



SAMPLE INTEGRITY GUIDE · 2D TUBES BY AUTOGEN

What's **really** in your sample tube?

"Medical-grade polypropylene" is where the conversation should start, not where it ends. What touches your sample depends on the exact resin recipe, how the tube is built and how the molding line is run. These are the questions to put to your tube supplier, and the proof you should expect back.

01 Start with the material

Polypropylene is a family of materials, not a single material. Resin makers compound **functional additives** into the polymer as tailored packages. They can go into homopolymer, copolymer or block copolymer grades, so the PP type alone tells you very little. What matters is the **exact grade and recipe** your tubes are molded from.

"Anything added to the polymer and incorporated into the base matrix can, especially over time, leach out again."

Four additive families are worth asking about by name:

Anti-static agents

Built to migrate to the surface so they can do their job, which puts them right where your sample is.

Nucleating / clarifying agents

Used to make PP look clearer. Their breakdown products can turn up in extracts.

Slip agents

Make parts release and handle more easily, and they also bloom to the surface.

Radiation additives

Stabilizers added to help resin get through sterilization. Ask whether your tube relies on them.

ASK YOUR SUPPLIER

- ? What exact resin grade is used, and can you show the resin maker's statement on intentionally added additives?
- ? Do any pigments, colorants or laser additives touch the sample?
- ? Are lubricants or release agents used on mold forming surfaces, and has this been audited?

02 Look at how the tube is built

Color, coding and sealing all need materials beyond plain PP. A well-designed tube keeps every one of them away from the sample.



Pure inner sleeve. Only an ultra-pure, additive-free layer touches the sample.

Outer layer carries the extras. Pigments and laser-marking additives sit only in the outer shell.

No mixing at the mold. Each layer runs on its own injection unit and hot-runner system.

03 Ask about the machinery

Mold release sprays, lubricants and machine grease are routine in plastics manufacturing. If any of them reach the **forming parts of the mold**, meaning the surfaces that shape the tube and cap, residues can end up on the part. Supplier datasheets almost never mention this, so ask directly.

How do you know if leachables are present?

You test for them, and your supplier should already have done it. Here's what credible data looks like and what to ask for.

Leachables

Substances that migrate from the tube into your sample under normal storage conditions.

Extractables

Substances forced out under harsh conditions. They show what *could* leach over time.

What good testing looks like

- **Broad screening by GC-MS and LC-MS**, always compared against a blank sample, to catch both volatile and non-volatile organics.
- **Realistic and aggressive media**, such as isopropanol, acidic and basic buffers, ethanol/water and DMSO, incubated for 72 h at 37 °C.
- **The whole closure system**: tubes, caps and seals, shredded and extracted together, not just the tube body.
- **Targeted analysis of PP processing residues** (see the table below).
- **Heavy metals by ICP-MS** per ISO 10993-18: arsenic, cadmium, chromium, lead, mercury and nickel.
- **Independent laboratories**, with documented methods, named labs and detection limits.

Common PP residues to test for

SUBSTANCE	WHERE IT COMES FROM
1-Dodecanol	Lubricant and mold-release agent used in PP processing
3,4-Dimethylbenzaldehyde	Breakdown product of sorbitol-based clarifying agents
Pentadecane	Thermal breakdown of additives or oligomers
Ethyl-4-ethoxybenzoate	Catalyst residue left from polymer synthesis

Fastest way to see the difference yourself: run a side-by-side GC-MS of your current tube against an alternative, using your own solvent and conditions. In independent comparisons, some tubes sold for the same applications have shown long-chain hydrocarbon signals and measurable lubricant or catalyst residues.

10 questions to ask your tube supplier

Every answer should come with documentation.

- 01 What is the exact resin grade, not just "medical-grade PP"?
Virgin? USP Class VI? From which resin manufacturer?
- 02 Are anti-static, nucleating/clarifying, slip or radiation additives intentionally added?
Ask for a written statement from the resin manufacturer.
- 03 Which material layer actually touches my sample?
- 04 Where are pigments and laser-marking additives, and can they reach the sample?
- 05 Are lubricants, release agents or grease used on the mold's forming surfaces?
Has an audit confirmed it?
- 06 Can I see GC-MS and LC-MS leachables data compared with a blank?
- 07 Were caps and seals included in extractables testing?
- 08 Have you tested for PP-specific residues like 1-dodecanol?
What were the detection limits?
- 09 Do you have heavy metal results by ICP-MS?
- 10 Who did the testing, and will you share the full reports?

How LVL SAFE® 2D Tubes answer

- ✓ SAFE® L3 virgin medical-grade PP with **no intentionally added functional additives**: no anti-static, nucleating/clarifying, slip or radiation additives.
- ✓ Sample-contact sleeve is additive-free. Pigments and laser additive are kept in the outer layer only.
- ✓ **No lubricants on mold forming surfaces** for tubes or caps, confirmed by production audit.
- ✓ No relevant leachable peaks vs. blank (GC-MS / LC-MS). All four PP residues below detection limits. Heavy metals below quantification limits.

Testing by independent labs including the University of Marburg (Dept. of Chemistry), ILK Dresden and Clean Controlling Medical. Ask us for the full LVL SAFE® Tech Note and test reports.