

North Carolina Department of Agriculture & Consumer Services  
Food & Drug Protection Division

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Title: Proficiency Testing	

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**1. PURPOSE**

To provide a written procedure for laboratory proficiency testing requirements and reporting.

**2. SCOPE**

This procedure applies to all proficiency tests and check samples analyzed by FDPD labs in support of accreditation.

**3. RESPONSIBILITY**

The **Chief Microbiologist** and **Section Supervisors** are responsible for:

- Ensuring participation in proficiency testing/check sample programs to meet the requirements of A2LA, ISO 17025, and AOAC ALACC requirements.
- Annually updating the Master List of Proficiency Testing programs for their respective lab areas, including verifying accreditation status.
- Ensuring that proficiency testing samples are about equally distributed among personnel trained and qualified for the relevant test
- Establishing internal proficiency testing when external schemes are not currently available, according to A2LA guidelines.
- Documentation of any corrective actions required per this procedure.

The **Supervisors** are responsible for:

- Ensuring that proficiency testing samples are about equally distributed among personnel trained and qualified for the relevant test
- Reporting proficiency results to the proficiency test provider within the required timeframe.
- Entering results from the Proficiency Test Provider into the Document Control and Training database *in the month the results are received*.
- Initiating the corrective action process in the event that a proficiency test result is unacceptable as described in this procedure.

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**Laboratory Personnel** are responsible for

- Completing the analysis of proficiency samples following the same procedures and test methods used for routine samples, and within required timeframes, unless otherwise specified in the instructions from the proficiency test provider.
- Following any external Proficiency Test Provider's instructions

The **Quality Systems Manager** is responsible for:

- Submitting proficiency test results to A2LA *monthly* and according to their requirements.

**4. REFERENCES**

ISO/IEC 17025 (2005) Subclause 5.9

AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals [ALACC Criteria], (FDPD-ExDoc.032)

R103: General Requirements: Proficiency Testing for ISO/IEC 17025 Laboratories, (FDPD-ExDoc.074)

R103a – Annex: Proficiency Testing for ISO/IEC 17025 Laboratories, (FDPD-ExDoc.077)

AOAC Official Method 2007.01, Pesticide Residues in Foods by Acetonitrile Extraction and Partitioning with Magnesium Sulfate :Gas Chromatography/Mass Spectrometry and Liquid Chromatography/Tandem Mass Spectrometry

**5. RELATED DOCUMENTS**

Control of Nonconformities and Corrective Action (FDPD-QMS.009)

A2LA Proficiency Testing Data Submission form (FDPD-ExDoc.160)

Training and Competence (FDPD-QMS.014)

Traceability (FDPD-QMS.021)

**6. DEFINITIONS AND ACRONYMS**

**Check sample** - programs that are available through well-organized inter-laboratory comparisons.

*Note: for the purposes of this document, the terms **check sample** and external **proficiency test** will be used interchangeably*

**External Proficiency Testing** – proficiency sample programs that provide samples from an external test provider or external authoritative source. Commercially available proficiency tests and check samples are examples of external proficiency tests.

**Internal Proficiency Testing** – proficiency tests generated in-house (FDPD) in which samples are prepared or purchased and are administered and evaluated by authorized FDPD personnel. Previously run external proficiency samples, in which an expected result is established, may be used for internal proficiency tests

**7. SAFETY**

Not applicable

**8. EQUIPMENT/MATERIALS**

Not applicable

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## 9. PROCESS DESCRIPTION

### 9.1 Participation

The Section Supervisors and Chief Microbiologist ensure that the Master List (in the Document Control and Training Database) is kept current for the Proficiency Testing programs their respective laboratory areas participate in.

Whenever possible, Proficiency Testing providers will be accredited to ISO Guide 43. The accreditation status of commercial Proficiency Test providers is documented in the Document Control and Training Database. Section Supervisors ensure accreditation status of Proficiency Test providers is verified annually..

Wherever possible, Proficiency Tests will be purchased to evaluate ongoing performance of accredited test methods. If there is not a relevant and available external Proficiency Test, the laboratory has determined alternate actions to take (refer to section 9.3, Internal Proficiency Testing).

