

Matching a COA to Supporting Reports

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Abstract. A COA and supporting laboratory report are comparable only when their identity, measurement basis and applicable requirements can be reconciled. Use this workflow for HA, β -TCP and 45S5 to identify missing evidence before accepting a sample or lot. Keep unresolved differences visible rather than selecting the more favorable result.

Keywords: COA review; test report; lot traceability; conformity; acceptance

1. Establish the document chain

Record the supplier, grade, material form, lot, sample identifier and test date from each document. Link the COA to the agreed specification revision and the supporting report number. If a report describes a development sample or another lot, label it as reference evidence rather than evidence for the delivered lot.

Ask which COA entries are measured on the lot, calculated, based on periodic testing or reported as typical values. Do not silently treat all four as equivalent. Record the responsible laboratory and any subcontracted work where relevant to the requested evidence.

2. Compare one requirement at a time

Copy the requirement, limit, result, unit and method into one comparison row. Also record sample preparation and the reporting basis. A difference in units, dry versus as-received basis, or phase normalization can prevent a valid comparison even when the numbers look similar.

Check whether the supporting method is suitable for the requested property. ISO 13779-3 covers HA-based material characterization [1]; it should not be assumed to define a 45S5 specification. Use the material-specific method and the applicable revision agreed for the order.

3. Separate results from a pass decision

A result below the quantification limit does not establish zero concentration. If the reporting limit cannot resolve the agreed acceptance limit, request an appropriate method or additional evidence. Keep the original report and the clarification together.

If a conformity statement is requested, identify the specification and decision rule, including how measurement uncertainty is handled. ILAC G8 explains that the rule should be agreed with the customer unless it is already inherent in the requested specification or standard [2]. There is no universal guard band for these materials.

4. Close or hold the discrepancy

For a mismatch, request a written explanation, a corrected record where justified, or a planned investigation. Do not average incompatible methods or replace an unfavorable result with an unexplained repeat. Record who resolves the issue and what evidence permits closure.

If accredited testing is needed, verify the laboratory and relevant accreditation scope. ISO/IEC 17025 concerns laboratory competence and operation [3]; accreditation is not product certification. A COA alone does not qualify the material for a finished medical device.

Table 1. A reconciliation record for each acceptance requirement.

Check	Compare or record	Disposition if unresolved
Identity	Grade, lot, sample and report identifiers	Request a traceable document link
Measurement	Method, preparation, units and basis	Clarify comparability before judging
Conformity	Limit, reporting limit and decision rule	Hold the acceptance decision
Resolution	Explanation, revision and accountable owner	Retain the issue and closure evidence

Scope. This is a document-review workflow, not a certificate, laboratory audit or release authorization. Acceptance remains subject to the agreed specification and the buyer's quality process.

References

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