



# CHOOSING A QUALIFIED LABORATORY

BRAD STAWICK  
AOAC INTERNATIONAL

# WHAT WE WILL COVER...

- ▶ **Why Test**
- ▶ **Laboratory requirements**
- ▶ **Technical qualifications**
- ▶ **Service qualifications**
- ▶ **Cost**
- ▶ **Ability to meet expectations**
- ▶ **Things to look for...**



# HYPOTHETICAL



**Mary is looking for a new contract laboratory. She has narrowed it down to 2 labs.**

**Laboratory A has a proven quality system, excellent customer service with strong recommendations by other parties, and can do all of her testing.**

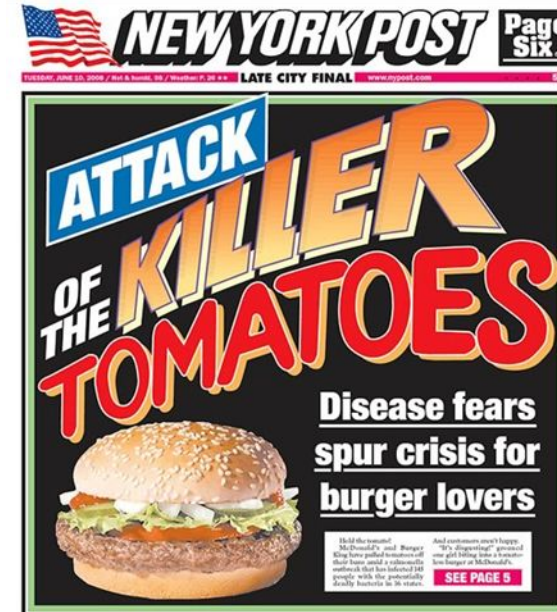
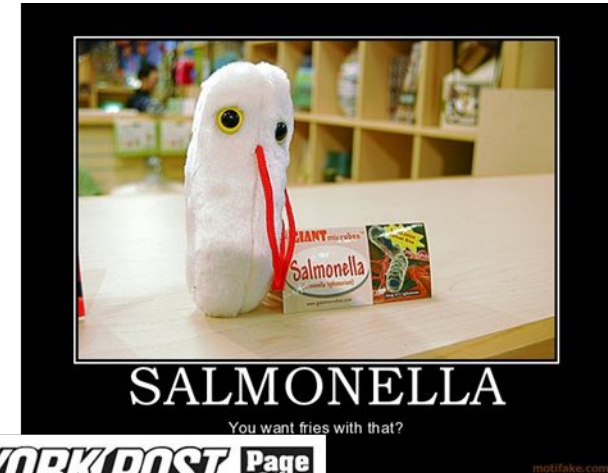
**Laboratory B has little experience with her matrix, has a basic quality system, and no one has a lot to say about them.**

**Lab B charges 20% less than Lab A.**

***What do you do?***

# WHY TEST?

- ▶ **Regulatory**
- ▶ **Product safety**
  - ▶ Recent recalls
  - ▶ Illness
- ▶ **Product quality**
- ▶ **Maintaining your brand**



# AREN'T ALL LABS THE SAME?

## Of course not...

- ▶ Specialties
  - ▶ Analysis
  - ▶ Matrix
  - ▶ Instrumentation
- ▶ Quality system
- ▶ Customer service
- ▶ Certifications and accreditations
- ▶ Cost