### 9.2 Schedule

The Section Supervisors and Chief Microbiologist ensure that proficiency testing activities are adequate to meet the needs of the laboratory with respect to the following:

- Adequate coverage over a 4-year period for every analyst trained and qualified on a particular method.
- A minimum of two proficiency tests per year in each of the types of test/method and/or techniques on the laboratory's scope of accreditation.

*Note: while the laboratory enrolls in a minimum of two proficiency tests per year per method/technology, not all proficiency test providers guarantee 2 occurrences of specific analytes per year. For example, the monthly medicated animal feed proficiency test usually includes decoquinatone 2 times per year, but this is not guaranteed. In cases like this, the lab is not required to conduct an internal proficiency test just to cover that analyte twice in a calendar year.*

- For test/method and/or techniques that are to be **added** to the laboratory's scope of accreditation: successful participation in at least one relevant and available proficiency test is required prior to an external assessment by A2LA.

*Note: Evidence of enrollment in suitable proficiency testing programs alone may suffice prior to being accredited for that method/technology but is subject entirely to A2LA's decision to accept this exception. This is normally done when the next scheduled round of the proficiency test will not occur for quite some time AND the laboratory has demonstrated competence through internal performance based data.*

The schedule is included on the Master List of Proficiency Testing programs located in the Document Control and Training database.

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The Quality Systems Manager is notified of any changes in participation in external proficiency test programs. The Quality Systems Manager notifies A2LA of changes related to the laboratory's scope of accreditation.

### **9.3 Internal Proficiency Testing**

The following alternatives are used when a relevant external Proficiency Test is not available.

- 9.3.1 Samples from a previous external proficiency study: Proficiency samples from previous cycles may be used when the frequency of established proficiency programs cannot meet the laboratory's needs. The analyst will not be told the identity or result from the prior cycle. Results will be compared/evaluated with the original study results (e.g. study standard deviation, study grand mean) .
- 9.3.2 Commercial premixed standards: Premixed commercial standards may be purchased and submitted to the analyst as a proficiency sample. The analyst will not be told the true value of the standard until after results are submitted. Results will be compared with Certificate of Analysis from vendor.
- 9.3.3 Laboratory prepared proficiencies: Laboratory Supervisors may prepare proficiency samples by mixing, spiking, and/or diluting known standards or organisms when other means are not available. The Laboratory Supervisor is responsible for ensuring samples are properly made and appropriate for the method. These proficiencies should represent the analytes and concentration that would normally be present in actual samples. The analyst will not be told the true value of the standard or organism until after final results are submitted.
- 9.3.4 Previously analyzed retained samples (For Qualitative Analysis ONLY): Due to lack of sufficient characterization data on samples, quantitative proficiency testing should not occur on previously retained samples. For qualitative proficiency testing a previously analyzed retained sample may be selected at random and resubmitted as an unknown. The Laboratory Supervisor is responsible for selecting, submitting, and determining the acceptance criteria. The analyst will not be aware of the prior identity of the sample or prior results.

***Note:** Preparation of Internal Proficiency Test samples from any of the alternatives above should be sufficiently documented in the individual laboratory section's PT Preparation logbook. The PT preparation logbook can take on many forms but must establish data traceability as per FDPD-QMS.021, Traceability. An example logbook page is provided in Attachment B to illustrate the information that should be captured.*

### **9.4 Analysis and Submission of Results to PT Provider**

#### **9.4.1 Analysis of a Proficiency Test**

FDPD personnel shall conduct proficiency tests in accordance with their normal testing/calibration and reporting procedures, unless otherwise specified in the instructions from the proficiency test provider. Running a PT more than once is prohibited except in the following instances:

