



ONELAB

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Version History

Version No.	Date	Editor	Description of action
V0.1	06-05-2024	P. Brinkman	Transferred all developed input into Deliverable document.
V0.2	30-01-2025	P. Brinkman	Developed TTP scan.
V0.3	29-09-2025	P. Brinkman	Finalized document and made links to other ONELAB deliverables.
V1.0	29-09-2025	L.Jongejan	Final edits and submission



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Table 1: Selection Criteria for Point-of-Care Diagnostic Tools and Biomarkers, a quick scan.

Abbreviations

Abbreviation	Description
WHO	World Health Organization
ATP	Analytical Target Profile
TPP	Target Product Profile
AQbD	Analytical Quality by Design
ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
Q2(R2)	Guideline on validation of analytical procedures
NASA	National Aeronautics and Space Administration
TRL	Technology Readiness Level
IVDR	In Vitro Diagnostics Regulation
CoU	Context of Use
ISO	International Organization for Standardization
IVDR	In Vitro Diagnostics Regulation

Executive Summary

This deliverable introduces ONEcheck, a structured evaluation framework to judge the quality, added value and usability of diagnostic tools and biomarkers for pandemic response and broader public-health use. It responds to the central challenge exposed during COVID-19: while “test, test, test” is essential to break chains of transmission, reliably selecting, validating, and deploying the right tests at the right place and time remains difficult without a harmonized approach.

ONEcheck provides transparent, evidence-based decision support for clinicians, developers, regulators and implementers. It aligns scientific performance with operational realities to ensure diagnostics are not only accurate, but also deployable and useful in their intended context.

ONEcheck integrates three complementary pillars, Analytical Target Profile (ATP), Target Product Profile (TPP) and Analytical Quality by Design (AQbD) into a practical, three-step pathway: Qualification, Analytical Validation and Utilisation.

- Qualification: weighs biological and epidemiological plausibility using Bradford-Hill Criteria to establish what to measure.
- Analytical Validation: specifies how well it must be measured and embedding AQbD for robust, lifecycle-ready methods. A Technology Readiness Level (TRL) checklist is provided to benchmark maturity.
- Utilisation: determines where, by whom and under which constraints a test can be used, via the structured TPP scan across seven topics: 1) clinical need & public-health context, 2) specimen & handling, 3) operational characteristics, 4) clinical-performance expectations, 5) quality, regulatory & interoperability, 6) implementation & sustainability and 7) programmatic & policy considerations.

Key outputs:

- Selection guidance for new biomarkers of diagnostic tools
- A 15-point quick-scan “Selection Criteria for Point-of-Care Diagnostic Tools and Biomarkers” to trigger thoughts on rapid, early triage of options.

ONEcheck contributes to ONELAB by providing measurable decision points (“go/no-go” criteria) for deployment of biomarker and diagnostics.

By unifying causality, measurement performance and context-of-use into a single, transparent pathway, ONEcheck accelerates selection and adoption of fit-for-purpose diagnostics.

1. Introduction

Despite huge scientific and medical advances, there are various indicators that new global pandemics lie in wait. Massive increase in globalisation, urbanization and connectivity has created circumstances where a virus or infectious disease can spread easily from one to another continent within a day.

The most important aspect to prevent a pandemic from happening is to stop the spread by breaking the chain of infections. The World Health Organization (WHO) director general, Tedros Adhanom Ghebreyesus, had a simple advice to fight the coronavirus outbreak and to break the chain of infections: 'Test, test, test'¹. Although this message was straightforward, in practice this turned out to be more difficult.

Diagnostic tools and biomarkers play a critical role in the early detection and management of infectious diseases, serving as the cornerstone of effective public health responses. Their timely application enables rapid identification of infected individuals, supports clinical decision-making, and allows for targeted interventions such as isolation, treatment, or vaccination. In the context of emerging pandemics, where transmission can occur swiftly across borders, diagnostics are essential for interrupting the chain of infection. The availability of accurate, accessible tests ensures surveillance systems can operate effectively, guiding containment strategies and informing policy decisions that mitigate widespread public health impact.