# LABORATORY REQUIREMENTS



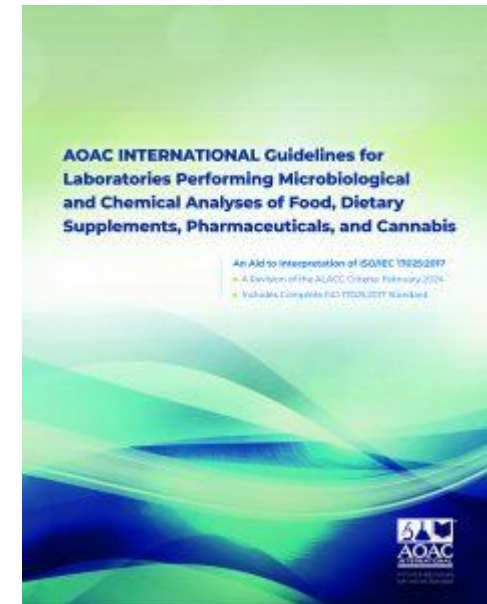
- ▶ **Subject to regulatory requirements**
- ▶ **Accreditation**
  - ▶ ISO 17025
  - ▶ ALACC criteria
  - ▶ Reputable accrediting body
- ▶ **Documented quality system**
- ▶ **Records**
- ▶ **Internal QC**
- ▶ **Training**
- ▶ **Reputable**

# ACCREDITATION

- ▶ **ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories**



- ▶ **AOAC International – Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, Pharmaceuticals, and Cannabis**



# ACCREDITING BODIES

## ▶ US

- ▶ A2LA
- ▶ ANAB
- ▶ NVLAP
- ▶ Perry Johnson

▶ <https://ilac.org/signatory-search/>

## ▶ Europe

- ▶ UKAS (UK)
- ▶ COFRAC (France)
- ▶ DakkS (Germany)
- ▶ Others

## ▶ Asia

- ▶ CNAS (China)
- ▶ IAJapan, VLAC (Japan)



# QUALITY MANAGEMENT SYSTEM

- ▶ **Quality Manual (optional)**
  - ▶ Roadmap to the system
  - ▶ Contains policies
- ▶ **Procedures**
  - ▶ Administrative, methods
  - ▶ Gives the “how to” for meeting policies
- ▶ **External documents**
  - ▶ Compendia/references
  - ▶ Standards



# QUALITY MANAGEMENT SYSTEM



- ▶ **Must be documented**
- ▶ **Should include:**
  - ▶ Quality manual/policy
  - ▶ Procedures
  - ▶ Documented methods
  - ▶ Best practices
  - ▶ Safety manual
- ▶ **Undergo periodic review**
- ▶ **MUST BE FOLLOWED**
- ▶ **Must be audited/assessed periodically**

# RECORDS

- ▶ **If you didn't record it, it didn't happen!**
- ▶ **Can include:**
  - ▶ Data
  - ▶ Audits
  - ▶ QC
  - ▶ Proficiency testing
  - ▶ Training



# INTERNAL QUALITY CONTROL



- ▶ **Proficiency testing**
- ▶ **Controls**
- ▶ **Reference material**
- ▶ **Training**
- ▶ **Approved vendors**
- ▶ **Calibrated equipment**

# TRAINING PROGRAM

- ▶ **Policies – often forgotten**
- ▶ **Methods**
  - ▶ Procedures
  - ▶ Demonstration of competence
- ▶ **General procedures**
- ▶ **Lab practices**
- ▶ **Focus on the details**



# TECHNICAL QUALIFICATIONS



- ▶ **Training**
  - ▶ **Proficiency testing**
  - ▶ **Calibration**
  - ▶ **Method validations**
  - ▶ **Quality Control**
  - ▶ **LCS**
- ▶ **Equipment qualification**
    - ▶ Maintenance
    - ▶ Verifications
    - ▶ Calibrations

# PERSONNEL



- ▶ **Hire competent people**
  - ▶ Experience
  - ▶ Schooling
- ▶ **Look at experience needed for job**
- ▶ **Personnel should:**
  - ▶ Read documents
  - ▶ Watch someone perform task
  - ▶ Prove competence
- ▶ **Records!!**

# TECHNICAL DEPTH



- ▶ **Do the lab managers have significant credentials?**
- ▶ **If you have a question, will they be able to help you?**
- ▶ **Do the analysts have the experience necessary to do their jobs?**
- ▶ **Is the testing you need part of the lab's primary focus?**

