition
  - **EP09:** Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition
  - **EP12:** Evaluation of Qualitative, Binary Output Examination Performance, 3rd Edition
  - **EP17:** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition
  - **EP25:** Evaluation of Stability of In Vitro Medical Laboratory Test Reagents, 2nd Edition
  - **EP35:** Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 1st Edition
  - **EP37:** Supplemental Tables for Interference Testing in Clinical Chemistry, 1st Edition

# TECHNICAL GUIDANCE SERIES

World Health Organization | Prequalification of Medical Products
IVDs, Medicines, Vaccines and Immunization Devices, Vector Control

The WHO's **Technical Guidance Series (TGS)** provides detailed technical guidance for the regulation, quality, safety, and performance of medical devices and in-vitro diagnostics (IVDs)

- List of TGS Documents:
  - **TGS 1:** Standards applicable to the WHO Prequalification of in vitro diagnostic medical devices
  - **TGS 2**: Establishing stability of in vitro diagnostic medical devices
  - **TGS 3:** Principles of performance studies
  - **TGS 4:** Test method validation for in vitro diagnostic medical devices
  - **TGS 5:** Designing instructions for use for in vitro diagnostic medical devices
  - **TGS 6:** Panels for quality assurance and quality control of in vitro diagnostic medical devices
  - **TGS 7:** Risk management for manufacturers of in vitro diagnostic medical devices
  - **TGS 8:** Quality control for in vitro diagnostic medical devices for WHO prequalification

# TECHNICAL SPECIFICATIONS SERIES

World Health Organization | Prequalification of Medical Products
IVDs, Medicines, Vaccines and Immunization Devices, Vector Control

The WHO **Technical Specification Series (TSS)** set out the performance evaluation criteria for meeting prequalification requirements.

Each TSS document is tailored to a specific pathogen/type of assay

A total of 23 TSS document. A selected list bellow, not completed:

- **TSS 1** - Human immunodeficiency virus (HIV) rapid diagnostic tests for professional and/or self-testing
- **TSS 3 -** Malaria rapid diagnostic test
- **TSS 4 -** In vitro diagnostic medical devices used for the detection of high-risk human papillomavirus (HPV) types in cervical cancer screening
- **TSS 5** - Rapid diagnostic tests used for surveillance and detection of an outbreak of cholera
- **TSS 6** - Syphilis rapid diagnostic tests
- **TSS 10** - In vitro diagnostic medical devices used for the qualitative and quantitative detection of hepatitis C RNA
- **TSS 11 -** In vitro diagnostic medical devices used for the quantitative detection of HIV-1 nucleic acid
- **TSS 12 -** In vitro diagnostic medical devices used for the qualitative detection of HIV-1 and HIV-2 nucleic acid
- **TSS 13 -** Rapid diagnostic tests to detect hepatitis B surface antigen
- **TSS 14 -** Immunoassays to detect hepatitis B virus surface antigen

FIND PHASES GATE SYSTEM

# ANALYTICAL PERFORMANCE TESTING BY PHASE


**Analytical Performance** should be **assessed along** all preceding **product development** phases must be a criteria in each of the gates

**Final Analytical Performance** Studies are done in strict compliance with applicable regulatory requirements

We **RECOMMEND** having well defined SOPs for each of the Analytical Parameters per phase and a pre-approved Analytical Performance Verification Protocol with well-defined acceptance criteria for Verification.

# EXAMPLE

| | Design and Development | | | |
|---|---|---|---|---|
| | **Phase 0 (Concept)** | **Phase 1 (Feasibility)** | **Phase 2 (Development)** | **Phase 3 (Verification and Validation** |
| **Limit of Detection (LoD)**<br>LoD is the lowest amount of a measurand and that can be consistently detected (≥95% of attempts).<br><br>*See also CLSI EP17 for approaches to calculation of LoD* | NR | Blank matrix or NEG specimen + serial dilutions of recombinant or purified native target analyte, n=3 replicates per dilution | Preliminary assessment of LoD. Serial dilution of one quantified POS specimen (or purified native analyte) into one NEG specimen, n=3 replicates per dilution.<br>Confirm LoD with 10-20 replicates: confirm ≥95% detection at LoD and <95% detection at one dilution below LoD on a minimum of 1 lot. | As per CLSI EP17 suggested study design: Minimum of 4 blank matrix or independent NEG specimens and 4 independent low level POS specimens (near LoD determined in Phase 2), minimum of n=2 replicates each over a minimum of three days (on 2-3 lots) to generate at least 60 blank replicates and 60 low level specimen replicates per lot tested. It is up to the developer to modify the number of specimens, replicates, days etc required to meet the minimum 60 replicate results required for analysis.<br>Confirm LoD with 20 replicates on minimum of 2 lots; confirm ≥95% detection at LoD and <95% detection at one dilution below LoD.<br><br>Expectation LoB < LoD; LoD ≤ LoQ |
| **Limit of Quantification (LoQ)**<br>(NA for qualitative methods)<br>LoQ is the lowest amount of a measurand that can be quantitively determined with a stated accuracy (commonly 20% CV).<br><br>*See CLSI EP17 for approaches to calculation of LoQ* | NR | Blank matrix or NEG specimen + serial dilutions of recombinant or purified native target analyte, n=3 replicates per dilution to generate a preliminary estimate of where CVs approach 10-20% | For a classical dilution assessment, serially dilute one quantified POS specimen into one NEG specimen, n=3 replicates per dilution, 1 lot.<br>May use probit or precision profile approach as applicable for the specific assay.<br><br>Expectation: Commonly LoQ is defined as that level where less than 20% CV is obtained. | Four independent low-level samples (near the LoQ determined in Phase 2) with known concentration should be tested in at least three replicates each over a minimum of three days on 2-3 lots.<br>May use probit or precision profile approach as applicable for the specific assay.<br><br>Expectation: Commonly LoQ is defined as that level where less than 20% CV is obtained. |