Validation often lacks a structured framework, making it difficult to assess clinical relevance, reproducibility, and regulatory readiness. Furthermore, the diversity of biomarker sources and technologies adds complexity to establishing performance benchmarks. These challenges hinder the translation of promising biomarkers into scalable solutions, particularly during health emergencies. Harmonization across protocols, regulatory pathways and data interpretation is essential to build trust in these tools and ensure their readiness for integration into both clinical practice and pandemic preparedness strategies.

The aim of this deliverable is to establish a framework for judging the quality, added value and usability of (new) biomarkers or diagnostic tools in pandemic situations.

2. Purpose of document

ONELAB anticipates on the need to establish a comprehensive evaluation framework for diagnostic tools and biomarkers towards pandemic preparedness². For this purpose, we introduce ONEcheck, a framework that provides a structured approach to determine if diagnostic tools meet the criteria to be scientifically and clinically meaningful for specified purposes², something which is essential for appraising the reliability and clinical utility of candidate diagnostics. This framework should not only contribute to improved and more efficient patient care, but also to improved fit-for-purpose measures as it concerns, creating testing capacity, setting up mass community testing and limiting freedom of movement (quarantine/lockdowns) during a pandemic outbreak.

ONEcheck integrates three product development concepts: Analytical Target Profile (ATP)³, Target Product Profile (TPP)^{4,5} and Analytical Quality by Design (AQbD)⁶, with the goal to ensure that diagnostics are fit-for-purpose and meet the contextual needs of pandemic and public health responses.

Analytical Target Profile (ATP)

The ATP defines the intended performance characteristics of an analytical method, such as accuracy, precision, specificity, and sensitivity. In ONEcheck, the ATP serves as a foundation for selecting and validating diagnostic tools based on their capacity to consistently deliver reliable results within defined acceptance criteria.

Target Product Profile (TPP)

ONEcheck incorporates the WHO's principles for TPPs, which outline the minimal and optimal requirements that a diagnostic product should meet in a specific use-case scenario (e.g. triage, surveillance, prognosis). These include features such as sample type, time-to-result, ease of use and required infrastructure. By aligning diagnostic development and selection with WHO's TPP standards, ONEcheck ensures relevance to clinical and public health priorities.

Analytical Quality by Design (AQbD)

Building on the ATP and TPP, ONEcheck applies AQbD principles to support method development and lifecycle management. AQbD emphasizes understanding the process parameters and their impact on method performance, enabling continuous improvement and robust performance in real-world conditions. The integration of AQbD ensures that diagnostic tools maintain quality and compliance as they scale from development to deployment.

By combining ATP, TPP and AQbD, ONEcheck offers a transparent, science-based framework that promotes the development and selection of diagnostics that are reliable, scalable, and tailored to evolving public health challenges. It ensures readiness not only for emergency pandemic responses but also for broader applications in health systems strengthening.

In 2017 Kosack *et al.*⁷ introduced their guide to aid the selection of diagnostic in-vitro tests. This six-steps counting guide, starts with the well-known questions: why, what, where, who? Questions that are well covered by ATP and TPP. The question that can be added to this is the ‘how’, which can be formulated as: “How is causality established between the disease and the foreseen biomarker?”. For ONEcheck this question is considered as the ‘qualification’ step of the evaluation our framework, for which is the Hill's Criteria are taken into account.

3. ONEcheck

ONEcheck is an evaluation framework developed within the ONELAB project to assess the scientific and clinical relevance of diagnostic tools and biomarkers, particularly for pandemic preparedness. The framework aims to support transparent, harmonized assessments using both qualitative and semi-quantitative metrics, helping identify 'fit-for-purpose' diagnostics during disease outbreaks, which should lead to effective public health intervention. The concepts 'Analytical Target Profile' (ATP)³, 'Target Product Profile' (TPP)^{4,5} and 'Analytical Quality by Design' (AQbD)⁶ are used as pillars for this framework.

