Purpose: This form is provided as a reference tool for laboratories 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.

1. General
   A. Did more than one challenge in this event fail? □ Yes □ No
   B. Did more than one analyte fail? □ Yes □ No
   C. Are there previous trends/unacceptable results for this test? □ Yes □ No
   D. Do the SDIs show a bias in the current event or from event to event? □ Yes □ No
   E. Was there low consensus for the analyte or sample? □ Yes □ No
   F. Were there <10 participants in the event peer group? □ Yes □ No
   G. Provide the scores from the three prior events (most recent first):

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Score</th>
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2. Administrative
   A. Was the PT kit ordered on time? □ Yes □ No
   B. Were results submitted to the PT provider? □ Yes □ No
   C. Were results submitted to the PT provider on time? □ Yes □ No
   D. Did the PT provider receive the results? □ Yes □ No
   E. Was the PT provider instructed to report the results to CMS? □ Yes □ No
   F. Other ________________________________

3. Clerical
   A. Were results transcribed correctly? □ Yes □ No
   B. Was the correct method code selected? □ Yes □ No
   C. Was the correct reagent code selected? □ Yes □ No □ N/A
   D. Was the correct instrument code selected? □ Yes □ No □ N/A
   E. Was unit conversion performed correctly, if applicable? □ Yes □ No □ N/A
   F. Other ________________________________

4. Methodological & Technical (problems attributable to either the test system or laboratory personnel actions)
   A. Problem with proficiency testing material
      1. Was the kit received without delays in transport? □ Yes □ No
      2. Did the kit arrive at the appropriate temperature? □ Yes □ No
      3. Were proper storage conditions maintained? □ Yes □ No
      4. Were the samples prepared per the PT provider instructions? □ Yes □ No
      5. Other ________________________________
   B. Instrument maintenance
      1. Were there any problems with routine instrument maintenance? □ Yes □ No □ N/A
      2. Was there any unscheduled maintenance? □ Yes □ No □ N/A
      3. Was there service or repair by a service rep? □ Yes □ No □ N/A
      4. Were any major parts replaced? □ Yes □ No □ N/A
      5. Other ________________________________
   C. Calibration or calibration verification
      1. Did the instrument have successful calibrations or calibration verifications? □ Yes □ No □ N/A
      2. Was calibration or calibration verification performed when it was due? □ Yes □ No
      3. Date of last calibration before PT testing: □ Yes □ No □ N/A
      4. Date of last calibration verification before PT testing: □ Yes □ No □ N/A
      5. Was PT result within the linear range of instrument? □ Yes □ No

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1 Prepared at recommended temperatures with proper reconstitution volumes, diluents, etc.
2 At the manufacturer suggested intervals and according to laboratory policy.
3 As required by the manufacturer and at least every six months.
**Investigation of Unsatisfactory Proficiency Testing**  

*Initial ____*  

*Subsequent ___*

6. Other

**D. Quality control and reagents**

1. Was there unacceptable QC on the day of PT testing?  
   - [ ] Yes  
   - [ ] No

2. Was there unacceptable QC during the month previous to the day of testing?  
   - [ ] Yes  
   - [ ] No

3. Was there unacceptable QC during the month following the day of testing?  
   - [ ] Yes  
   - [ ] No

4. Were any shifts or trends identified?  
   - [ ] Yes  
   - [ ] No

5. Date of last lot change in QC material before PT testing:   
   - [ ] N/A

6. Date of last lot change in reagents before PT testing:   
   - [ ] N/A

**E. Microbiology specific**

1. Was QC acceptable for:
   - [ ] the media used?  
   - [ ] No  
   - [ ] N/A
   - [ ] the identification system?  
   - [ ] No  
   - [ ] N/A
   - [ ] other biochemical testing?  
   - [ ] No  
   - [ ] N/A
   - [ ] susceptibility testing?  
   - [ ] No  
   - [ ] N/A
   - [ ] stains used?  
   - [ ] No  
   - [ ] N/A

2. Was the correct culture media selected for inoculation?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

3. Were the growth conditions acceptable (temp, CO₂, humidity)?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

4. Were the cultures mixed?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

5. Were adequate isolation techniques used by the personnel?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

6. Was the McFarland standard acceptable?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

7. Did the organism demonstrate a typical biochemical reaction pattern?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

8. Were purity plates OK?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

9. Did the lyophilized organism demonstrate typical characteristics?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

**F. Immunohematology specific**

1. Was there a weak reaction?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

2. Was antibody detectable, but not identifiable?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

3. Was there interference caused by a positive direct antiglobulin test?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

**G. Repeat testing, if performed**

1. Repeat testing result:   
   - [ ] Specimen not available

2. Is result now acceptable?  
   - [ ] Yes  
   - [ ] No  
   - [ ] N/A

**5. Evaluation of Patient Results**

A. Determine if patient results could have been affected by the error since the last successful PT event.

B. If results could be affected, conduct an evaluation for potential adverse patient outcomes.

C. If the potential for adverse patient outcomes is identified, notify the patient's physicians, per 42 CFR 493.1282.

**6. Plan of Action Review**

A. Are policies and procedures written in a manner to prevent recurrence?  
   - [ ] Yes  
   - [ ] No

B. Are systems and processes designed to prevent recurrence?  
   - [ ] Yes  
   - [ ] No

C. Are personnel trained and competent on the above (items 6A & 6B)?  
   - [ ] Yes  
   - [ ] No

D. Is there ongoing oversight in place to prevent recurrence?  
   - [ ] Yes  
   - [ ] No

**Testing personnel:**

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Signature of Laboratory Director / Date  
Signature of General Supervisor/ Date

Retain this record for at least two years.

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4 Reference standards not expired, correct standard dilution was used, pipette delivered correct volumes, etc.

5 Lyophilized organisms sometimes lose their characteristics and require multiple culture passes to regain expression.