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**INCREASE COMPLEXITY AND RIGOR OF THE METHOD**

**Increase veracity of the result**

MALARIA LFT EXAMPLE

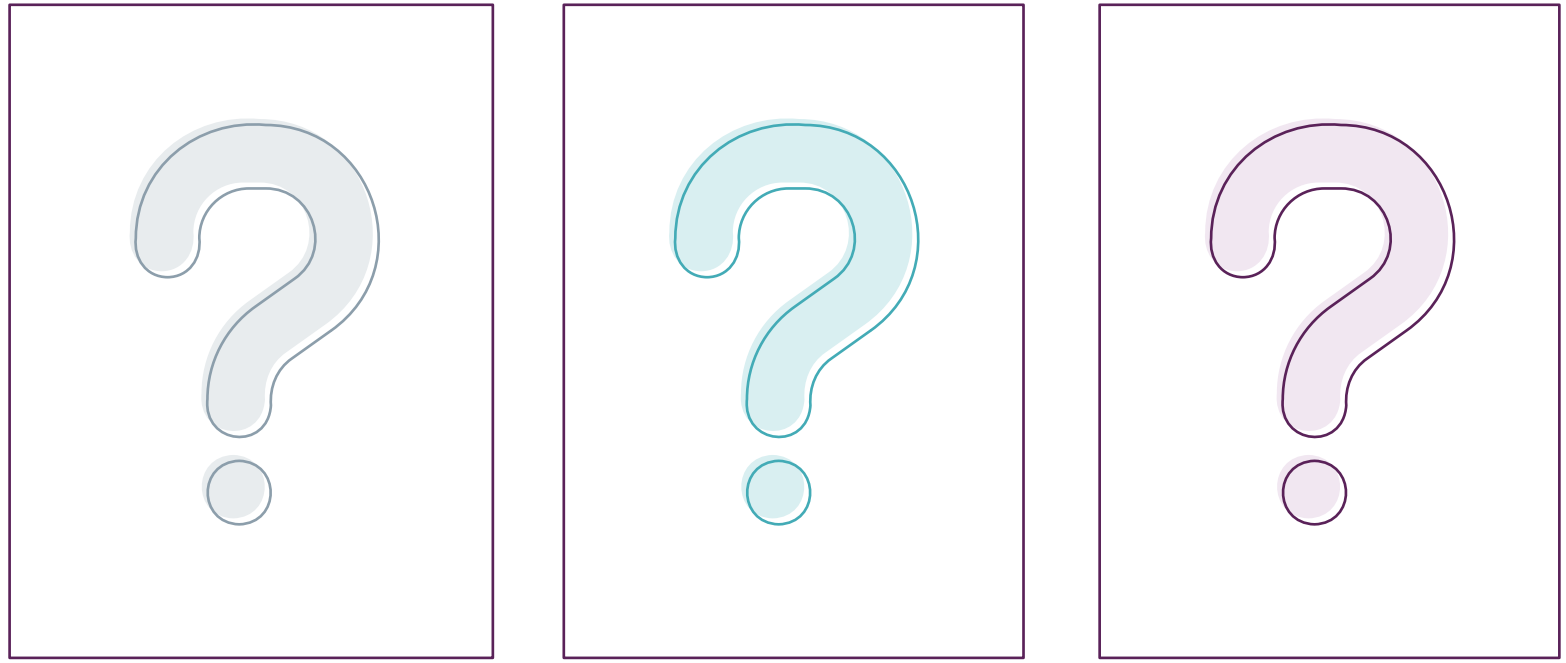
# VERIFICATION: STORAGE STABILITY

FAST MALARIA RAPID TEST
FAST TEST INC.

**Product Requirement Document**

Storage Stability:

- Minimal: ≥ 12 months at 35ºC and 70% RH with transport stress (3 days at 60ºC), no cold chain needed
- Optimal: ≥ 12 months at 45ºC and 90% RH with transport stress (3 days at 60ºC), no cold chain needed



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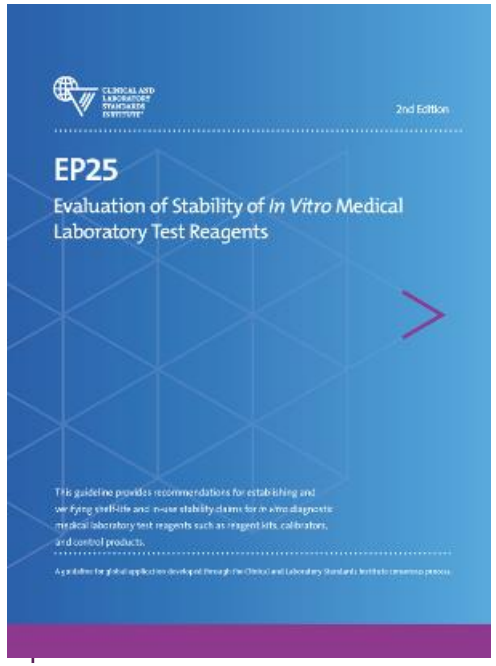
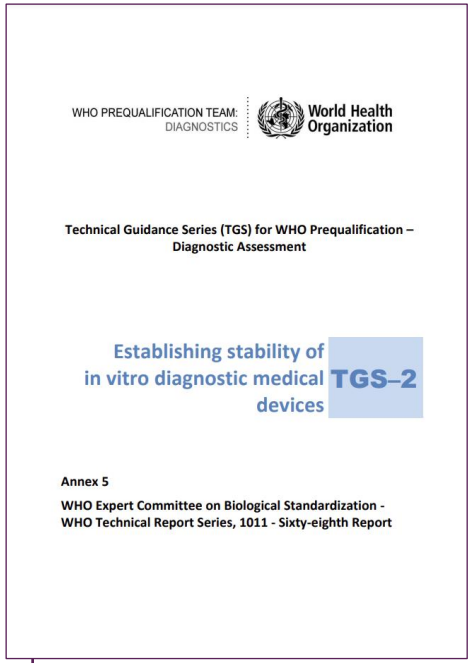
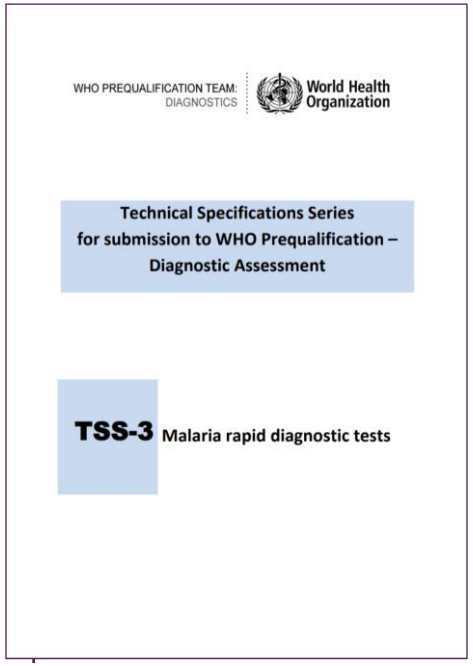