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- 9.4.1.1 External PT Provider instructions specify running the sample more than once;
- 9.4.1.2 FDPD Test Method requires sample duplicates for routine samples; if you always run a sample duplicate, you may use the PT as a sample duplicate;
- 9.4.1.3 Quality Control results fail and are documented;
- 9.4.1.4 The precision between allowed replicates does not meet the Precision control chart.
- 9.4.1.5 If normal practice requires additional analysis of suspected violative samples, PTs may be treated as violative samples.
- 9.4.1.6 Samples which do not fall within the calibration curve may be diluted and re-analyzed.
- 9.4.1.7 Other circumstances may arise which could result in the need for repeated analysis. As long as the lab can demonstrate that customer samples would be re-analyzed if the same circumstances arose, the additional analysis is permitted, but explanation is documented in the data log or packet.
- 9.4.2 Distribution of Proficiency Tests Among Personnel
  - 9.4.2.1 Proficiency samples are distributed among personnel who might perform the analysis. The exception is in the case where only one specific person ever performs the analysis.
  - 9.4.2.2 Over the course of 4 years, all personnel who normally perform the test in question should have performed a PT.
- 9.4.3 External Proficiency Tests
  - 9.4.3.1 The supervisor compiles and submits the data to the external test provider by the provider's specified deadline. The supervisors maintain copies of submissions.
  - 9.4.3.2 Retention of the Proficiency Test sample is at the discretion of the lab section.
- 9.4.4 Internal Proficiency Tests
  - 9.4.4.1 Internal Proficiency Tests are reported to the Laboratory Supervisor via the normal reporting process. If the supervisor performed the analysis, results are reported to another analyst or the Section Supervisor. Name Internal Proficiency tests as follows:  
PT\_TMxxxx\_mmyy

## **9.5 Evaluation of Results**

- 9.5.1 At a minimum, the laboratory proficiency test report shall contain the following information for each test:

### For Qualitative Results:

- Reported value
- Assigned value<sup>†</sup>

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- Test rating (pass/fail, satisfactory/unsatisfactory, acceptable/unacceptable)<sup>†</sup>

For Quantitative Results

- Reported value
- Assigned value<sup>†</sup>
- Standard Deviation (estimation of variation)<sup>†</sup>
- Z-score<sup>†</sup>
- Test rating (pass/fail, satisfactory/unsatisfactory, acceptable/unacceptable)<sup>†</sup>

[<sup>†</sup> see notes after z-score calculation in section 9.5.4.1]

It is important that all Proficiency Test scores/ratings be entered into the Document Control and Training database during the month that they are received.

**9.5.2** External Proficiency Tests

9.5.2.1 Reports from the Proficiency Test Provider are reviewed by the Laboratory Supervisor and entered into the Document Control and Training database. Be sure to report negative z-scores as negative values.

9.5.2.2 The Laboratory Supervisor need to establish a test rating for quantitative or qualitative results if it is not given in the Proficiency Test Provider's report. Reasons for any exceptions to this should be documented. For quantitative results, calculate a z-score using the z-score calculation function in the Document Control and Training database. Suspected outlier points may only be removed after a statistical analysis proves them to be outliers. The rating and reasoning used (e.g. z-score, % recovery, x% of known value, % guarantee, quality control, correct ID, etc.) should be clearly indicated on the external providers report.

9.5.2.3 When calculating or recording the z-score, be sure to use the method-specific z-score whenever possible. If too few labs participated in a Proficiency Test using your particular method, it is acceptable to use the overall z-score.

9.5.2.4 If FDPD is the only lab who participated in the Proficiency Test, enter a pass/fail rating if the Proficiency Test Provider gives one. Otherwise, at least record the fact that you did the Proficiency Test in the Document Control and Training database.

**9.5.3** Internal Proficiency Tests

9.5.3.1 When applicable, previously run external proficiency test samples with quantitative results should have a z-score computed using the previous Proficiency Test Provider's reported mean and standard deviation values. Document the score in the Document Control and Training database.

9.5.3.2 For purchased standards or check samples used as in-house proficiency samples, the value obtained from analysis must match the value stated on

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the Certificate of Analysis, within the stated uncertainty; or, the value obtained from analysis must fall within the acceptance range stated on the purchased sample's documentation. Document the result in the Document Control and Training database.

*Example:* a purchased TDS check sample has a certificate which states it is 750mg/L ±50 mg/L. The acceptance criteria for this sample is then 700-800 mg/L. The result obtained by analysis must therefore be within 700-800 mg/L to be considered passing.

