Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Preparing for an application audit for in-vitro diagnostic medical devices

Guidance for preparing a technical file review, as part of your application to include an in-vitro medical device (IVD) in the Australian Register of Therapeutic Goods.

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Contents

Purpose

This guidance is intended for sponsors seeking to include an in-vitro diagnostic (IVD) medical device in the Australian Register of Therapeutic Goods (ARTG).

We select some ARTG inclusion applications for IVD medical devices for in-depth reviews referred to in the legislation as application audits. For more information about how we select applications for audit, see selection criteria for medical device application audits and Understanding the application audit process.

Legislation

Therapeutic Goods (Medical Devices) Regulations 2002

What an application audit involves

Examples of what we may consider in an application audit are:

- Is the product a medical device as defined by section 41BD of the Act?
- Is the product an IVD medical device as defined by Regulation 1.3?
- Is the conformity assessment procedure appropriate for the class of device?
- Are the Unique Product Identifier (UPI) details valid, where applicable?
- Is the GMDN term in the device application appropriate for the device?
- Based on the manufacturer's intended purpose, the details in the application form, and the information provided by the sponsor, has the device been correctly classified?
- Is there any evidence of non-compliance with any of the Essential Principles?
- Does the manufacturer's Australian Declaration of Conformity (only for class 1 IVD medical devices, Systems or Procedure Packs, and for devices supported by a TGA Conformity Assessment certificate) comply with Schedule 3 of the Regulations?
- Have representative labelling and Instructions for Use (IFU) been provided, and do they demonstrate compliance with Essential Principle 13?
- Has a risk management report been included and has it identified risks and mitigation aspects applicable to the IVD medical device?
- Does the stability data support the stability claims?
- Does the clinical evidence meet the requirements of:
    - Essential Principle 14
    - Part 8, Schedule 3 of the Regulations?
- Does the analytical performance data and usability studies meet the requirements of Essential Principle 15?

Information requested for an application audit

We will contact the sponsor to request the information needed to complete the application audit. For an IVD, an

application audit is primarily a review of the manufacturer's technical documentation.

For applications that include several IVDs of the same kind and require a mandatory audit, we will usually select representative IVDs for detailed review on a case-by-case basis considering possible risks associated with the use of the devices, and the similarities in their composition.

For applications selected for non-mandatory audit, we will request information based on the reason for audit selection.

Manufacturers may produce multiple IVDs that share common technical documentation such as the assay with a specific instrument. Appropriate referencing is important.

Documents the sponsor must provide

Document	Description	Legislative Reference	Note
A copy of the manufacturer's Australian Declaration of Conformity	As part of the Conformity Assessment procedures, the manufacturer of an IVD application is required to make a Declaration of Conformity which declares that the device complies with the Australian legislative requirements.	Schedule 3 of the Regulations	The Declaration of Conformity must be for the Australian requirements. This is only applicable for class 1 IVD and those applications supported by TGA Conformity Assessment certificate.
Conformity Assessment evidence for the IVD and the manufacturer	Conformity Assessment evidence is the certificates issued by the TGA, Australian Conformity Assessment body or comparable overseas regulator that demonstrates: • a manufacturer has been assessed and has the appropriate systems in place to manufacture the device and • the design of the device has been assessed Conformity Assessment evidence is used to demonstrate that an appropriate Conformity Assessment procedure has been applied by the manufacturer.	Conformity Assessment procedures, Schedule 3 of the Regulations	Includes: • quality management system certificates • design examination certificates • evidence of comparable overseas regulatory approval that apply to the Class of the IVD. If the manufacturer has applied the Conformity Assessment procedure for system or procedure packs under Schedule 3, Clause 7.5 of the Regulations, the sponsor may be required to submit copies of the certification for IVDs in the system or procedure pack. Refer to guidance on use of market authorisation evidence for medical device applications.
Technical File or Design Dossier	Manufacturers of all classes of IVDs are expected to demonstrate conformity to the Essential Principles through the preparation and holding of a technical file that shows how each IVD was designed, developed and manufactured.	Schedule 1 of the Regulations	Sponsors are required to either hold, or have timely access to, technical documentation that shows the IVD complies with the Essential Principles.
The sponsor may also be requested to provide documented evidence for other matters related to the application.	• Whether the application is in accordance with section 41FC • Whether matters certified under section 41FD are correct.	Section 41FI	Example: • Is the device correctly classified • Is the information included in the application complete and correct.

Technical file

A technical file is all the information a manufacturer keeps about a particular IVD.