**CLSI EP25** Evaluation of Stability of In Vitro Medical Laboratory Test Reagents



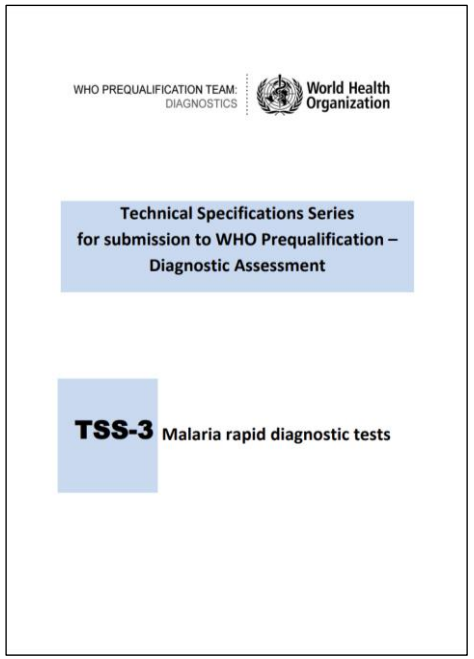

**TGS-2** Establishing stability of in vitro diagnostic medical devices




**TSS-3** Malaria rapid diagnostic test

## MALARIA LFT EXAMPLE

# VERIFICATION: STORAGE STABILITY STUDY OUTLINE




panel

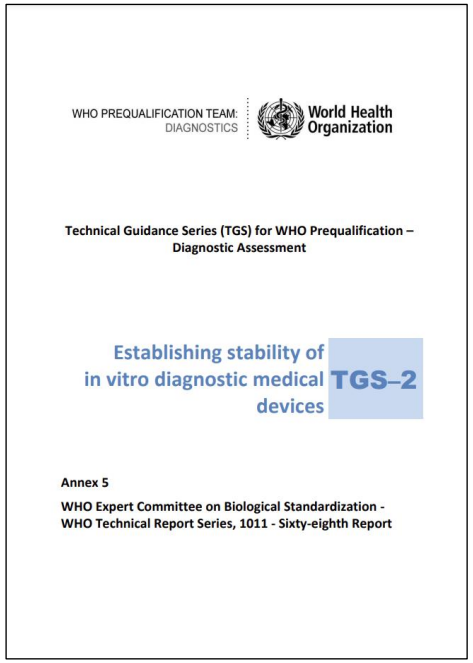
lots

study

| 1.9 Stability | | | |
|---|---|---|---|
| 1.9.1<br>IVD stability | Replicate testing shall be undertaken using a panel consisting, for each claimed analyte, of at least:<br>• 1 analyte non-reactive specimen<br>• 2 low-reactivity specimens near assay cut-off<br>• 1 medium-reactivity specimen.<br>Where possible, specimens chosen for the testing panel shall include panel members that reflect the main specimen types intended for use with the IVD (e.g. capillary whole blood). | 1. The testing panel shall include all claimed antigens (e.g. PfHRP2, pLDH, etc.) and, where 'pan-specific' detection is claimed, address stability in relevant *Plasmodium* species.<br>2. Testing shall include whole blood specimens in accordance with intended use (for example to verify proper flow, no background interference and account for other variables).<br>3. Lots shall comprise different batches of critical components.<br>4. Low-reactivity specimens shall be chosen that are sufficiently close to the assay cut-off as to allow changes in IVD sensitivity to be detected.<br>5. The numbers of invalid tests shall be reported.<br>6. Determination of shipping stability shall be performed using simulated extreme stress conditions, ensuring that application of those conditions is consistent and controlled.<br>7. Claims for stability shall be based on the second-last successful data point from the least stable lot, with, if lots are different, a statistical analysis showing that the bulk of lots will be expected to meet the claimed life. For example: for testing conducted at 3, 6, 9, 12 and 15 months, if stability was observed at 15 months, then the maximum stability claim is 12 months.<br>8. Accelerated studies do not replace the need for real time studies.<br>9. In-use stability of labile components shall be conducted using components in their final configuration. | ISO 23640:2011 (12)<br>CLSI EP25-A (13)<br>Technical Guidance Series for WHO Prequalification – Diagnostic Assessment (14)<br>ASTM D4169-14 (15) |
| 1.9.2<br>Shelf life | • Real time studies using a minimum of 3 lots of final design product<br>• transport stressed (simulated) before real time studies are undertaken<br>• IVD in final packaging also subjected to drop-shock testing. | | |
| 1.9.3<br>In-use stability | • Minimum of 1 lot using panel(s) compiled as above<br>• testing of all labile components (e.g. buffers vials, sealed cartridges, etc.; see Comment 9). | | |