# METHOD SELECTION

- ▶ **Many customers of labs rely fully on the lab to select the method needed**
- ▶ **That might be fine, but it may not...ASK QUESTIONS!**
  - ▶ Does it give a meaningful result?
    - ▶ Quantitative
    - ▶ Qualitative
  - ▶ Does it meet your needs?
    - ▶ TAT
    - ▶ Sensitivity
    - ▶ Specificity
    - ▶ Validated in matrix

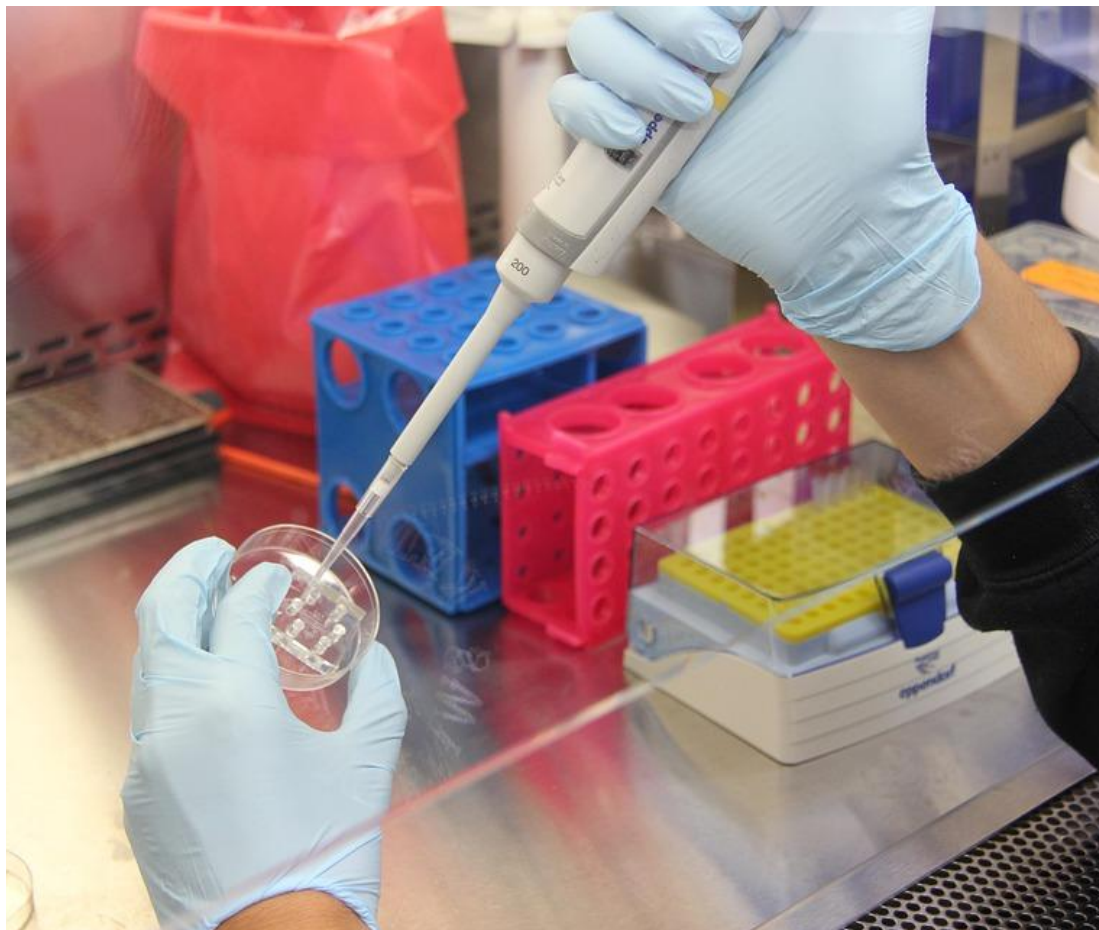


# MATRIX CONSIDERATIONS

- ▶ **Matrix interference**
  - ▶ Chemical interference
    - ▶ pH
  - ▶ Microbiological interference
    - ▶ Background flora
  - ▶ Physical interference
    - ▶ Homogenization of sample