This file is usually created through the manufacturer's quality management system. It includes documents made during the design, development, production and ongoing monitoring of the IVD.

In 2024, the International Medical Device Regulators Forum (IMDRF) published Table of Contents (ToC) to help

manufacturers understand what documents may be needed when submitting an IVD to a regulator like the TGA. Manufacturers do not have to follow every recommendation in the IMDRF ToC, but this document can help them prepare the information the TGA may ask for during an application audit.

The amount of detail needed depends mainly on the IVD's risk level. More information may be required if the IVD is complex, uses new technology, detects a new analyte, or has a new clinical use.

Components of the technical file

Device description

A detailed description of the IVD must be provided.

It must include:

- Intended purpose
- Intended user
- Risk classification according to Australian regulations
- Acceptable specimen types
- GMDN that aligns with the intended purpose and analytes consistent with the information in the application.
- UPI, applicable for class 4 IVDs and Companion Diagnostics
- Description of the methodology used for all IVD classes and operating principle of the assay for class 4 IVDs, and
- Description of individual components included in the IVD.

Where applicable, the following should also be provided:

- A description of the specimen collection and transport materials required or recommended to be used
- A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IVD
- a description of any instrumentation required to be used with the assay
- For devices including software, the software version number, build number and details of how software updates will be delivered and applied
- A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.

Relevant information should be provided to enable us to review all the platforms, instrumentation and any other materials, including dedicated specimen receptacles, that are required (or recommended) to be used in combination with the IVD.

Device history

We will request a summary of the product history in Australia and any other jurisdictions where it is supplied to assess the IVD's post-market safety and efficacy. Details should include a list of the number of units of IVDs supplied in each jurisdiction, by year.

Provide a consolidated summary of post-market surveillance data, including complaints, field safety corrective actions (FSCA) and recalls, clearly mapped to the relevant device variants.

The summary should also address any reported adverse events, recalls, corrective and preventive actions (CAPA),

and any instances where the device has been refused approval for supply in any jurisdiction.

The inclusion of information clearly identifying products either as new to the Australian market, or as previously registered will assist us in prioritising and scoping the assessment of these products.

Essential Principles checklist

We may ask for an Essential Principles checklist that explains how the manufacturer has met each relevant Essential Principle, using standards or other suitable evidence.

Evidence of compliance must point to the documents, reports, and internal procedures used. It should also show where each document can be found in the checklist. We may ask for more information about any documents listed or expected to be included in the product's technical file.

We will accept a European General Safety and Performance Requirements checklist under IVDR. It must include a short statement from the manufacturer confirming that the Australian Essential Principles have been met.

Risk analysis and control summary

You must provide a summary of the risk management activities carried out by the manufacturer. For Class 1-3 IVDs, this summary may take the form of the Risk Management Report described in Clause 8 of ISO14971. For Class 4 IVDs, you must provide comprehensive risk management documentation in accordance with the current ISO 14971 or an equivalent standard.

As a minimum the summary should include:

- A list of possible hazards arising from false positive or false negative results. For quantitative devices, the risks must be carefully assessed in relation to the relevant medical decision points.
- Indirect risks associated with IVD use, such as instability of test components, packaging integrity, or specimen selection.
- User or operator hazards, including any risks linked to reagents or specimens that contain infectious agents.
- For self-test and point-of-care IVDs, additional risks related to the intended user population, the intended use settings, and any reasonably foreseeable misuse must also be considered.
- Risk mitigation strategies that have been implemented to reduce unacceptable risks.

Considering risk mitigating activities, the results of the risk analysis should provide a conclusion that the remaining risks are acceptable when compared to the benefits. The risk analysis and control summary may be submitted either in a summary (text) format or as a reduced table.

Documentation should also include a documented process for reviewing production and post-production information to ensure that risks are identified, evaluated, and addressed throughout the life cycle of the device.

Design and manufacturing information

You should provide a summary of how the device is designed and manufactured, with enough detail to match its risk level.

This summary should explain the design features that help the IVD work as intended.

It should also include an:

- overview of manufacturing processes and controls and manufacturing sites
- a description of critical assay ingredients,
- a description of the major systems or critical processes, and
- details of any decision pathways or algorithms used, as appropriate.

Clinical evidence report

All medical devices require clinical evidence. For IVDs this evidence includes information that supports the IVD's scientific validity, clinical performance and clinical utility as intended by the manufacturer.