MALARIA LFT EXAMPLE

# VERIFICATION: STORAGE STABILITY STUDY OUTLINE



WHO PREQUALIFICATION TEAM: DIAGNOSTICS

World Health Organization

Technical Guidance Series (TGS) for WHO Prequalification – Diagnostic Assessment

Establishing stability of in vitro diagnostic medical devices TGS–2

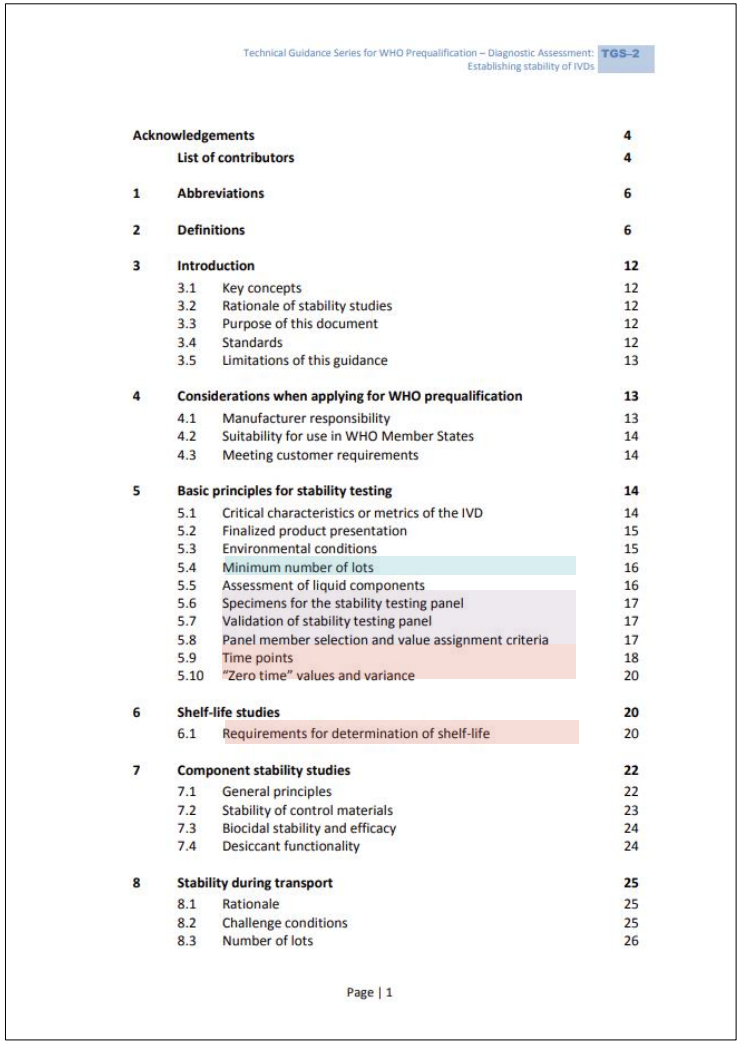
Annex 5

WHO Expert Committee on Biological Standardization - WHO Technical Report Series, 1011 - Sixty-eighth Report

panel

lots

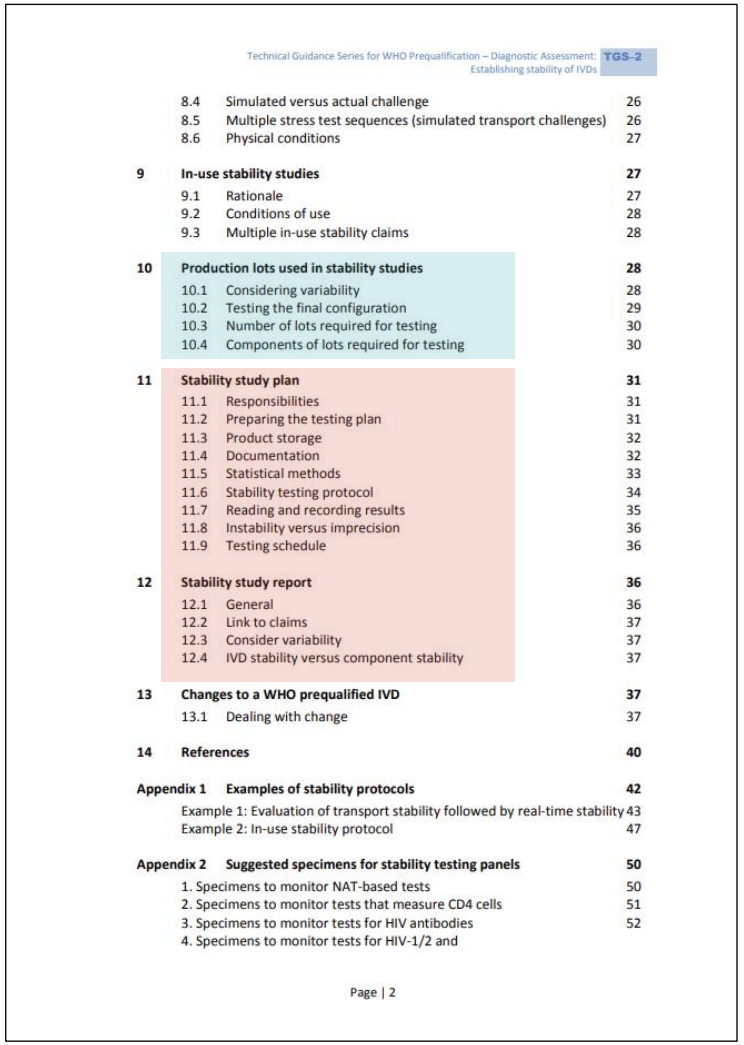
study





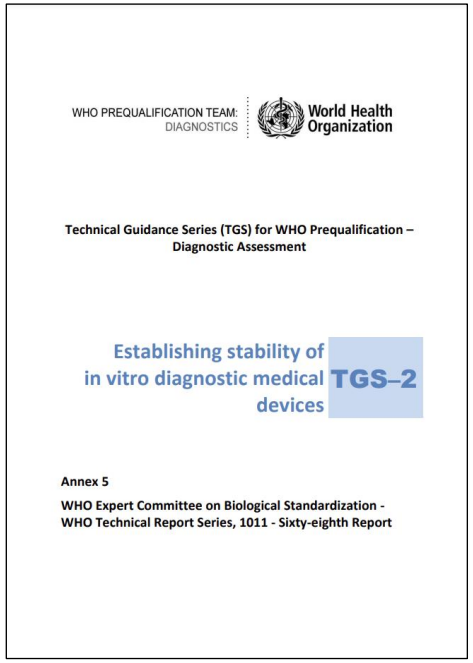






# VERIFICATION: STORAGE STABILITY STUDY OUTLINE

## LOTS



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### 5.4 Minimum number of lots

The design of stability studies must take into consideration lot-to-lot variability, with a risk assessment conducted to identify the most important sources of variability. The degree of variation of individual lots affects the confidence that a future production lot will remain within specification throughout its shelf-life. Lot variability is most often caused by minor differences in the biological reagents rather than by lack of reproducibility of the manufacturing process. Although existing standards *(1, 2)* recommend the use of a single lot for certain stability studies, the impact of lot-to-lot variability must be taken into consideration and the use of additional lots may be necessary. Three lots, at a **minimum**, must be used to establish or verify shelf-life; in-use claims require testing on a **minimum** of one lot. To ensure that the potential for lot-to-lot variability is addressed, independent lots must be used – that is, lots containing different batches of critical constituents such as nitrocellulose membranes, recombinant antigens, peptides, nucleic acids and the enzymes used in nucleic acid test-based (NAT-based) testing technologies.