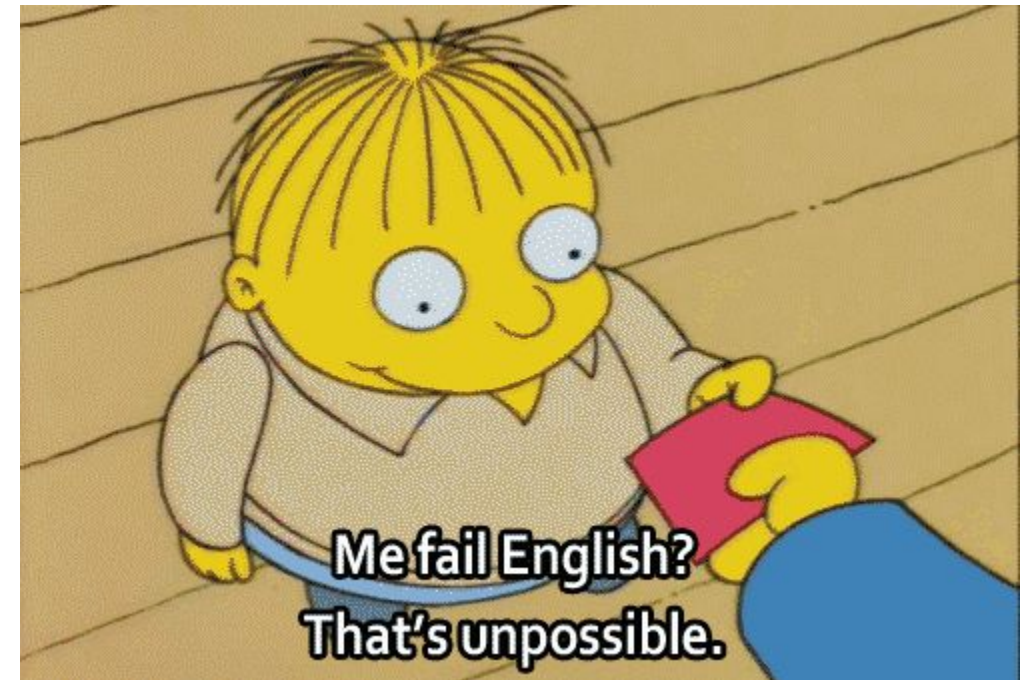
# ANALYSES



- ▶ **What is the source of the lab's methods?**
- ▶ **How is the lab ensuring that their tests are working?**
- ▶ **Are the analyses validated?**
- ▶ **Has the lab confirmed that the analyses work in their facility?**
- ▶ **Is the lab modifying the methods? Are they validated?**
- ▶ **Are all methods included in proficiency testing program?**

# PROFICIENCY TESTING

- ▶ **Compares lab to others**
- ▶ **Compares your performance over time**
- ▶ **Can be used for training**
- ▶ **Similar to auditing of lab**



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# PT OBJECTIVE



- **To improve analytical performance by providing an independent measure of the quality of the data.**
- **Demonstrates Technical Competence**
- **Demonstrates the lab is meeting Specific Quality Requirements**
- **Meets Accreditation (PT) or other Certification Requirements**

# BENEFITS OF PARTICIPATION



**Participating in a PT program has the following benefits:**

- **An independent evaluation of the general performance of the laboratory.**
- **A reasonably good estimate of the laboratory's bias for a particular analyte in relation to a peer group.**
- **A possibility of evaluating the long-term stability of the method in relation to the peer group.**
- **If the Programs acceptance criteria are not met, the investigation to reveal the cause of this will often result in a quality improvement affecting the real sample testing.**
- **The importance of meeting the Programs acceptance criteria will focus the laboratory on quality assurance issues such as daily QC measurements, QC-data comparison, training of personnel, standard operating procedures, and maintenance of equipment and will generally improve the overall quality of the testing process**