These three concepts are distinct but have clear alignment. At the strategic level, the TPP defines the ideal diagnostic tool by outlining the product's intended use, target population, setting, and performance expectations. It answers the critical question: What should the diagnostic product achieve for users and the healthcare system?

Before translating this high-level vision into measurable goals, the ATP provides the quantitative analytical criteria that the method must meet to fulfil the TPP. It includes parameters such as accuracy, precision, sensitivity, specificity, and reportable range. The ATP ensures that the diagnostic method is fit-for-purpose, aligning the analytical performance with the real-world needs defined by the TPP.

Finally, at the technical level, AQbD applies a structured, risk-based approach to develop and validate methods that consistently meet the ATP. At its core, AQbD emphasizes thorough method development, where most of the effort is focused on identifying and addressing potential weaknesses early on. By systematically testing and refining the method during development risks or vulnerabilities can be minimized through targeted improvements or controls. This proactive approach not only reduces the likelihood of future re-development or re-validation, but also leads to a more robust and reliable analytical method overall.

While the Analytical Target Profile (ATP) and the Target Product Profile (TPP) can be described as the criteria a biomarker or diagnostic must ultimately satisfy and Analytical Quality by Design (AQbD) can be viewed as the structured route for getting there, these concepts do not in themselves constitute a qualification or scoring system capable of determining whether a given biomarker is actually suitable for a specific clinical application or an emerging pandemic threat.

This is precisely the gap that ONEcheck fills. With ONEcheck diagnostic candidates can be examined from three complementary angles: Qualification, Analytical Validation and Utilisation⁸. During Qualification it weighs the biological and epidemiological plausibility of the marker against Bradford-Hill criteria⁹. During Analytical Validation the experimental performance against analytical requirements

and the technology readiness of a product are evaluated, thereby integrating AQbD where possible.

Finally, the Utilisation layer evaluates operational fit, health-system constraints, and real-world benefit-risk to produce a deployment grade. By integrating these three perspectives into a single, easy-to-interpret index, ONEcheck converts abstract quality concepts into actionable decision support for regulators, developers and outbreak response teams. It thereby strives to accelerate evidence-based adoption of novel diagnostics and reduces uncertainty when time is critically limited for responders.

In summary, Bradford-Hill criteria checks causality, the ATP sets the analytical goals, the TPP defines the practical requirements and AQbD provides guidance on how a method is built correctly and can reliably achieve the desired performance. Together, they form a cohesive, lifecycle-driven framework for developing high-quality diagnostics.

Step 1: Qualification of biomarker

By centring qualification around causality, Step 1 ensures that only biomarkers with a demonstrable and biologically plausible link to disease onset or host response are advanced. Applying a selection of the Bradford Hill criteria⁹ provides a structured, yet flexible, method to evaluate this relationship, recognizing that no single criterion can confirm causation in isolation. Instead, a cumulative assessment strengthens confidence in the biomarker's relevance (annex 1).

- Temporality:
 - Does the biomarker precede or coincide with disease manifestation?
- Strength & Consistency:
 - Do robust associations across diverse studies and populations support the biomarker's validity?
- Biologic Gradient:
 - Do higher marker levels correlate with disease severity or progression?
- Plausibility & Coherence:
 - Is there a sound biological mechanism, and does the association align with existing scientific knowledge?
- Specificity:
 - Is the marker linked to a single disease or narrowly defined condition?

As stated, none of these viewpoints alone offer definitive proof for or against a cause-and-effect relationship. However, temporality should be regarded as an essential prerequisite. Strong answers to these guiding questions help ensure that only biomarkers with credible, biologically supported and contextually relevant evidence

move forward. This evidence-driven qualification is critical to avoid premature validation of markers lacking a solid foundation, ensuring that subsequent steps in the ONEcheck process are grounded in rigorous scientific reasoning.