### 10.2 Testing the final configuration

Shelf-life, in-use and transport stability must be determined for the finalized approved product in terms of:

- manufacturing specifications
- release-to-market QA criteria
- packaging and labelling (see section **10.4**)
- validated manufacturing scale on qualified manufacturing equipment.

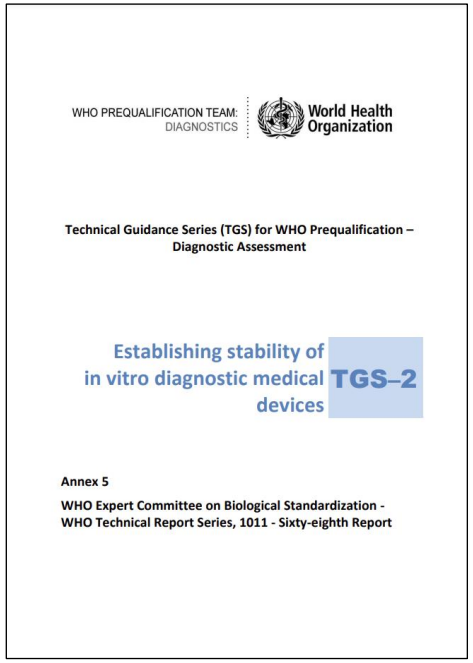
Note 1: For WHO prequalification, it is important that the stability studies have been conducted using the IVD intended to be prequalified, and not surrogates and/or closely related products. Changes perceived as small (for example, change in production scale, bulk container materials, supplier of a critical biological or vial stopper) can have unexpected effects on stability and other performance characteristics. After such changes, a new documented risk assessment and, if necessary, a stability plan and study, is needed. Manufacturers should have change-control procedures in place compliant with ISO 13485 *(15)*.

Note 2: Stability studies undertaken in the R&D phase of the product life-cycle provide an important understanding of how to design the product so that it will meet the final stability requirements identified in the input documentation. However, these studies are usually not sufficient for submission to WHO prequalification assessment since they may not reflect the final design and manufacture of the IVD.

MALARIA LFT EXAMPLE

# VERIFICATION: STORAGE STABILITY STUDY OUTLINE

## TESTING PANEL



WHO PREQUALIFICATION TEAM: DIAGNOSTICS

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### 5.6 Specimens for the stability testing panel[1]

The specimens used in the stability testing panel(s) must reflect the performance claims related to the IVD. The specimen types most likely to be used in those WHO Member States in which the IVD is intended to be used must be considered and, as appropriate, included in the specimen panels used throughout the stability studies (see Appendix 2). If a variety of specimen types (for example, serum, plasma, whole blood and saliva) are claimed as being suitable for use in the IFU, the stability study plan must be designed to provide evidence that the IVD will meet its claims (for example, for sensitivity, specificity, proportion of valid runs and precision) for each of the specimen types for the whole of the claimed shelf-life, including during transport to the final users, unless an alternative approach can be justified using a documented rationale. Evidence must be statistically valid (see section 11.5). Regulatory requirements may also dictate the addition of specified panel members.

### 5.7 Validation of stability testing panel

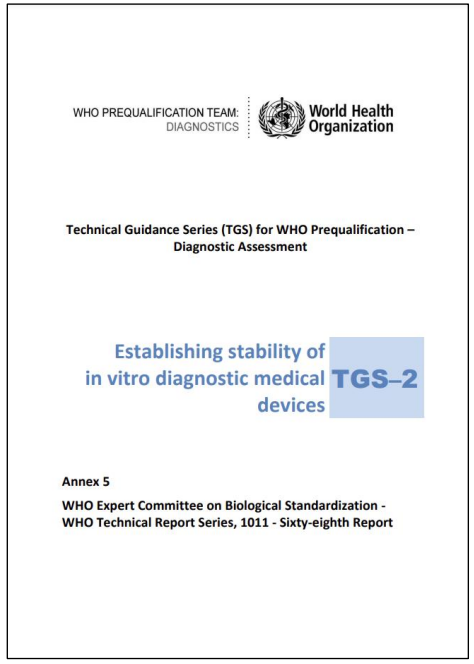
The stability testing panel(s) must be validated, and rejection and replacement criteria must be established. The validation of the panel members used is crucial. Panel members themselves must be stable and they must monitor parameters that are useful in controlling the characteristic being tested.

Storage of a validated panel for testing stability is not always feasible. For example, this is often the case for assays requiring fresh and/or whole blood specimens (for example, assays for counting CD4 cells). When replacing panel members, particularly for CD4 monitoring, the accuracy of results generated using the replacement material must be confirmed using an appropriate reference method (for example an instrument validated for use in an ISO 15189 *(17)* accredited laboratory). Replacement criteria for unstable panel members must include the duration for which a critical member will give valid results.

MALARIA LFT EXAMPLE

# VERIFICATION: STORAGE STABILITY STUDY OUTLINE

## STUDY PLAN AND REPORT



WHO PREQUALIFICATION TEAM: DIAGNOSTICS

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**5.9 Time points**

A more effective and well-established approach routinely used is to test at a number of additional predetermined intermediate time point intervals (between 1 and 2 above). Typically, testing is carried out at relatively short intervals (every 10 or 14 days) for the first 3 months, and then at monthly intervals until at least one month beyond the design input-specified shelf-life. This protocol provides information on whether the IVD ages more rapidly in the period just after manufacture than later on in the shelf-life, and usually provides sufficient data to enable the assignment of a confidence interval to the shelf-life.

The manufacturer could identify the most practical intermediate test points from a risk evaluation of a specific IVD and include them in the stability study plan/protocol. Such planning will also help manufacturers to estimate the resources required to implement the testing.

