

**Laboratory Quality Systems**  
**Unit III: Validation of Analytical Procedures**  
**(Weeks 6 - 8)**

If you need help, please e-mail [prabha@otsc.tamu.edu](mailto:prabha@otsc.tamu.edu)

**Learning Objectives**

- Learn both the terminology and procedures for calculating performance indicators in laboratory method validation to assess fitness for purpose with an emphasis on instrumental methods.
- Understand the purpose of analytical procedure validation in a quality control laboratory with an emphasis on rapid methods

**Method Validation Overview**

Presentation

- [Method Validation](#) (33 min.) | [PDF](#)

Excel Demonstrations

Demonstrations	Associated Excel Files and other files
<a href="#">LOD and LOQ</a> (1 min.)	<a href="#">LOD/LOQ Excel File</a>
<a href="#">Horrat Value</a> (2 min.)	<a href="#">Horrat Annotated Excel File</a> Optional Readings: <a href="#">The Horwitz Ratio (HorRAT): A Useful Index of Method Performance with Respect to Precision</a>
<a href="#">Calibration Curve</a> (2 min.)	<a href="#">Calibration Curve Excel File</a>
<a href="#">Cochran Test and Grubbs Test</a> (7 min.)	<a href="#">Cochran and Grubbs Test Annotated Excel File</a> Optional Reading: <a href="#">Sample Criteria for Testing Outlying Observations</a>

Assigned Readings (Applies to all methods)

- [Harmonized Guidelines for Single Laboratory Validation of Methods of Analysis \(IUPAC Technical Report\)](#)
- [OTSC SOP – Validation of New Methods of Analysis \(2022\)](#)
- [Guidelines for the validation and verification of quantitative and qualitative test methods \(National Association of Testing Authorities, Australia, 2012\)](#)
- [AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals](#)

**Laboratory Quality Systems**  
**Unit III: Validation of Analytical Procedures**  
**(Weeks 6 - 8)**

If you need help, please e-mail [prabha@otsc.tamu.edu](mailto:prabha@otsc.tamu.edu)

**Rapid Tests**

Presentation

- [Method Validation of Rapid Tests](#) (27 min.) | [PDF](#)

Literature used in the Presentation

- [Design Criteria and Test Performance Specification for Biotechnology Rapid Kits](#)
- [Aflatoxin risk management in Texas: Test kit approval for maize](#) (Dai et al. 2013)
- [Design Criteria and Test Performance Specifications for Quantitative Aflatoxin Test Kits](#) (GIPSA, 2018)
- [BAM: Rapid Methods for Detecting Foodborne Pathogens](#) (FDA, 2001)
- [Validation Study of Rapid ELISA for Detection of Aflatoxin in Corn](#) (Lupo et al, 2010)
- [Validation of Qualitative Analytical Methods](#) (Trullols et al, 2004)

**Microbiology**

Presentation

- [Validation of Microbiological Processes](#) (31 min.) | [PDF](#)

Required Reading

- [Guidelines for the Validation of Analytical Methods for the Detection of Microbiological Pathogens in Foods and Feeds](#) (FDA 2015)

**Chemical Methods**

Presentation

- [Validation of Analytical Procedures: Chemical](#) | [PDF](#)
  - [Example Excel slide 28: Validation Data](#)
  - [Example Excel slide 31: Calibration Curve](#)

Literature used in the Presentation

- [AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals](#)
- [Rapid Determination of Fumonisin in Corn-Based Products by Liquid Chromatography/Tandem Mass Spectrometry](#) (Li et al, 2010)
- [Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis](#) (AOAC 2002)

**Laboratory Quality Systems**  
**Unit III: Validation of Analytical Procedures**  
**(Weeks 6 - 8)**

If you need help, please e-mail [prabha@otsc.tamu.edu](mailto:prabha@otsc.tamu.edu)

### **Spectroscopy**

Presentation

- [Method Validation of NIR Spectroscopy Method](#) (12 min.) | [PDF](#)

Demonstration

- [NIR Data Evaluation Annotated Excel Sheet](#)

### **Discussion**

Graded Discussion # 4: Due by Midnight on Monday, March 23, 2026 pts)

Method validation is an essential component of the measures that a laboratory should implement to allow it to produce reliable analytical data. All methods selected for use in a laboratory needs to be validated prior to use. Explain the criteria that should be used to select methods in a laboratory. List the steps involved in validating a method including any statistical analysis that should be conducted. Use assigned readings as appropriate.

Submit in course Google Group under Graded Discussion #4 Thread;

Access google group @[Laboratory Quality Systems – Spring 2026 - Google Groups](#)

E-mail: [lqs\\_2026\\_spring@lists.tamu.edu](mailto:lqs_2026_spring@lists.tamu.edu)

Graded Discussion # 5 –Due by Midnight on Monday, April 6, 2026 (5 pts) Reference Materials play a very important rule in method validation. However, in some cases, reference materials are not readily available. In this case, how would you validate the method without a reference material? Use assigned readings as appropriate.

Submit in course Google Group under Graded Discussion #5 Thread;

Access google group @[Laboratory Quality Systems – Spring 2026 - Google Groups](#)

E-mail: [lqs\\_2026\\_spring@lists.tamu.edu](mailto:lqs_2026_spring@lists.tamu.edu)

### **Assignments**

- [Homework # 5 \(Calculations for Validation\)](#) – Due by Midnight on Monday, March 30, 2026 (20 pts)  
Submit via e-mail to [outreach@otsc.tamu.edu](mailto:outreach@otsc.tamu.edu)