Within an Analytical Quality by Design (AQbD) framework, Bradford Hill's viewpoints sit upstream of method development and steer validation strategies. Temporality and biological gradient inform sampling schedules and stability assessments. Plausibility and coherence motivate selectivity and interference experiments, whereas strength and consistency inform effect-size assumptions and multi-site robustness testing. Specificity informs clinically meaningful cut-offs. Together, these aspects translate into concrete method requirements and experimental plans. Cut-off selection and error tolerances are tied to clinical consequences (false-positive/false-negative costs), ensuring optimization never undermines causal relevance. The Hill's criteria determine what is worth measuring and why, while AQbD supports translation of these criteria in robust and reliable biomarkers.

Step 2: Analytical Validation of biomarker

Once a biomarker has been qualified based on a credible causal relationship to disease, the next step in the ONEcheck framework is to evaluate if the marker can be measured accurately, reliably and reproducibly through a fit-for-purpose analytical method and whether it is ready for practical application.

2.1 Analytical Target Profile

The first step of Analytical Validation determines whether the procedure used to detect or measure a biomarker meets pre-defined performance criteria under various conditions and use cases, confirming the test's reliability for its intended clinical or public health application. According to ICH Q2(R2) guidance⁶, these performance parameters should be evaluated through well-designed studies that reflect the method's intended purpose, operational environment and target analyte.

The Analytical Target Profile (ATP, annex 2) defines the method's intended purpose and sets prospective performance requirements, including thresholds for accuracy, precision, specificity, sensitivity, reportable range (detection and quantitation limits), and probability. For biomarkers measured in ex-vivo samples (e.g. blood, saliva, exhaled breath), carry over and analyte stability are especially important.

The ATP serves as a quality benchmark, ensuring the analytical method produces scientifically valid results suitable for decision-making in clinical or regulatory contexts. By establishing these expectations early, the ATP guides method development, validation and lifecycle management under the principles of Analytical Quality by Design (AQbD)¹⁰.

2.2 Technology Readiness Level

The evaluation of a biomarker's Technology Readiness Level (TRL)¹¹ is imperative to measure its maturity and readiness for practical application. Assessing TRL provides insights into the current stage of development, ensuring that the proposed biomarkers are not only scientifically promising but also technologically robust and reliable. This assessment is crucial for determining the feasibility, scalability, and potential impact of each biomarker in real-world clinical or public health settings.

TRLs, as defined by the European Commission and originally developed by NASA, range from TRL 1 (basic research and principles observed) to TRL 9 (fully operational system in actual use). In the context of diagnostics, this scale helps categorize whether a biomarker is still in the conceptual or preclinical phase, has been validated in relevant environments or is ready for routine deployment. Evaluating a biomarker through this lens ensures that only candidate biomarker tests with appropriate development status are advanced to subsequent validation and implementation stages.

A TRL assessment (annex 3) within the ONEcheck framework supports resource prioritization and risk management. It indirectly also ensures alignment with regulatory pathways and user needs, making the diagnostic pipeline more efficient and responsive to evolving epidemiological challenges.

Step 3: Utilisation

The third step of the ONEcheck evaluation framework focuses on utilisation, assessing the applicability of results and the instrument or biomarker itself. Contextual fit and deployability of the qualified, analytically validated test are determined through a structured Target Product Profile (TPP) scan (annex 4), which captures real-world requirements for the intended use case and setting across seven key topics, which are derived from the TPPs published by the WHO⁵. While some questions of this scan may overlap with the ATP, the perspective is more end-user oriented. Together, these sections seek to ground performance claims in real-world use and make trade-offs explicit before adoption.

3.1 Clinical need & public-health context

Utilisation begins with purpose. A diagnostic only adds value if it changes a decision at a specific point in the care pathway (e.g. screening, triage, diagnosis, treatment-monitoring). Without a clearly stated role and target population, downstream comparisons of performance, cost or usability float free of context. Prevalence and severity also shape thresholds: at high prevalence, lower specificity may be tolerated in triage; at low prevalence, false positives carry greater harm. These judgments are not absolute "pass/fail" rules; they help rule out weak alternatives and make trade-offs explicit.