A clinical evidence evaluation report must be available for every IVD. This report must show that the device meets the applicable requirements of the Essential Principles, specifically EPs 14 and 15(1).

The Clinical Evaluation Procedures described in Clause 8, Schedule 3 of the Regulations set out the requirements, and focus on the manufacturer obtaining clinical investigation data through conducting performance evaluations or carrying out a literature review of published and unpublished scientific literature.

Unpublished literature refers to clinical performance evidence that is not formally published in peer-reviewed journals but is systematically generated, documented, and suitable for critical appraisal. This may include regulatory submissions from other jurisdictions, post-market performance data, conference abstracts, academic theses, and laboratory performance proficiency testing; provided their methodological quality and relevance are adequate.

Evidence to demonstrate the clinical competence of the author (e.g. short curriculum vitae) must accompany the submitted clinical evidence report to provide assurance that the clinical evidence has been evaluated by a competent clinical expert.

Clinical utility

The clinical utility of a parameter is the demonstration of its potential or established usefulness for patient management decision making and provides the means for making decisions about effective treatment or preventive strategies.

For many common IVDs with a broad history spanning many years of use, clinical utility has long been established and there are well-recognised associations with a particular disease or condition. For these IVDs it is not expected that extensive information be further documented simply for the purpose of submission for premarket approval.

For more recently developed IVDs which involve the use of a new technology, a new application, a new biomarker, pharmacogenomics, etc., evidence of clinical utility may be required.

Where confirmation of an IVD's clinical utility is required to be documented, the process for generating appropriate evidence should commence at the research phase and often involves ongoing collaborative development over time.

Evidence of clinical utility is initially established using a summary of literature searches and expert opinions and is supplemented with appropriate clinical or research data as it becomes available.

If a manufacturer decides that clinical utility evidence is not needed because the IVD has a well-recognised link to a particular disease or condition, this decision must be documented and clearly justified in the clinical evidence report.

Scientific validity

Scientific validity refers to the established association between the analyte measured by an IVD and the relevant clinical condition or physiological state for its intended purpose.

For more recently developed IVDs which involve the use of a new technology, a new application, a new biomarker, pharmacogenomics, etc., evidence of scientific validity may be required.

Demonstrating scientific validity requires evidence that the analyte is clinically relevant and that its presence, absence, or level has a meaningful relationship with the condition being investigated.

This is typically supported by well-established scientific knowledge, such as peer-reviewed literature, clinical guidelines, or consensus statements, and must be appropriate to the intended use and target population.

Scientific validity provides the foundational rationale for why an IVD result is clinically meaningful but does not assess how accurately or reliably the test performs, which is addressed separately through analytical and clinical performance evidence.

Clinical performance evaluation

The clinical performance of an IVD is shown by demonstrating how well it identifies a specific clinical condition in the intended population and user group.

Clinical performance measures how accurately the IVD identifies patients who have a particular disease or condition, and those who do not, based on their true clinical status.

Key clinical performance characteristics include:

- Diagnostic sensitivity and diagnostic specificity, which may change depending on the assay's cut-off value
- Positive and negative predictive values, which depend on the disease prevalence in the target population, or alternatively, positive and negative percentage agreements to comparator devices when a gold standard reference method is unavailable.

If multiple specimen types are claimed, performance data must be provided for each type unless specimen equivalence is clearly demonstrated.

For well-established and standardised analytes, clinical performance evidence can come from:

- Clinical performance studies
- Published literature
- Experience from routine diagnostic testing
- Post-market surveillance data
- Summaries of adverse events
- Field safety corrective actions (such as recalls, notifications, or hazard alerts)

Where a manufacturer chooses not to provide full clinical performance data, they must justify why this is appropriate.

For IVDs intended for lay users or point-of-care settings, clinical performance studies must consider the knowledge, skills, and practical abilities of these users. Evidence should show that the IVD performs appropriately in the

intended setting.

For more information see Clinical Evidence for IVD medical devices.

Analytical performance evaluation

Evidence demonstrating the analytical performance characteristics of the IVD is required under Essential Principle 15 and forms a key part of the manufacturer's performance evaluation studies.

These studies support the clinical evidence for the device. Whenever possible, analytical performance studies should be conducted using the intended specimen type matrix, unless there is a clear justification for using another approach.

Each study should include enough detail to understand how it was conducted. This includes information about the characteristics of specimens or samples used, the acceptance criteria, any explanations for anomalous results, and the final outcomes or conclusions.