5.9.1 Duration of testing

Testing conducted in stability studies should extend beyond the shelf-life determined from user needs. At a minimum, testing should extend at least one time point (one testing interval) beyond the predetermined user requirement to provide a margin for uncertainty. The length of the time periods chosen will depend on risk assessment, but should provide a safeguard in the event of unexpected IVD failure during the testing period,

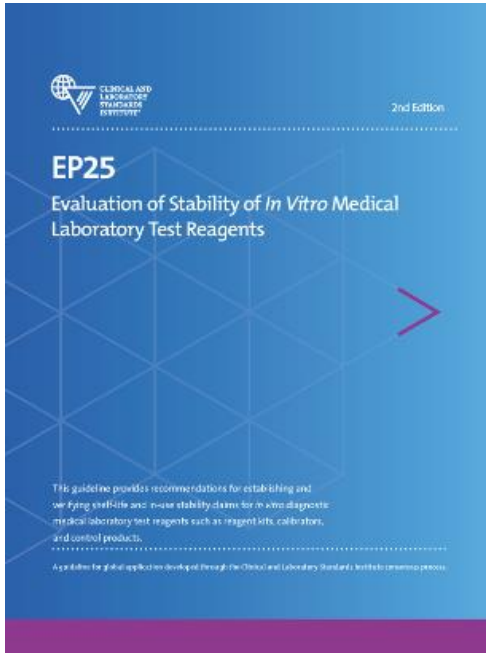
**5.10 "Zero time" values and variance**

The value of each measured characteristic at the beginning of the stability study and its variability over the course of the study are important pieces of information. They should be measured independently for each lot of material in the stability study. Analysis of the data will indicate if a statistically significant change has occurred to any measured parameter from any lot during the course of the study. A statistically significant change may not be of practical significance. Relevant practical limits will have been predetermined in IVD or process development. However, all statistically significant changes must be thoroughly evaluated to decide whether they represent some important change that would otherwise be undetected.

Zero time values could be obtained by evaluating each measured characteristic for each lot on five or more occasions to establish the value and its variance with freshly made materials. A definition of "occasion", following appropriate consideration, could be specified, for example, as involving a different day, a different operator and a different set of equipment in order to investigate potential sources of analytical variation. Later in the study, apparent differences in the values of the characteristics can be detected reliably, relative to the "zero time" value.

MALARIA LFT EXAMPLE

# VERIFICATION: STORAGE STABILITY STUDY OUTLINE




- panel
- lots
- study

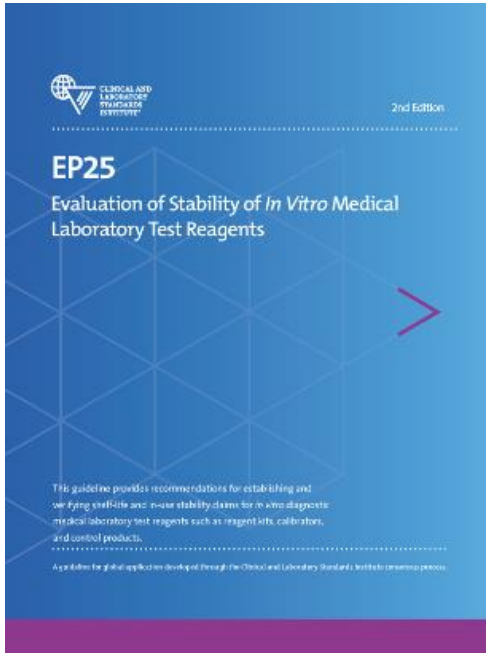
## Contents



## Contents (Continued)

MALARIA LFT EXAMPLE

# VERIFICATION: STORAGE STABILITY STUDY OUTLINE




panel

lots

study

### 3.2.11 Test Schedule

Because regression of the stability time point data is performed to establish claims, it influences how testing should be scheduled. Initiation of the stability study (time zero [$T_0$]) should be as close as possible to the time of product production. The testing duration must cover a time frame approximately 10% to ≥20% beyond the intended claim to provide a margin for uncertainty. For the intended claim, a data point must be collected at $T_N$ as well as at $T_{N+1}$. For example, if the time claim is 12 months, a time point at 12 and 13 or 14 months should be tested. In the absence of other considerations, an absolute minimum of four time points (beginning, middle, end, and end + 10% to 20% beyond the claimed time) are tested. The first three points can be equally spaced across the study duration. However, additional time points are highly recommended to:

- Identify early drift
  - More data points are collected early in the study.
- Support reduced claims
  - To reduce the risk of needing to repeat a study, additional time points near the desired claim should be included, so if the desired stability duration is not achieved, two successive earlier time points that are within the allowable drift limit can be used to report revised claims. For example, if $T_N$ and $T_{N+1}$ is 100% and 110% of the intended shelf-life claim, respectively, and the regression interpolation fails at $T_{N+1}$, then $T_{N-1}$ is the longest claim possible. Therefore, $T_{N-1}$ should be as high as possible if the manufacturer desires to make a longer shelf-life claim.
  - **NOTE:** If it is necessary to revise the intended claims, removing the original point data (eg, $T_N$ and/or $T_{N+1}$) and reanalysis should be avoided unless deviation from linearity can be demonstrated. If the data trend continues to be linear at $T_N$ and $T_{N+1}$, including these time points in the analysis increases the precision of the revised estimate.
- Identify nonlinear behavior to help establish whether there are deviations from the linear drift assumption

Intermediate time points can be reduced or eliminated in subsequent studies as knowledge of the product stability increases.

MALARIA LFT EXAMPLE

# VERIFICATION: STORAGE STABILITY STUDY OUTLINE


Optional: perform informal accelerated and/or real time stability on one lot using one POS and one NEG control

Perform accelerated studies on intermediate prototype, 3 lots, using chosen stability panel. Initiation of real time stability studies optional.

Perform accelerated and real time studies on final “locked” prototype, 3 lots from different critical raw material.