3.2 Specimen & handling

A test that depends on impractical sampling will fail in practice even if analytically sound. Acceptability (e.g. finger-prick vs saliva vs breath), feasibility of self-collection, biosafety and chain-of-custody drive uptake and reliability. Pre-analytical stability can be frequent weak link: delays, transport temperature and consumables can shift results enough to alter clinical decisions.

3.3 Operational characteristics

Operational fit determines whether a method can run at scale. Time to first result and throughput affect queuing and transmission risk; user skill dictates training burdens; footprint and portability decide where the test can live (desktop vs mobile unit); power/connectivity requirements shape deployment (mains, battery, solar; offline vs cloud). Consumables, shelf-life, storage, and waste/biohazard management are recurrent bottlenecks in outbreaks and must be feasible for the setting of employment.

3.4 Clinical-performance expectations

Minimum acceptable sensitivity/specificity must be tied to the intended decision, not abstract ideals. Reporting format (quantitative/qualitative/semi-quantitative) and interpretation aids (cut-offs, colour change, dashboards) reduce ambiguity at the bedside. As taken from the Hills criteria, no single metric settles utility; rather, these items help exclude explanations where error or bias would overwhelm benefit. Clear decision thresholds prevent “drift” across sites and enable consistent action.

3.5 Quality, regulatory & interoperability

The way a test or tool is classified determines what kind of evidence and supervision are required. Having good quality management processes in place helps make sure the product can be made consistently and reliably. Rules about data protection and how systems share information are important for keeping data safe and trustworthy. These factors are essential, if they are not met, the test or tool cannot be used. No matter how strong the science behind it is.

3.6 Implementation & sustainability

Unit cost and total cost of ownership (devices, disposables, training, service) determine coverage and equity; fragile supply chains collapse under surge; inadequate training/support drives misuse; maintenance models define uptime; environmental impact (energy, plastics, end-of-life) influences procurement and public acceptance. These factors compound over time, small frictions become large failures at scale.

3.7 Programmatic & policy considerations

A test that cannot report to surveillance, align with guidelines or earn stakeholder trust, will not be used, even if accurate. Integration with electronics health records turns

results into action; concordance with care algorithms prevents contradictory advice; acceptability and equity guard against widening disparities. As with Hill's viewpoints, these are judgment-aiding lenses: they surface conflicts with values, law or practice before deployment.

Applying ONEcheck

ONEcheck's three-step pathway moves, using the different questionnaires, from causal credibility (Qualification) to measurement reliability (Analytical Validation) and finally to context-of-use fit (Utilisation). By completing the questionnaires, the framework can help to find an answer on whether a proposed biomarker fits for purpose.

In practice: 'Bradford-Hill'-informed plausibility defines what to measure, the ATP specifies how well it must be measured and the TPP scan determines where and by whom it can be used. Bringing these steps together exposes trade-offs (e.g., sensitivity vs time-to-result; robustness vs portability) and surfaces go/no-go criteria that are transparent to clinicians, regulators and implementers.

Operationalising the ATP against a defined Context of Use (CoU) avoids over-engineering methods for settings that do not need it (e.g. screening vs confirmatory testing). The TPP scan translates end-user constraints into concrete design targets (sample type, operator, power, connectivity, waste, regulatory route). This enables earlier procurement alignment, realistic timelines for regulatory readiness.

The combined lenses Qualification, Analytical Validation and Utilisation provide a pragmatic, defensible route from biomarker promise to clinical and public-health value, while keeping AQbD reflective approach for method development.