9.5.3.3 For proficiency samples prepared in-house (i.e. spikes) the Laboratory Supervisor should compute the z-score for quantitative results based on Percent Relative Standard Deviation (% RSD) of Control Chart(s). If a new analyst is running the Proficiency Test sample, one should consider whether this is reflected in the current control chart. Document the z-score in the Document Control and Training database.

9.5.3.4 For internal proficiency tests; the report generated in the database (after entering z-score, rating, etc.) serves as the Final Proficiency Test Report for that specific analysis.

9.5.4 Calculations

9.5.4.1 The z-score calculation using standard variation is shown below:

$$z = \frac{x - \mu}{\sigma}$$

Where x = FDPD's result (reported value)

μ= the grand mean from the PT provider (assigned value)

σ = the standard deviation reported from the PT provider  
(estimation of variation)

*†Note: The above formula typically works with external Proficiency Test schemes. However, sometimes in the absence of adequate participants in the external scheme, one must determine the best assigned comparator(s) and document the justification in the narrative provided in the Document Control and Training database (e.g. only one participant in a check sample program where an assigned value, mean and standard deviation do not exist).*

9.5.4.2 The z-score calculation based on %RSD is shown below:

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$$z = \frac{x - \mu}{\% RSD}$$

Where x = FDPD's result (reported value)

μ = mean from Control Chart data (assigned value)

% RSD = % Relative Standard Deviation (estimate of variation)

$$\% RSD = 100 * \left( \frac{\sigma}{\mu} \right)$$

Where σ = standard deviation from Control Chart data

μ = mean from Control Chart data (assigned value)

9.5.5 Pass/Fail Criteria

9.5.5.1 Quantitative Rating:

$|z| < 3 \longrightarrow$  Pass / Satisfactory / Acceptable

$|z| \geq 3 \longrightarrow$  Fail / Unsatisfactory / Unacceptable

**Note:** The laboratory Supervisor **should** evaluate instances where  $2 < |z| < 3$ . Although these values are passing/acceptable, they are considered questionable and could indicate issues with the analytical process/method performed [ISO/IEC 17025:2005 5.9.1 (3) ALACC Criteria March 2010].

9.5.5.2 Quantitative Rating (**Pesticide Residue Analysis, Internal Proficiency Test Only**):

50 – 150% Recovery [AOAC Official Method 2007.01]

9.5.5.3 Semi-Quantitative Rating:

If a test is read in a qualitative way, but the results are based on an underlying quantitative scale (i.e. a color reading that equates to a numerical value), it is considered a semi-quantitative test. If the semi-quantitative test is a screening test, and confirmation by another method would normally be performed for results above a certain reading, it is acceptable for the Proficiency Test to test whether the lab is competent to determine whether confirmation is needed.

*Example:* Indicator color strip testing is used to screen for nitrates in forages. Results above a particular color require the sample to be confirmed by IC. The PT need only test whether the lab correctly identifies the need for confirmation.

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9.5.5.4 Qualitative Rating:

Result Obtained	Rating
Correct Identification of presence or absence	Pass/Satisfactory/Acceptable
False Positive	Fail/Unsatisfactory/Unacceptable
False Negative	Fail/Unsatisfactory/Unacceptable
Incorrectly identified pathogen/property	Fail/Unsatisfactory/Unacceptable
Result not reported on time	Fail/Unsatisfactory/Unacceptable

*[ISO/IEC 17025:2005 5.9.1 (3) ALACC Criteria March 2010]*

*Note: Ratings established by the Proficiency Test Providers themselves supersede the above rating criteria and should be used in reporting test ratings.*

**9.6 Corrective Action**

9.6.1 Corrective action is initiated if the result of a proficiency test is unacceptable. A result will be unacceptable if any of the following are true:

- It is evaluated as “unacceptable” by the proficiency test provider
- The absolute value of the z-score is **greater than or equal to 3**
- The result is outside of the laboratory’s claimed estimation of uncertainty (using % RSD in determination)
- Result not reported on time

9.6.2 If an unacceptable result is received on an external proficiency test sample, then the laboratory will enroll in the next available round of proficiency testing, if that round had not already been scheduled. Such enrollment is documented in the corrective action initiated in response to the unacceptable result.