- Stability panel: 1 negative, 2 low positive, 1 medium positive serum sample.
- Transport stress (3 days at 60°C) before time 0 of the real time study.
- Study duration: 12 + 1 months
- Study measurement points: Day: 0, 10, 20, 30, 40, 50, 60, 90 (3 months), Month: 4, 5, 6, 7, 8, 9, 10, 11, 12 and 13.
- Replicas per point: 5
- Study temperature:
  - Real time: 4°C, 35°C at 70% RH
  - Accelerated: 45°C, 55°C


STORAGE STABILITY STUDY

# RECOMENDATIONS

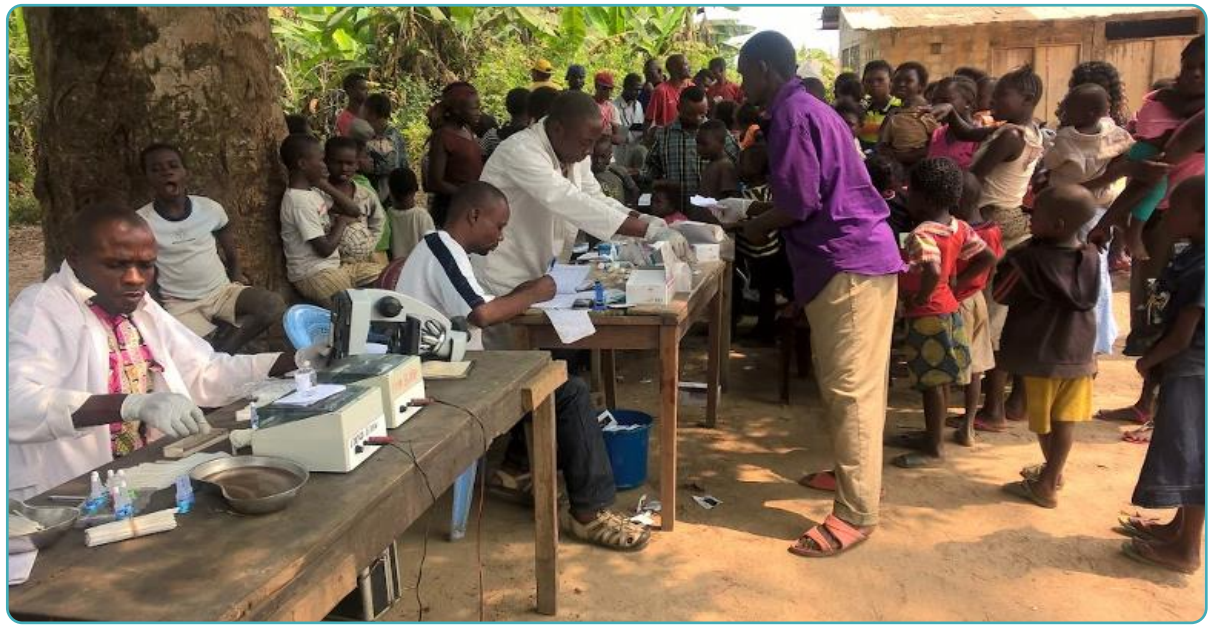
- Ideally stability studies should be performed in-house.
- If stability studies facilities are not available, you will need to outsource the studies. Make sure you identify your partner well in advance and you allocate budget for the stability studies.
- A stability testing plan helps to identify potential stability issues early, which can help to reduce the risk of product failures and costly manufacturing delays.
- Demonstrate test stability for LMIC relevant temperatures. Expand temperature claims after launch may cause design changes and resubmission to regulatory authorizations.

# VALIDATION

# VALIDATION

**Purpose of validation is to verify a device's intended use in the hands of the intended user in the intended use setting:**

Typically, IVD's are validated in one or more clinical performance evaluations.



## IMPORTANT

A test should be validated for each claimed specimen type or matrix equivalency demonstrated. Therefore, samples types like finger-prick require fresh samples.