It is acceptable to combine two or more aspects of analytical performance into fewer separate studies provided each of the studies is well designed and all relevant variables and test characteristics are effectively demonstrated.

The following analytical performance characteristics should be addressed, as appropriate to the type of IVD.

Specimen type

You must provide a list of all specimen types that can be used with the IVD.

This list should include the appropriate anticoagulants, matrices, and any special instructions or conditions for collecting the specimen.

Specimen stability

You should also include information about specimen stability, suitable storage conditions, and, where relevant, transport conditions.
Storage details may include:

- Storage duration
- Temperature limits
- Relative humidity (where applicable)
- Number of freeze and thaw cycles

Analytical performance study reports should describe the specimen types used (for example, spiked or wild-type) and, where appropriate, the geographic location where the specimens were obtained.

Specimen equivalence

If the IVD is intended for use with multiple specimen types that have similar matrix characteristics, you must provide performance data for each type—unless you can clearly demonstrate equivalence.

A specimen equivalence study should:

- Use paired or matched specimens

- Include a statistically justified sample size
- Cover the full concentration range, with particular emphasis on concentrations near the limit of detection and relevant clinical decision levels.

Reduced testing may be accepted only when strong evidence or a well-supported scientific rationale shows that the specimen types are equivalent.

Accuracy

The term accuracy refers to both trueness and precision (reproducibility and repeatability).

Demonstration of trueness requires utilisation of an acceptable reference method or comparison with reference material of a higher order.

Reproducibility should include information on studies that estimate total variability, as well as, where relevant, variability between-days, runs, sites, lots, operators and instruments.

Repeatability should include information about studies to estimate total variability and as appropriate, within-run variability.

The results of testing should include samples that represent the full range of expected analyte concentrations within the target population.

Analytical sensitivity

Analytical sensitivity should be demonstrated by establishing the limit of detection (LoD), defined as the lowest analyte concentration detected with at least 95% positivity, supported by a clearly defined study design.

The study should specify the analyte tested, the number of lots used, how the concentration levels were established, specimen characterisation and number of replicates tested at each concentration, and the specimen matrix relevant to the intended specimen types.

Reference materials should be appropriately characterised, with sufficient replicates at each level to support the analytical sensitivity assessment. For verification of the LoD, a minimum of 20 replicates tested at concentrations near the LoD is expected to support estimation of a 95% detection rate.

For additional details, refer to CLSI 17 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures or an equivalent standard.

The reference material or standard used to establish LoD should be clearly identified, with traceability to a recognised international standard demonstrated where available. This should include the source, composition, assigned value (where applicable), and quality information. Where available, a Certificate of Analysis should be provided to support the identity, assigned value and traceability of the reference material used in the LoD determination.

The statistical methods and calculations applied must be described and justified, and the results should support the claimed LoD for each intended specimen type.

For quantitative devices, analytical sensitivity studies are additionally expected to include determination of limit of blank (LoB) and limit of quantification (LoQ) using appropriate statistical methods.

Analytical specificity

Information relating to studies conducted to assess analytical specificity should be provided, including evaluation of the effects of potentially interfering and cross-reacting substances or agents on test results.

You should consider both:

- endogenous substances—naturally occurring compounds, metabolites, or disease-related factors likely to be present in the intended specimen types
- exogenous substances —medications, supplements, and other substances likely to be present in the intended use population

The selection and dosage of each potentially cross-reacting or interfering substance should be justified with reference to clinically relevant or worst-case concentrations.

Studies should be performed in the presence and absence of the target analyte, including at low-positive concentrations near the limit of detection (typically 2–3 times the LoD), to demonstrate that interference or cross-reactivity does not adversely affect detection at clinically relevant levels.

Testing should be conducted using sample matrices representative of the intended specimen types to ensure the results are relevant to the conditions of use.

Measuring range of assay

You should include a summary of the studies used to define the measuring range of the quantitative or semi-quantitative assay for both linear and non-linear systems as applicable.

The information should explain how the lower limit of detection was determined— for example, through the preparation of dilutions, use of standards, and number of replicates tested.

If relevant, the summary should also describe any investigation into potential prozone or high-dose hook effect.

Traceability of calibrator and controls

Information summarising the traceability of calibrators and trueness control materials should be provided, if applicable.

Methods used to determine traceability to reference material of a higher order, acceptance criteria, and the assignment and validation of values should be included.

For assays intended for point-of-care use, the manufacturer is expected to identify and recommend appropriate, validated external quality control materials in the IFU to support verification of test performance. The presence of an internal procedural control within the assay, which confirms correct test execution, is not sufficient to independently verify assay performance and does not replace the need for external quality controls for point-of-care devices.