# AOAC OFFERS:

## PROFICIENCY TESTING

## EDUCATIONAL SAMPLES



- **Experienced Lab Personnel**
- **Established/Validated Methods**
- **Meets Customer Requirements**
- **Accreditation/Certification**
- **Ensure continuing quality from the lab**
- **Inexperienced/New Lab Personnel**
- **New Methods or Method Validation**
- **Training**
- **Corrective Action**
- **More.....**

# SERVICE QUALIFICATIONS

- ▶ **Communication**
- ▶ **Turn around time**
- ▶ **Sample set up**
- ▶ **Consulting ability**
- ▶ **Reporting**
- ▶ **Expertise**
- ▶ **Willingness to help**
- ▶ **Good reputation**



# CUSTOMER SATISFACTION



- ▶ **Does the lab solicit feedback from customers?**
- ▶ **Does the lab use the data?**
- ▶ **Has the lab provided references?**
- ▶ **Does the lab have a complaint policy?**
- ▶ **Do they use it?**

# COST



- ▶ **Balance of cost and service**
- ▶ **Balance of cost and expertise**
- ▶ **Balance of cost and modern methods**

# TOP 10 THINGS TO LOOK FOR...

1. **Documented quality system in place**
2. **Hiring practices and training**
3. **Proficiency testing**
4. **Customer satisfaction**
5. **Technical depth**
6. **Basis for analysis**
7. **Ongoing test performance**
8. **Accreditation**
9. **Appropriate methods**
10. **Equipment**

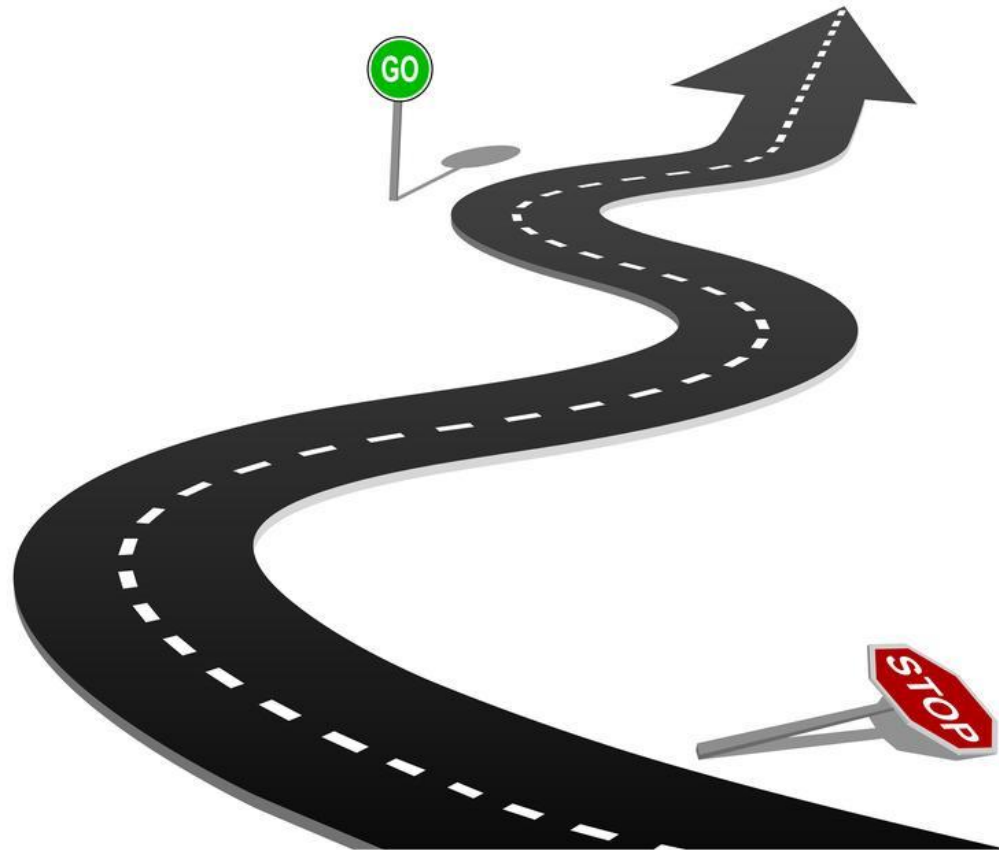


# THIS IS A LOT OF STUFF!

- ▶ **How do I get answers to all these questions?**
- ▶ **Scopes of accreditation**
- ▶ **Promotional material/websites**
- ▶ **Check references**
- ▶ **Visit the lab**
- ▶ **Ask questions**
- ▶ **Audit**



