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the pure observer

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Reviewing Certificates of Analysis for Microbiological Media: TSA and TSB

In any sterile compounding operation, tryptic soy agar (TSA) and tryptic soy broth (TSB) are foundational tools used for environmental monitoring, sterility testing, and media fills. However, their effectiveness—and regulatory defensibility—depends on more than just purchasing from a reputable supplier. A critical step is thoroughly reviewing the certificate of analysis (COA) for each lot to confirm suitability before use. Below, we'll cover the essential elements you should verify, best practices for documentation, and tips for COA storage.

Key Elements to Review on the COA

1. Dates

Carefully check and reconcile all dates on the certificate:

- Manufacturing date
- Expiration date
- Date of sterilization or irradiation (if applicable)
- Certificate date

Make sure these dates are logical (e.g., the manufacturing date precedes the expiration date, and any sterilization or irradiation occurred prior to release). The shelf life should be consistent with the manufacturer's stated stability data.

If any date looks inconsistent, contact the manufacturer for clarification before use. We have seen date errors on COAs in the past.

2. Visual Characteristics

The COA should list:

- Appearance (color, clarity, presence or absence of precipitation, condensation)
- Media fill level (for pre-filled plates or tubes)
- Packaging integrity

Verify that the actual product matches the description in the COA when you receive it if possible. Depending on the packaging of the TSA plates, this may not be possible. If this is the case, train staff to verify that the media looks acceptable at the time of use. If you notice cloudiness, cracks, dehydration, or contamination, quarantine the lot, contact the manufacturer, and investigate. Be sure to thoroughly document the investigation.

3. pH

Acceptable pH ranges are typically specified, for example:

- TSA: 7.3 ±0.2
- TSB: 7.3 ±0.2

The pH must be tested by the manufacturer as part of release criteria and documented on the COA. pH outside of range can compromise growth promotion or inhibit recovery of organisms.

4. Growth Promotion

One of the most critical aspects of media quality control is growth promotion testing, which demonstrates that the media can recover low levels of specified microorganisms. The COA should document:

- the organisms tested (for TSA and TSB: *Staphylococcus aureus, Pseudomonas paraeruginosa, Bacillus subtilis, Candida albicans, Aspergillus brasiliensis)*
- the acceptance criteria (usually specified recovery within a given range)
- results of the test

If your media supplier does not provide growth promotion data for each lot, it's time to find another supplier.

5. Sterility

For sterile media, the COA should indicate:

- a confirmed absence of contamination (no growth during the incubation period)
- the methods used to test sterility

This is essential for applications such as sterility testing or media-fill simulations.

6. Irradiation (if applicable)

If your media is irradiated (common with gamma-irradiated TSA plates), the COA should state:

- the irradiation dose
- the date of irradiation
- confirmation that irradiation achieved sterility without compromising growth promotion

Recommendations for Reviewing and Approving COAs

1. Assign responsibility

- Designate a qualified individual (e.g., designated person, trained staff member) to review each COA before release of the media for use.

2. Use a standardized checklist

- Many facilities develop a review checklist or SOP covering:
  - lot number match to received inventory
  - verification of all dates
  - pH confirmation
  - growth promotion and sterility results
  - irradiation records (if applicable)
  - visual inspection upon receipt

2. Sign and date

- It is best practice to document the review by signing and dating the COA or the associated review form.
- Record any comments or deviations and retain evidence of resolution.

Storage of COAs

Paper-Based:

- Store in a controlled document binder or filing system.
- Organize by supplier, product type, and lot number.
- Ensure records are protected from damage and unauthorized access.

Electronic:

- Scan and store in an electronic document management system.
- Ensure the system is backed up regularly.
- Limit access to authorized personnel.

Regardless of format, retain COAs in accordance with your record retention policy and regulatory requirements—often at least 3–5 years or longer, depending on your operation.

Final Thoughts

Certificates of analysis are not just a formality—they are essential records demonstrating that your microbiological media is fit for purpose, compliant, and reliable. Consistent, critical review of each COA, along with thorough documentation and secure storage, helps protect your patients, supports regulatory compliance, and strengthens your overall quality system. Want to do more? Have your contract microbiology lab verify the COA by performing pH, sterility, and growth promotion testing on each lot of media you receive.

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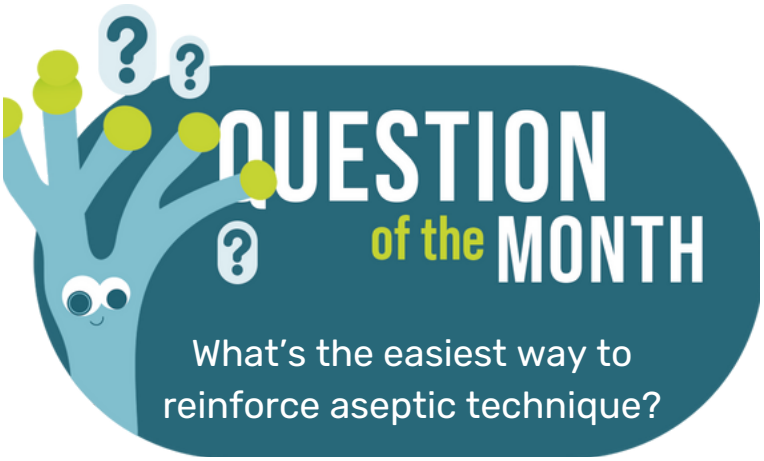
Reserve the infamous “triple clean” for cleanroom shutdowns and when there’s a total loss of the microbial state of control. Doing a triple clean after every microbial excursion is a waste of time, effort, and supplies.



- Conduct short, focused observations regularly—just 5–10 minutes a day will help you understand the challenges.
- Use a simple checklist to track compliance (e.g., touch contamination, slow hand movements, proper cleaning).
- Provide immediate, supportive feedback so staff can correct issues in the moment.
- Share positive examples to build a culture of pride in technique and patient safety.

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Abby Roth, founder of Pure Microbiology, has been supporting the testing and consulting needs of the pharmaceutical, medical device, and compounding industries since 2004. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring. Abby also has participated in multiple microbial excursion investigations, providing guidance on contamination sources and remediation options.