



Diagnostics & Testing Products: evidence guidance

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Prepare the evidence for a diagnostics & testing products entry. This guide covers the product details, reports and use information reviewers need.

Define the test

Name the target, sample type, collection or preparation requirements, users and setting. Identify the reader, reagent and software combinations covered. Describe research-use or clinical-use status and the declared market accurately.

Separate analytical and clinical evidence

Organise reports by the questions they answer. Explain the reference method, sample selection, relevant population, performance measures and limitations. Clinical claims need evidence addressing those claims; analytical findings alone do not establish every clinical interpretation.

Explain the workflow and its limits

Provide current instructions, result interpretation, invalid-result handling, relevant interferences and restrictions. Tie reports to the entered version and remove identifiable patient data. Online demonstrations explain the workflow without replacing the evidence required for a performance claim.

Evidence checklist

Area	Required material	Check before submitting
Identity	Target, sample, users, setting, components and version	The assessed scope is explicit.
Analytical performance	Protocols, references, conditions, results and uncertainty	Relevant properties, interferences and limits are addressed.
Clinical performance	Population, sample selection, reference approach and analysis	Findings apply to the intended clinical setting.
Interpretation	Instructions, warnings and invalid or indeterminate results	Users can understand the result's scope.
Quality and supply	Relevant market records, batches, versions and concerns	Reports and supply claims concern the entered product.



Explaining applicability

Evidence for one sample type and setting does not automatically cover another. Identify exclusions and uncertainty and explain how indeterminate results were handled. Research-use material must not be presented as clinical authorisation. Use summaries or de-identified evidence, rather than personal patient records, for review.

Map claims to sources

For each principal claim, record its exact wording, report or study, file and page, assessed version, method or population, finding and limitation. Identify the author and relevant relationship with the applicant. Explain how evidence about a different formulation, component or version applies to your product.

Prepare readable files

Supply readable reports, with the original and relevant English passages where needed. Keep private reports separate from proposed public information. Remove personal information not needed for review.

The entry permits up to 20 attachments and 250 MB in total: 25 MB per PDF and 10 MB per image. Video is supplied by link. Contact the awards team if an essential report exceeds these limits.

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