# EVALUATION



- ▶ **Comparing apples to apples**
  - ▶ Won't get all the same information from all labs
  - ▶ Prioritizing criteria
  - ▶ Determine your litmus tests
- ▶ **Ask for help**
  - ▶ Check references
  - ▶ Talk to your clients and vendors
  - ▶ Follow your suspicions

# WHAT TO EXPECT FROM LABS



- ▶ **Live up to their reputation**
- ▶ **Answer your questions**
- ▶ **Respond to any complaints**
- ▶ **Provide realistic answers to your concerns**
- ▶ **Meet your TAT**
- ▶ **Provide accurate and reliable data**

# CONCLUSIONS

- ▶ **All labs are not created equal**
- ▶ **Size of lab does not always mean a good lab**
- ▶ **Look at expertise**
- ▶ **Weigh options carefully**
- ▶ **Determine litmus tests**
- ▶ **Prioritize criteria**
- ▶ **Collect data**
- ▶ **Cost is not the only consideration**
- ▶ **Set reasonable and mutually agreed expectations with the lab and hold them to them**

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- ▶ **Academia:** Engage with colleagues – both students and faculty – at all career and research levels



*PERFORMANCE TESTED  
METHODS (PTM) PROGRAM*

- ▶ AOAC Research Institute program
- ▶ Provides independent third-party review and certification for proprietary test method performance
- ▶ Helps companies and their customers safeguard their businesses, mitigate risk, and protect consumers

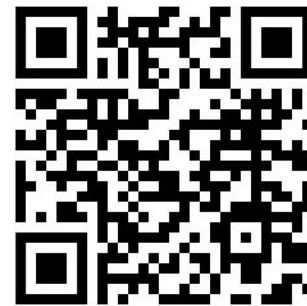


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**AOAC Membership Team:**

[CustomerService@aoac.org](mailto:CustomerService@aoac.org)

+1 (301) 924-7077 ext. 170



# AOAC PROFICIENCY TESTING



## Food & Environmental PT Programs

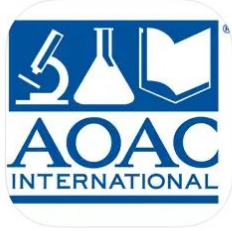


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## Cannabis & Hemp PT Programs

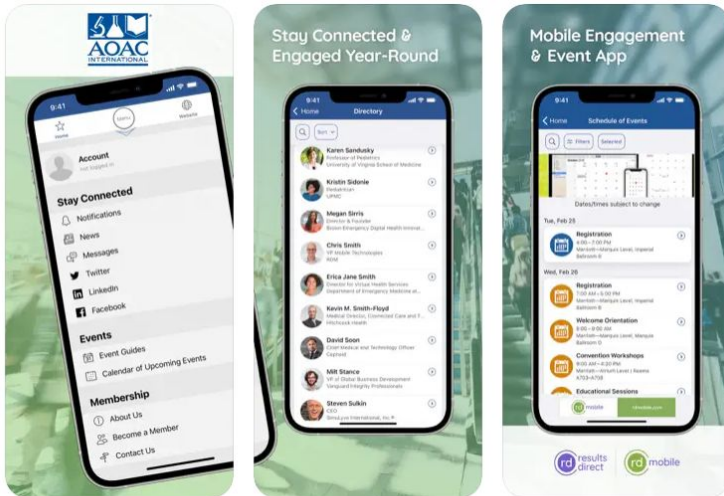


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