9.6.3 Prompt attention to questionable or unacceptable proficiency test results is critical.

9.6.4 When a corrective action is required as a result of a proficiency test, the completed corrective action report shall be promptly submitted to A2LA.

**9.7 Location of Proficiency Test Results**

9.7.1 The Laboratory Supervisor submits copies of the report by

- 1) scanning the complete Proficiency Test Report as one file in *Q:\quality\ISO Controlled Docs\Lab\Proficiency Tests\lab group\Year*. The file should be named so as to facilitate timely future retrieval, such as:  
PT provider name\_report number.

**-AND-**

2) should submit an email with the report or a summary of results (i.e. pass/fail) to

- the lab personnel who worked on the sample
- the supervision chain of command up to the Section Supervisors

9.7.2 Data packets supporting PT data are stored in the laboratory’s records.

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9.7.3 If the results are related to the Laboratory's Scope of Accreditation, the Quality Systems Manager is responsible for reporting the results to A2LA using the A2LA Proficiency Testing Data Submission form (see *Attachment A, Submitting PT Results to A2LA*, for process description).

9.7.4 Where applicable, Proficiency Test results may be used to support an employee's ongoing competency. Data for ongoing competency is retained per FDPD-QMS.011, Control of Laboratory Records .

*Note: Proficiency Test Samples submitted for evaluation can **only** be analyzed by laboratory personnel who already have an initial Demonstration of Competence (DOC) for that method/technology. If adequate PT sample exists after analysis by an analyst with a DOC, the sample can be used as an initial DOC sample for an untrained analyst but **cannot** be submitted as a proficiency test result.*

**10. ATTACHMENTS AND WORKSHEETS**

- Individual Laboratory Section PT Preparation Logbooks
- Attachment A, Submitting PT Results to A2LA
- Attachment B: Sample PT Preparation Logbook Page (for example only)

**11. APPROVAL/DOCUMENT HISTORY**

Document History		
Version #	Status (I, R)	Change History
5	R	Global re-write
Approved By: Chief Microbiologist		Date
Approved By: Bob McIntyre, Organic Section Supervisor		Date
Approved By: Teresa Grant, Food/Feed/Forage/Fertilizer Section Supervisor		Date
Approved By: Brenda Jackson, Quality Systems Manager		Date

I = Initial document; R = Revised

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**ATTACHMENT A**

**Submitting PT Results to A2LA**

PT results must be reported promptly to A2LA. Within the first week of each month, PT results should be reported to A2LA by the following process, to be carried out by the Quality Systems Manager or designee.

1. Search the Document Control and Training Database for all PT results entered within the last calendar month.
2. Report each PT Report (internal as well as external) for which we are accredited on A2LA's form F-104.
3. Email the Accreditation Officer the form and the cover sheet for each reported PT.
4. Save the email in *Q:\quality\ISO Controlled Docs\Lab\Proficiency Tests\Submitted\_to\_A2LA\*

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**ATTACHMENT B**  
Internal Proficiency Sample Preparation

PT ID #
Test Method:
Method Title:

Samples from a previous proficiency study  \_\_\_\_\_

Commercial premixed standards  \_\_\_\_\_

Laboratory prepared proficiencies  \_\_\_\_\_

Previously analyzed retained samples (Qualitative Only)  \_\_\_\_\_

Balance ID: \_\_\_\_\_

Weight/ Volume: \_\_\_\_\_

PREPARER INITIALS	DATE	LAB ID #	SAMPLE DESCRIPTION	ANALYTE	LOT #	MATRIX	SPIKE AMOUNT ADDED	EXPECTED RESULT	EXPECTED RESULT SOURCE (Z-SCORE, % RECOVERY, X% OF KNOWN)

Comments/Calculations:

Analyst(s) Assigned Sample: \_\_\_\_\_

Reviewed by:	Date Reviewed:
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