This deliverable is very much focused on screening or testing biomarkers through extensive questionnaires and should be considered as a biomarker selection tool. The document is linked to other ONELAB deliverables that which go much more in detail concerning topics like guidelines for mass community testing, concepts of operations, target panel development and the pandemic testing playbook:

- D2.4 - Ethical, legal and operational guidelines for mass community testing¹²
- D3.1 - Concepts of operations for mobile laboratory deployments²
- D4.3 - Diagnostic/prognostic target panel development workflow and pipeline¹³
- D6.1 - Pandemic Testing Playbook¹⁴

The tens of questions that need to be completed, cause that completing ONEcheck takes time and expertise. For a quick scan of topics that should be taken into consideration when dealing with point-of-care diagnostic tools and biomarkers, a 15-points counting 'Selection Criteria for Point-of-Care Diagnostic Tools and Biomarkers'-

list can be considered (table 1). It addresses key aspects of analytical goals, product requirements, and regulatory compliance and standardization.

Table 1: Selection Criteria for Point-of-Care Diagnostic Tools and Biomarkers, a quick scan.

Selection Criteria for Point-of-Care Diagnostic Tools and Biomarkers			
Assessment Criteria -level required or expected to reach/needed-	Home Testing	Decentralized Testing	Central Laboratory Testing
Test Sensitivity (true positives)	+	++	+++
Test Specificity (true negatives)	+	++	+++
Test Accuracy	Moderate	High	Very high
Time to Result	<30 minutes	<1 hour	1–4 hours
Invasiveness	Non-invasive	Non-/Minimally invasive	Invasive
Sample Type	Saliva, breath, urine, nasal swab	Saliva, breath, urine, nasal swab, blood	Saliva, urine, nasal swab, blood, tissue
User-Friendliness	+++	++	+
Level of Operator Expertise	Lay person	Nurse / GP	Laboratory technician
Need for Equipment	No	Small / Portable device	Advanced lab infrastructure
Stability / Shelf-life	6–12 months	12–18 months	18–36 months
Cost per Test	Low	Medium	High
Scalability / Throughput	Moderate (self-test volume)	High (dozens/hour)	Very high (hundreds/hour)
Regulatory Readiness	IVDR 2017/746 - Class A	IVDR 2017/746 - Class B, C or D	ISO 15189:2022
Data Privacy / GDPR Compliance	Basic	Enforced via software	Fully integrated & auditable
Data Connectivity / Integration	Limited	Good	Excellent
Key elements of an Analytical Target Profile – performance characteristics of an analytical method.			
Key elements of a Target product profile – desired characteristics of a product.			
Key elements of regulation, compliance and standardization.			

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13. ONELAB Deliverable D4.3 - Diagnostic/prognostic target panel development workflow and pipeline
14. ONELAB Deliverable D6.1 - Pandemic Testing Playbook

5. Annexes

Annex 1:

Causality Assessment – Bradford Hill Criteria Checklist

Purpose: Assess the scientific and clinical relevance of the biomarker by evaluating its causal relationship to the disease or condition of interest using key Bradford Hill viewpoints.

Biomarker Name: _____

Disease/Condition: _____

Intended Use (e.g., triage, diagnosis, prognosis): _____

Criterion	Question	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unclear
Temporality	Does the biomarker precede or coincide with disease manifestation? Comments / Evidence:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Strength & Consistency	Do robust associations across diverse studies and populations support the biomarker's validity? Comments / Evidence:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Biologic Gradient	Do higher marker levels correlate with disease severity or progression? Comments / Evidence:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Plausibility & Coherence	Is there a sound biological mechanism, and does the association align with current scientific knowledge? Comments / Evidence:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specificity	Is the biomarker linked to a single disease or a small group of related conditions? Comments / Evidence:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall Qualification Outcome:

- Biomarker qualifies for further validation
- Biomarker does not qualify; justification needed
- Further evidence required before decision

Reviewer Name: _____

Date: _____

Annex 2:

Analytical Target Profile (ATP)^{6,10}

Purpose: to define the required method performance to ensure the biomarker result is reliable for its intended clinical or public health use.

