# IQA Investigation Form

**Date:** **Site:**

**Proficiency Provider & Panel:**

**Test Analyte(s):** **Reported Result:** **Acceptable Result:** **Previous Survey Problems:**

## Laboratory Investigation: *(Please attach all supporting documentation. Include detailed comments when ever possible. The comment section will expand as needed.)*

1. Was the survey report examined for discrepancies, clerical errors and appropriate codes?
Comments:

2. Were there problems noted for the survey material (i.e., receiving temperature, handling, reconstitution, storage or analysis)?
Comments:

3. Was the method & instrument history reviewed (i.e., Was daily preventative maintenance performed? Were reagents investigated –open date, expiration date, number of tests left on the reagent, instrument settings, etc.)?
Comments:

4. Was Quality Control reviewed? ☐ YES ☐ NO
A. How did you establish QC Mean? ☐ parallel testing ☐ Use manufacturer's
B. How did you set your QC ranges? ☐ Manufacture's range (package insert) ☐ Your lab established
C. What QC rules do you use? Please explain.
D. Number of levels of QC run? ☐ 1 ☐ 2
E. Does your laboratory track Coefficient of Variation (CV*) for analytes? ☐ YES ☐ NO *(*CV =SD/Mean x 100)*
F. Was your QC for this analyte within ±2 SD on day the survey was run? ☐ YES ☐ NO
G. Were any biases, shifts, or trends seen in your QC? Please Explain.
Comments:

5. Was the manufacturer consulted or service requested about this issue? When did the manufacturer's last service the instrument?
Comments:

6. Were the survey samples assayed again after the investigation? (Please attach results below or as a separate file.)
Comments:

7. Was the instrument's calibration data investigated? ☐ YES ☐ NO
A. Was the calibration data reviewed from before and after the survey run? ☐ YES ☐ NO
B. Prior to running the survey, when was the instrument last calibrated?
C. What date was the calibrator opened?
D. When do you recalibrate (i.e., with new reagents or only with new lots?)?
Comments:

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8. Was personnel competency reviewed? (Conduct staff education or retraining if applicable.)
Comments:

9. Were study participant results assessed for adverse effects? If applicable, review participant results, amend results and notify physicians, study staff, network representatives.
Comments:

## Type of Error:

- ☐ Methodological
- ☐ Technical
- ☐ Clerical
- ☐ Survey evaluation problem
- ☐ Other (explain) _____

**Investigative Actions and Root Cause:** Briefly discuss what actions were taken in this investigation and what you believe is the primary cause of this EQA problem.

**Future Preventative Measures:** Briefly discuss how you will prevent this problem from occurring in the future.

## Prepared by:

_____

Name/Title Date Signature

Note: Please complete the report and submit it to IQA within 30 days.

| **For IQA use only.** | | | | |
|---|---|---|---|---|
| **IQA Review:** | ☐ | Acceptable and complete Investigation. | ☐ | Investigation is incomplete. See comments. |
| Comments: | | | | |
| Name/Title | | Date | | |