Determination of assay cut-off

Where applicable, you should provide a summary of how the qualitative assay cut-off was established.

This summary should include the rationale for selection of the cut-off value, study population, specimen types, methods used to determine true positive and true negative status and any statistical methods applied to support the

cut-off determination.

Verification and validation of instrumentation and software

For verification and validation of instrumentation or software IVDs, the study report should include a summary of performance testing undertaken conducted in a valid end-user environment. This summary should describe the testing conditions, user types, workflow, and system configuration under which the performance evaluation was conducted.

Stability

You must provide stability studies that show the IVD keeps working properly for its whole shelf-life, including when it is stored, used and transported.

For Class 3 and Class 4 IVDs, you must include:

- A copy of the study protocol
- A detailed study report and raw data showing all test results
- Any calculations performed
- The final conclusions supporting the claimed shelf life

For Class 2 IVDs, a summary report is acceptable. This should describe:

- The type of stability study conducted
- Any unexpected results and investigations
- A conclusion that supports the proposed shelf life and storage conditions.

For closed shelf-life studies, data must be generated from testing at appropriate time intervals using at least three separate production batches of the IVD.

Temperature ranges assigned for testing should encompass both the upper and lower storage temperatures claimed. Real-time data which extends beyond the proposed shelf-life should be provided for at least one batch of product.

Accelerated data generated using product stored under exaggerated conditions (including elevated temperature, high humidity, increased light and vibration, as appropriate) are not generally accepted to support shelf-life claims. In limited circumstances, such data may be considered only as an interim measure for subsequent batches until real-time studies can be completed.

In-use (open vial) stability studies and transport simulation studies must be performed on at least one batch. Study design should reflect the intended use and the conditions the product is likely to encounter during handling and transport.

For further guidance, refer to CLSI standard EP25-A, Evaluation of Stability of In Vitro Diagnostic Reagents or an equivalent standard.

Information to be supplied with the IVD

that is to accompany the kind of IVD medical device when supplied in Australia, including:

- Labelling
- Instructions For Use and
- Advertising material (e.g. brochures, webpages, published advertisements, etc.), where available. The sponsor needs to ensure the material complies with the Advertising code.

Labelling and instructions for use are not necessarily required for every model or variation, unless there are significant differences in content.

However, the copies provided are required to be representative of what will be supplied in Australia.

The sponsor's name and address must be provided with the IVD in such a way that the user can readily identify the sponsor. Labelling requirements are prescribed in Regulation 10.2 and Essential Principle 13.2 in Schedule 1.

All representative information must be provided in English.

> Device specific guidance available here**:** Guidance on clinical performance requirements and risk mitigation actions for Human Immunodeficiency Virus (HIV) test kits

Depth of information to be provided

The following table summarises the depth of detail required to be contained in the device technical file.

Section	Class 1	Class 2	Class 3	Class 4
Device description including intended use				
Device description	Address each point - all classes			
Reference to comparison to similar or previous generation of devices	Summary	Summary	Summary	Summary
Global market history including incident reports and recalls	Summary	Summary	Summary	Summary
Risk management including analysis and control	Summary or reduced table			Detailed
QMS: Design and manufacturing information				
Device design and development	Summary	Summary	Summary	Detailed
Manufacturing processes	-	-	-	Summary
Analytical performance and other evidence				
Specimen validation	Summary	Summary	Summary	Detailed

Accuracy - Trueness	Summary	Summary	Detailed	Detailed
Precision - Reproducibility and repeatability	Summary	Summary	Detailed	Detailed
Traceability of control and control materials	Summary	Summary	Summary	Detailed
Analytical sensitivity	Summary	Summary	Detailed	Detailed
Analytical specificity	Summary	Summary	Detailed	Detailed
High Dose Hook Effect	Summary	Summary	Detailed	Detailed
Measuring range of the assay	Summary	Summary	Detailed	Detailed
Validation of assay cut-off	Summary	Summary	Detailed	Detailed
Other studies - including software and usability studies	Summary	Summary	Detailed	Detailed
Stability				
Claimed shelf-life	Summary	Summary	Detailed	Detailed
In use stability	Summary	Summary	Detailed	Detailed
Shipping stability	Summary	Summary	Detailed	Detailed
Clinical evidence				
Clinical evidence	Summary	Summary	Detailed	Elaborated

The following information provides explanations for the terms used in the table to describe the depth of detail required:

Summary information

- Brief description of protocol
- Study results
- Study conclusion

Detailed information

- Study protocol
- Method of data analysis
- Study report (summary of external reports)
- Study conclusion

Elaborated information

- Study protocol

- Method of data analysis
- Study report (all external reports)
- Study conclusion
- Raw or line data

See

- GHTF Study Group 1 - Pre-market Evaluation
- IMDRF Table of Content for IVD medical devices

General document submission guide

We require all the requested information to be provided as a complete stand-alone submission.