Biomarker Name: _____

Disease/Condition: _____

Intended Use (e.g., triage, diagnosis, prognosis): _____

Intended purpose		
Measurement of {XXX}, a marker for disease {XXX}.		
A metabolite {XXX} (or signal/pattern) derived from {e.g. blood, saliva, breath}		
Performance characteristics		
Characteristic	Acceptance criteria	Rationale
Accuracy	Relative accuracy can assessed via a linearity experiment that covers the reportable range. No trend in relative bias is should be found between tested and observed range.	Selected performance characteristic ensures that the intended method delivers the quality reportable result. To demonstrate the closeness of measurements to accepted known values
	The 95% Confidence Interval of the slope of the fitted regression line between theoretical and measured potency falls within a range of {0.8 to 1.25} ¹ . The upper and lower 90% confidence interval for the relative bias calculated at each potency level is not more than {20%} ¹ , considering the intended purpose of the measurement.	
Precision	{upper/lower} ¹ 95% Confidence Interval for the average intermediate precision across levels across the reportable range is not more than {20%} ¹ , considering the intended purpose of the measurement.	To demonstrate the closeness of replicate measurements to one another.

		“intermediate precision”: Across days and operators
Specificity	Method is specific to marker of interest in the presence of components expected to be present. No interference from relevant process related impurities or matrix components should occur.	Process related and matrix components do not significantly affect the characteristics of the dose response curve.
	Assay is stability indicating through a method capable of detecting a change in potency; confirmed using forced degraded samples (eg. high/low temperature or humidity).	To ensure that the product remains within specification over its shelf-life and/or changes in environmental settings.
Reportable range	The relative potency range is the range that meets accuracy and precision.	Stated range for which the required accuracy and precision characteristics are demonstrated.
Analytical measurement range	Upper limit of quantification Lower limit of quantification	To define the largest values measurable in the assay
Carry over	carry over should be assessed by analysing blank samples after tests at the upper limit of quantification.	To demonstrate carry over does not interfere with the accuracy and precision of the lower limit of quantification.
Analyte stability	Stability evaluations should be carried out to ensure that every step taken during sample taking, storage, preparation, processing and analysis do not affect the concentration of the biomarker.	To demonstrate within which period a sample needs to be analysed.
<p>Context Of Use (COU):</p> <p>A {screening/diagnostic/monitoring} biomarker, that enables identification of people with {disease/infection}.</p> <p>The following section lists considerations when using the biomarker for this COU:</p>		

General Considerations:

{provide the boundaries for the use of the biomarker}

- age of patients
- confounders

¹ *Individual values may differ per marker.*

Overall ATP Outcome:

- Biomarker qualifies for further validation
- Biomarker does not qualify; justification needed
- Further evidence required before decision

Reviewer Name: _____

Date: _____

Annex 3:

TRL	Readiness Statement	Yes	No
TRL 1	Have the basic scientific principles underlying the diagnostic method been observed or reported? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 2	Has a specific diagnostic concept or application been formulated based on these principles? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 3	Has a proof of concept been demonstrated in a laboratory (e.g., benchtop or prototype performance)? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 4	Has the diagnostic technology been validated in a controlled laboratory environment (including integration)? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 5	Has the method been tested in a simulated or relevant environment (e.g., mock clinical setting)? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 6	Has a working prototype been demonstrated under relevant conditions (e.g., actual sample use)? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 7	Has the system been demonstrated in an operational environment (e.g., field test or clinical pilot)? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 8	Is the complete diagnostic system qualified and proven to meet all regulatory and performance requirements? Description:	<input type="checkbox"/>	<input type="checkbox"/>
TRL 9	Has the diagnostic been used successfully in real-world settings (e.g., hospital, community health, outbreak)? Description:	<input type="checkbox"/>	<input type="checkbox"/>

Overall TRL:

Reviewer Name: _____

Date: _____

Annex 4:

Target Product Profile Scan.

Purpose: to determine technical feasibility, contextual fit in the final stage on ONEcheck.

