AAFP PROFICIENCY TESTING

Investigation Checklist of Unsatisfactory Proficiency Testing

This form is provided as a reference tool to investigate the possible causes of unsatisfactory proficiency testing results. Not all errors can be identified with one particular tool. Laboratories should consider the unique factors for each test system and expand its investigation when indicated. Complete the Proficiency Testing Corrective Action Form and attach to this checklist along with all records reviewed and other related documentation.

1. General
   - a. Did more than one challenge in this event fail? ☐ Yes ☐ No ☐ NA
   - b. Did more than one analyte fail? ☐ Yes ☐ No ☐ NA
   - c. Are there previous trends/unsatisfactory results for this test? ☐ Yes ☐ No ☐ NA
   - d. Do the SDIs show a bias in the current event? ☐ Yes ☐ No ☐ NA
   - e. Was there low consensus for the analyte? ☐ Yes ☐ No ☐ NA
   - f. Provide the scores for the failed analytes from the three prior events (most recent first):

Year	Event	Score
20___	_____	_____
20___	_____	_____
20___	_____	_____

2. Administrative
   - a. Were results submitted to AAFP-PT by the due date? ☐ Yes ☐ No ☐ NA
   - b. Did you print off the Data Submission Report? ☐ Yes ☐ No ☐ NA

3. Clerical
   - a. Were results transcribed correctly? ☐ Yes ☐ No ☐ NA
   - b. Verify that the decimal point and units of measure are correct. ☐ Yes ☐ No ☐ NA
   - c. Was the correct instrument/reagent kit in PT Central? ☐ Yes ☐ No ☐ NA
   - d. Were calculations performed correctly (even if automated)? ☐ Yes ☐ No ☐ NA
   - e. Do the values on Data Submission Report match the Evaluation report? ☐ Yes ☐ No ☐ NA

4. Specimen Handling
   - a. Was kit refrigerated immediately upon arrival? ☐ Yes ☐ No ☐ NA
   - b. Were contents of kit correct and in good condition? ☐ Yes ☐ No ☐ NA
   - c. Were specimen handling instructions followed? ☐ Yes ☐ No ☐ NA
   - d. Was testing performed within seven to 10 days of receipt? ☐ Yes ☐ No ☐ NA
   - e. Was sample at room temperature when tested? ☐ Yes ☐ No ☐ NA
   - f. Was sample mixed well before testing? ☐ Yes ☐ No ☐ NA
   - g. Was sample diluted properly, if required? ☐ Yes ☐ No ☐ NA

5. Quality Control
   a. Were quality control materials within the acceptable range on the date of PT testing? ☐ Yes ☐ No ☐ NA
   b. Were there unacceptable QC during the month previous to the day of testing? ☐ Yes ☐ No ☐ NA
   c. Were there unacceptable QC during the month following the day of testing? ☐ Yes ☐ No ☐ NA
   d. Any evidence of trends or shifts in the periods just before and just after PT was tested? ☐ Yes ☐ No ☐ NA
   e. Does QC demonstrate an even distribution (above/below) the mean? ☐ Yes ☐ No ☐ NA

6. Calibration
   a. Does the instrument require calibrations and/or calibration verifications? ☐ Yes ☐ No ☐ NA
      i. Was calibration or calibration verification performed when it was due? ☐ Yes ☐ No ☐ NA
      ii. When was the last calibration performed? _____ /_____ /_____
      iii. When was the last calibration verification performed? _____ /_____ /_____
      iv. Were any calibration problems noted? ☐ Yes ☐ No ☐ NA

7. Instrument
   a. Was daily maintenance performed on the date of PT testing? ☐ Yes ☐ No ☐ NA
   b. Was special maintenance (ex: annual PM) performed just prior to PT testing? ☐ Yes ☐ No ☐ NA
   c. Were instrument problems noted when PT was performed? ☐ Yes ☐ No ☐ NA
   d. Were results within reported linearity for instrument? ☐ Yes ☐ No ☐ NA
   e. Does the sample demonstrate a “matrix effect”? ☐ Yes ☐ No ☐ NA
   f. Have you contacted your instrument manufacturer for assistance? ☐ Yes ☐ No ☐ NA

8. Reagents/Kit
   a. Were new reagents or calibrators recently introduced at or near the time PT was performed? ☐ Yes ☐ No ☐ NA
   b. Are reagents/kit within expiration dates? ☐ Yes ☐ No ☐ NA
   c. Verify that open stability of reagents/kits was not exceeded. ☐ Yes ☐ No ☐ NA
   d. Were reagents/kit components reconstituted properly according to manufacturer package insert? ☐ Yes ☐ No ☐ NA
   e. Were kit components substituted from other kits? ☐ Yes ☐ No ☐ NA
   f. Was reagent/kit log checked for notation of any recent problems? ☐ Yes ☐ No ☐ NA
   g. Has there been changes in manufacturer formulary of reagents/kit? ☐ Yes ☐ No ☐ NA
   h. Were procedure versus manufacturer’s most current package insert reveiwed for any changes or updates? ☐ Yes ☐ No ☐ NA

9. Testing Personnel
   a. Date of last competency assessment for testing personnel. _____ /_____ /_____
   b. Were assay procedure and proficiency sample preparation instructions reviewed to ensure instructions were followed? ☐ Yes ☐ No ☐ NA
   c. Did you review with testing personnel how samples were loaded to rule out misidentification or transposition of samples? ☐ Yes ☐ No ☐ NA
   d. Was retraining of testing personnel required and if so is this completed? ☐ Yes ☐ No ☐ NA

10. Repeat Testing
    a. Repeat testing result: _____
    b. Is result now acceptable? ☐ Yes ☐ No ☐ NA

11. Microbiology specific
    a. Was QC acceptable for
        i. The media used? ☐ Yes ☐ No ☐ NA
        ii. The identification system? ☐ Yes ☐ No ☐ NA
        iii. Other biochemical testing? ☐ Yes ☐ No ☐ NA
        iv. Susceptibility testing? ☐ Yes ☐ No ☐ NA
        v. Stains used? ☐ Yes ☐ No ☐ NA
    b. Was the correct culture media selected for inoculation? ☐ Yes ☐ No ☐ NA
    c. Were the growth conditions acceptable (temp, CO2, humidity)? ☐ Yes ☐ No ☐ NA
    d. Were the cultures mixed? ☐ Yes ☐ No ☐ NA
    e. Were adequate isolation techniques used by the personnel? ☐ Yes ☐ No ☐ NA
    f. Was the McFarland standard acceptable? ☐ Yes ☐ No ☐ NA
    g. Did the organism demonstrate a typical biochemical reaction pattern? ☐ Yes ☐ No ☐ NA
    h. Were purity plates OK? ☐ Yes ☐ No ☐ NA
    i. Did the lyophilized organism demonstrate typical characteristics? ☐ Yes ☐ No ☐ NA

Additional Notes