If an Essential Principle covers several different requirements or attributes (for example, EP 15 – Analytical Performance, or EP 5 – Stability), we recommend providing separate documents for each attribute. This helps keep the supporting evidence clear and easy to trace.

The quality, structure, and accessibility of your documents have a direct impact on how efficiently we can assess them. Well organised, clear, and searchable reports support a faster review and can significantly reduce assessment and turnaround times.

Cross-referencing to information submitted for previous applications—whether already included in the ARTG or still in progress—is not acceptable.

The sponsor must ensure the following submission format is used:

> **If your documents are not submitted in the recommended format, the assessment may be delayed, and we may need to ask you to resubmit the information in the correct format.**

Cover letter

Your cover letter should include:

- A list of the devices covered in the application
- The scope of the application
- The rationale for the device classification
- Any relevant background information (for example, details of pre-submission meetings)

This information should supplement what you have already provided in the Inclusion Application Form.

Table of contents

Provide a table of contents that clearly shows which documents correspond to each question in the Request for

Information.

You may use the In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (IVD ToC) as a reference.

Response to the request for information

Submit a clear response to each question in the Request for Information.

When preparing your documents:

- Ensure all documents are controlled in line with your quality management system procedures.
- Include version history when submitting updated documents, showing what has changed.
- Submit files preferably in PDF (or MS Word) in either of the following formats:
    - A single PDF with working bookmarks and a clickable table of contents, or
    - Individual files with clear, descriptive file names
- Use PDF images instead of JPEGs where possible, as they are easier to view and enlarge.
- Do not password-protect your files.
- Ensure all data is digitally searchable.
- Make sure all hyperlinks and bookmarks work.
- Set PDFs to “Inherit Zoom.”
- Provide documents in English.
- Ensure translations are completed by a certified translator.

Use descriptive file names and avoid special characters.

Depth of information

The level of detail required depends on the device’s classification.

Below is an explanation of the types of study information commonly required.

Study protocol

Your study protocol should include:

- Administrative details (sign-off by the instigator and facility, approval date, revision date, version number, etc.)
- The purpose of the study
- Study procedures, including materials used:
    - Reagents (with lot number, manufacturing or expiry dates), calibrators, controls, reference materials (with certificate of analysis)
    - Instruments (with serial or model number) and software (with version number)
    - Comparator method and any jurisdictional approvals
- Sample information (clinical or contrived):
    - Concentrations, matrix type, preparation, spiking method

- Test procedure details:
    - Testing dates, time points, material lots, replicates, and any retesting

Method of data analysis

Include:

- A description of the analysis methods used, including any statistical methods
- Acceptance criteria
- How discrepant results were handled

Study report and results

Your report should include:

- A summary of study results
- Results presented clearly with tables and graphs
- Confidence intervals
- Disaggregated data where relevant (for example, by age group or Ct value)
- An investigation of discrepant results

Study conclusion

Provide the final claims and conclusions supported by the study results.

Related links

Fees and payments links
Essential Principles checklist

Page history

12 May 2026

Update the document to:

- Add information acknowledging the release of the IMDRF ToC for IVD medical devices.
- Update references to various guidance

Improve clarity on the expectations around performance requirements including additional detail for Point of care testing devices

5 November 2024

Title changed from 'Application audit (technical file review) of IVD medical device applications' to 'Preparing for technical file review (application audit) for in-vitro diagnostic (IVD) medical devices' as part of migration to new 'Guidance' content type:

- Consistent ‘Purpose’ heading.
- ‘Legislation’ section to clearly show which laws the Guidance relates to.
- ‘Page history’ section replaces document version history.
- New page navigation features.
- Updated page summaries.
- Complex images include long descriptions.
- New ‘Save as PDF’ feature.

1 August 2022

Updated contact details.

1 February 2011

Original publication.

Related guidance

Complying with the Essential Principles on the safety and performance of medical devices

20 November 2025

Guidance on how medical devices must comply with the Essential Principles.