Category	Item	Circumstantial Fit			
		NA	Yes	No	Unclear
Clinical need & public-health context	1. Intended clinical purpose / role in care-pathway <ul style="list-style-type: none"> Does the solution fit the intended clinical purpose (e.g. screening, triage, diagnosis, treatment-monitoring)? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	2. Target population & setting <ul style="list-style-type: none"> Does the solution fit the target population characteristics (age range, symptom status) and the foreseen healthcare setting? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specimen & handling	3. Acceptable specimen type(s) <ul style="list-style-type: none"> Are the required specimen (e.g. finger-prick blood, saliva, breath) specified? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	4. Sampling logistics <ul style="list-style-type: none"> Are collection and handling requirements (self-collection feasibility, special consumables, cold-chain) documented? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Operational characteristics	5. walk-away time & throughput <ul style="list-style-type: none"> Does the required sampling time and patient throughput fit the requirements? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	6. Time to first result <ul style="list-style-type: none"> Does the time to first result fit the requirements? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	7. User skill level & training required <ul style="list-style-type: none"> Do the minimum operator skill levels fit the circumstances? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	8. Equipment footprint & portability <ul style="list-style-type: none"> Do instrument size and portability expectations fit the circumstances? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	9. Power & connectivity needs <ul style="list-style-type: none"> Do power-supply and data-connectivity requirements fit the circumstances? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	10. Consumables & re-agents <ul style="list-style-type: none"> Are consumable needs, shelf-life and storage conditions suitable for the circumstances? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	11. Waste & bio-hazard management <ul style="list-style-type: none"> Are waste-management and biosafety requirements suitable for the circumstances? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinical-performance expectations	12. Minimum acceptable clinical sensitivity / specificity <ul style="list-style-type: none"> Does the solution meet the minimum acceptable clinical sensitivity and specificity values? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	13. Result reporting format	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	<ul style="list-style-type: none"> Does the solution's result reporting format (quantitative, qualitative, semi-quantitative) fit the circumstances? 				
	<p>14. Result interpretability & decision thresholds</p> <ul style="list-style-type: none"> Are decision thresholds or interpretation aids (e.g. colour change, Ct cut-offs, dashboards) provided? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality, regulatory & interoperability	<p>15. Required classification</p> <ul style="list-style-type: none"> Does the anticipated solution meet the required regulatory classifications? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>16. Quality-management system alignment</p> <ul style="list-style-type: none"> Are the applicable quality-management standards referenced? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>17. Data & cybersecurity compliance</p> <ul style="list-style-type: none"> Are data-protection and interoperability standards (e.g. GDPR, HL7-FHIR) specified? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Implementation & sustainability	<p>18. Unit cost & total cost of ownership</p> <ul style="list-style-type: none"> Is the target price per test and/or per instrument defined? Does it fit the budget? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>19. Supply-chain robustness & local manufacture</p> <ul style="list-style-type: none"> Do measures for supply-chain robustness (e.g. dual sourcing, local manufacture) full-fill requirements? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>20. Training & support package</p> <ul style="list-style-type: none"> Is a user-training and support package available? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>21. Service & maintenance model</p> <p>Is the service and maintenance plan specified?</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>22. Environmental impact</p> <ul style="list-style-type: none"> Are environmental considerations (energy use, plastics, end-of-life) documented? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Programmatic & policy considerations	<p>23. Fit with surveillance / reporting systems</p> <ul style="list-style-type: none"> Is integration with existing electronic health records or surveillance dashboards addressed? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>24. Alignment with guidelines</p> <ul style="list-style-type: none"> Are treatment algorithms or clinical workflows updated to accommodate the test? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>25. Stakeholder acceptance & equity impact</p> <ul style="list-style-type: none"> Have stakeholder acceptability and equity implications (marginalised groups) been considered? 	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall TPP outcome:

- Method fits circumstances.
- Method does not fit circumstances; further justification needed.

Reviewer Name: _____

Date: _____