

Appendix 11: Method Validation Study Report Format Example

Method / Kit Title:

AOAC Performance Tested Methodsm MMYYYX

Abstract (Not more than 200 words.)

Scope of method

- *Target organisms*
- *Matrices*
- *Summary of validated performance claims*

Method Authors

Name, address

Submitting Company

Name, address

Independent Laboratory

Name, address

Reviewers

Name, address

Name, address

Introduction

General Information

General information about the target organisms (or analyte), matrix, occurrence of the organism or analyte in nature and its effect.

Principle

General description of the scientific principle of the test method.

Definitions

Sensitivity

Specificity

Accuracy

Materials and Method

Test Kit Information

Kit Name

Catalog Number

Ordering Information

USA. — address with telephone, fax, e-mail, and website addresses.

Europe. — other offices if available.

Test Kit Reagents

Reagent one. — brief description.

Reagent two.—

Additional supplies and reagents

Cite supplies and reagents as needed. — brief description, specifications, and source.

Apparatus

1. *Heating block. — brief description, specifications, source.*

2. *Temperature-controlled waterbath. — brief description, specifications, and source.*

Standard Reference Materials

Example: ECRC 96-1555 (available from the *E.coli* Reference Center, Pennsylvania State University, University Park, PA., USA)

Standard Solutions

Example: *Tris-borate EDTA electrophoresis buffer (TBE)*.— Dissolve 108 g Tris, 9.3 g Na_2EDTA , 55 g boric acid in ca 800 mL H_2O . Adjust pH to 8.2 with concentrated HCl and bring final volume to 1 L with H_2O .

Safety Precautions

Example: Electrophoresis gels contain ethidium bromide which is a potential mutagen. Observe all of the manufacturer's precautions for handling and disposal of these gels.

General Preparation

Examples:

1. Prepare media according to the manufacturer's instructions.
2. Turn on the heating blocks and set temperatures to 37° and 95° C.

Sample Preparation

1. Step-by-step description of sample preparation.

Analysis

1. Step-by-step description of process.
2. Etc as needed.

Interpretation and Test Result Report

Description of interpretation procedure and how results are reported.

Internal Validation Studies

Validation studies conducted in the laboratories of the Sponsor Company

1. Title of first study such as "Ruggedness Testing"
General description of the study such as: The effects of perturbations in four method parameters were investigated: 1) enrichment time (6-8 h); 2) sample volume (80-120 μL); and 3) incubation temperature (35-39°C)..
 - 1.2 Methodology
Describe the procedures used to conduct the study.
 - 1.3 Results
Describe the results of the study with reference to data tables and figures as needed.
2. Title of the second study such as "Inclusivity"
General description of the study.
 - 2.1 Methodology
Describe the procedures used to conduct the study.
 - 2.2 Results
Describe the results of the study with reference to data tables and figures as needed.

Independent Validation Studies

Validation studies conducted by the independent laboratory under the direction of the AOAC Research Institute.

1. Title of study such as "Method Comparison"
General description of the study.

1.1 Methodology

Describe the procedures used to conduct the study.

1.2 Results

Describe the results of the study with reference to data tables and figures as needed.

Discussion

General discussion of the all of the studies with particular emphasis on unexpected results, new knowledge about the analyte, target organism, matrix, or analytical technique.

References