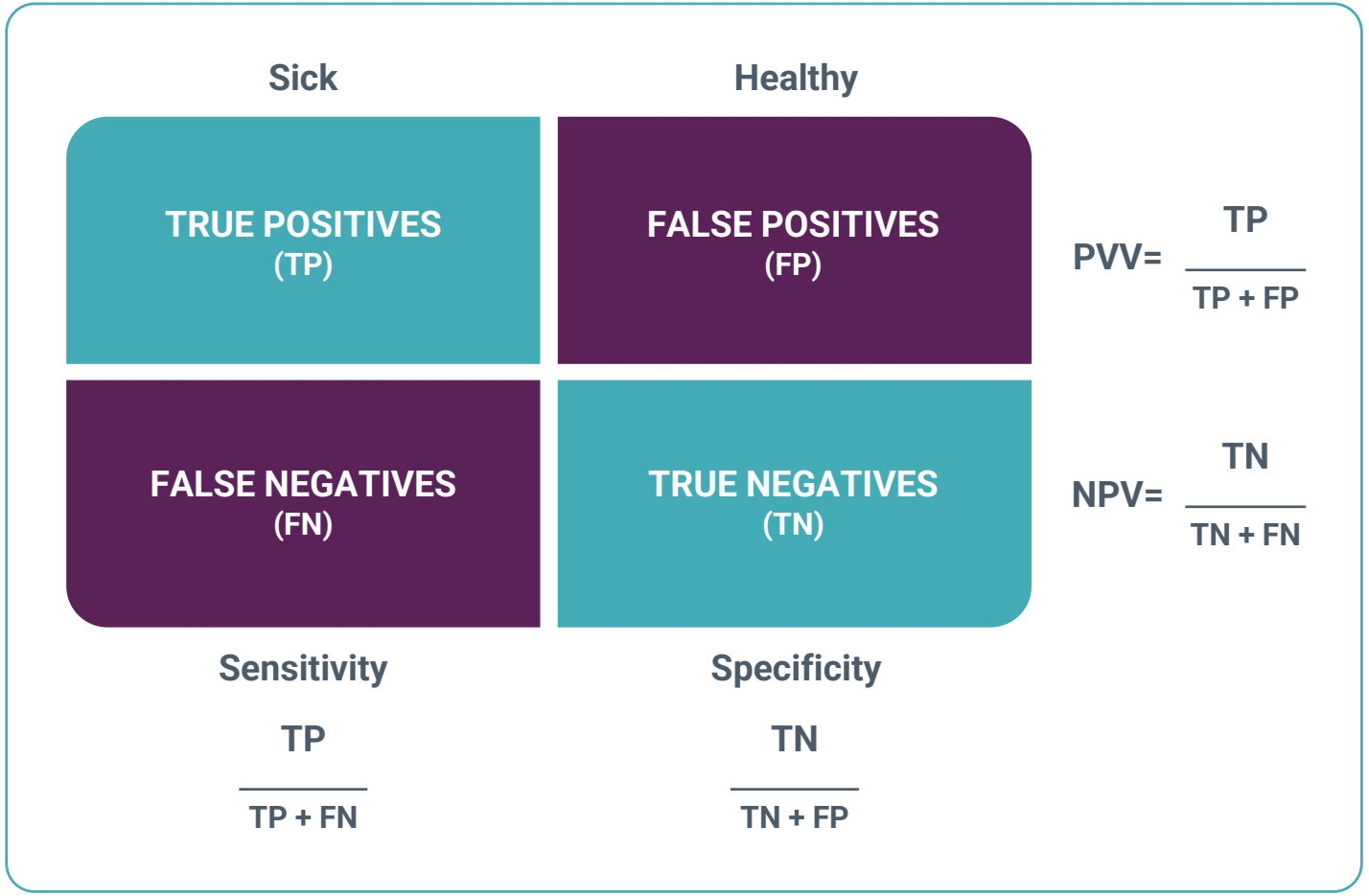
## REFERENCES

**ISO 20916:2019** In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects

VALIDATION

# DESIGN CLINICAL PERFORMANCE EVALUATIONS

- **Diagnostic sensitivity:** ability of a diagnostic test to correctly identify individuals who have the disease (true positives).
- **Diagnostic specificity:** ability of a diagnostic test to correctly identify individuals who do not have the disease (true negatives).
- **Positive predicted value:** the likelihood that a person with a positive test result actually has the disease.
- **Negative predicted value:** the likelihood that a person with a negative test result does not have the disease.



VALIDATION

# DESIGN CLINICAL PERFORMANCE EVALUATIONS

1. Review the device **intended use** and **indications for use**
2. For each desired performance claim, clearly identify the user, the actual use environment, and the specific parameter (e.g. study population or clinical trait) to be tested
3. Identify the appropriate **reference standard** or comparator method for the study (always use reference standard according its IFU)
4. Carry out power calculations to determine **sample size**
5. Create a **Clinical Study Protocol** and Identify clinical study sites
6. Obtain **required ethics approvals** and **Conduct** study
7. **Analyze** study data and **Compile** study report.

VALIDATION

# DO'S AND DONT'S

## DO's

- Do make sure the IVD workflow is exactly as intended for use in the field, from sample collection methods, sample processing, results interpretation and reporting.
- Do complete cybersecurity validations.

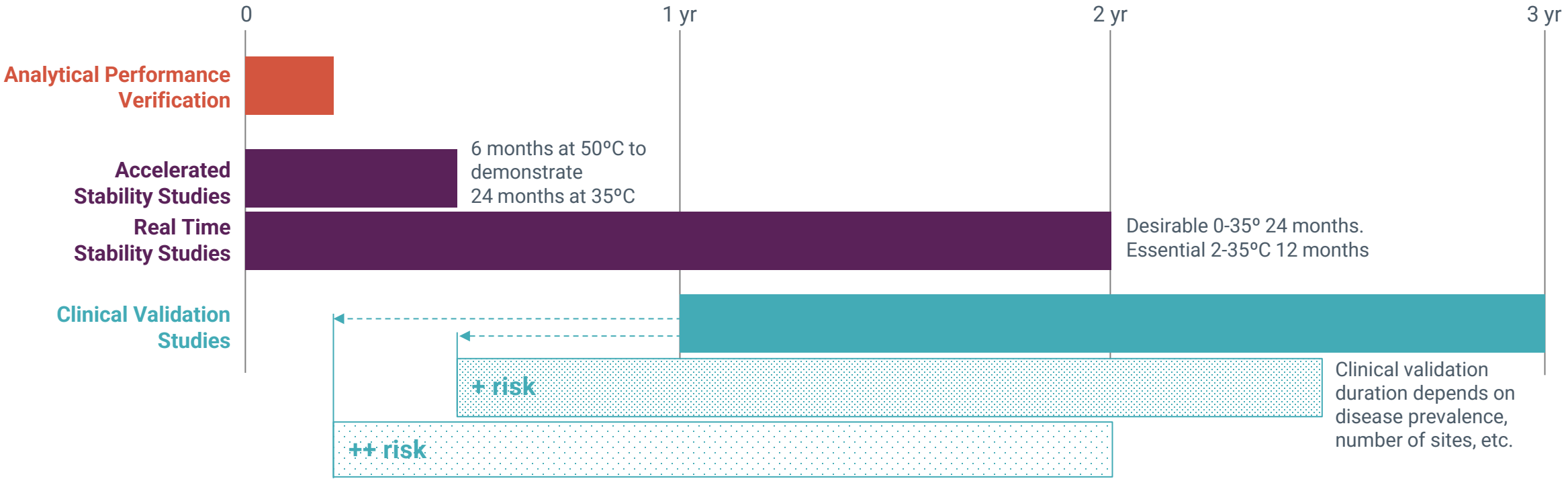
## DON'Ts

- Don't forget to validate usability (refer to IEC 62366 or FDA Human Factors Engineering).
- Don't underpower the study because of cost.
- Don't underestimate the time it takes a good clinical performance evaluations.
- Don't forget to evaluate integration and interoperability with other systems that will be used in the intended use setting.

**REMEMBER**

**If ANY design change has occurred, RE-VALIDATE!**

# TIMELINES




- Some regulatory authorizations accept accelerated stability studies plus some on-going real time stability data for submissions.
  **Important:** there is still a risk that real time studies fail even if successful accelerated stability data was obtained.
- The recommended good practice is to have met critical analytical performance targets (e.g. analytical sensitivity, specificity, precision, some shelf life, critical interferences) before starting clinical validation studies
- V&V is lengthy and costly, be realistic when planning timelines and budget.

# KEY TAKEAWAYS

1

**Verification** is the process of confirming that and IVD test performs according to its intended use through rigorous testing and analysis.

2

**Validation** assesses the IVD test in real-world conditions, confirming its fitness for intended clinical use.

3

Analytical performance must be well-determined along the product development process (use standards and guidelines).

4

Follow **ISO 20916:2019** to design Clinical performance evaluations.

5

**If ANY design change has occurred, RE-VERIFY and RE-VALIDATE!**

FIND

# QUESTIONS & FEEDBACK