

FREQUENT REASONS OF “OUT-OF-CONTROL” CASES AND WHAT TO DO

Dr. Hilmar Luthe
LAB consulting

Introduction

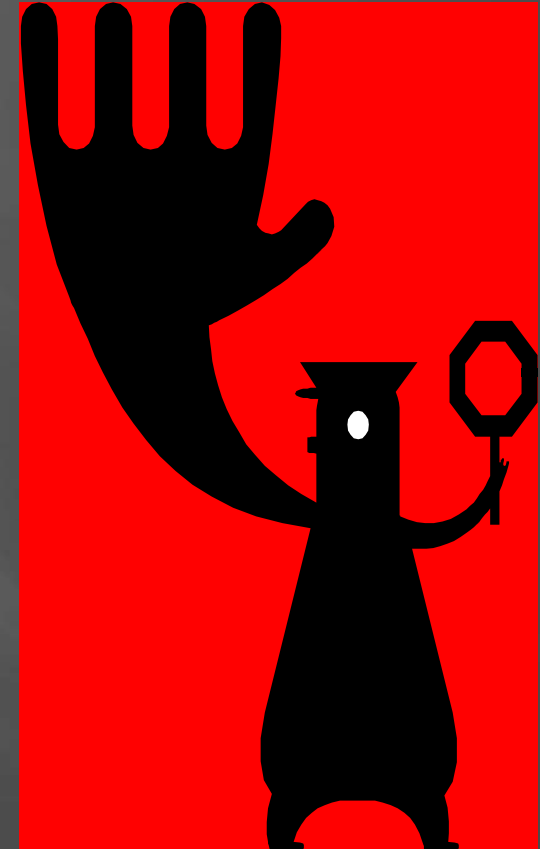
When making measurements, there is always some level of inaccuracy. The challenge is to reduce the level of inaccuracy as much as possible given the limitations of our testing systems. An accuracy level of 99% may at first glance appear acceptable but the resulting 1% error can become quite large in a system where many events occur such as laboratory testing.

MONITORING QC DATA

- Statistics are used to draw lines in a diagram for patient specimens, control specimens and calibrators
- If the results are “normal”, we are comfortable about them and don't worry
- But if they are abnormal, we are uncomfortable and we fear that there is something wrong with the patient
- or just as bad, something is wrong with the test procedure

If QC is out of control

- **STOP testing**
- identify and correct problem
- repeat testing on patient samples and controls after correction
- **Do not report patient results** until problem is solved and controls indicate proper performance



Solving out-of-control problems

- identify problem
- refer to established policies and procedures for remedial action



Possible Problems

1. degradation of reagents or kits
2. control material degradation
3. operator error
4. failure to follow manufacturer's instructions
5. an outdated procedure manual
6. equipment failure
7. calibration error

Possible Problems

1. Degradation of reagents or kits

- ✓ Reagents and supplies are stored improperly
- ✓ Reagents become out-dated before they are used
- ✓ The life-span of reagents can vary from a few weeks to a number of years
- ✓ Make sure the reagents have not expired

Possible Problems

2. Control material degradation

- ✓ If in-house control material is used, freeze aliquots and place in the freezer so that a small amount can be thawed and used daily
- ✓ Do not thaw and refreeze control material
- ✓ Monitor and maintain freezer temperatures to avoid degradation of the analyte

Possible Problems

3. Operator error

- ✓ Good protocols for troubleshooting and corrective action are important for the quality control process.
- ✓ There must be written policies and procedures that are followed by all laboratory staff
- ✓ The operator has to observe instrument drift
- ✓ It is important to repeat the preventive maintenance procedures as a first step to resolve the problem

Possible Problems

4. Failure to follow manufacturer's instructions and outdated procedure manual

- ✓ Reagents should be stored according to manufacturer's instructions, labelled with the date they are opened and put into use
- ✓ Test kits may come with modified manufacturer's instructions, and these modifications need to be reflected in the SOPs
- ✓ Incorrect sample or reagent quantities can cause very serious errors and should always be suspected when several employees obtain erroneous results.

Possible Problems

5. Equipment failure

- ✓ Maintenance includes measures such as systematic and routine cleaning, adjustment, and replacement of equipment parts at scheduled intervals
- ✓ Train staff on the use and maintenance of the equipment and assure that all staff understand their specific responsibilities
- ✓ **Do not use faulty equipment!** Seek help from the manufacturer or other technical expert

Possible Problems

6. Calibration error

- ✓ Everyone who uses the equipment should be trained in calibration and daily maintenance
- ✓ Follow the manufacturer's directions carefully when performing the initial calibration of the instrument
- ✓ Confusion about who has responsibility for calibrating an instrument could result in the calibration is not being done

Conclusions

- Laboratories not implementing a good quality management system are guaranteed that there will be many errors and problems occurring that may go undetected.
- Implementing such a quality management system may not guarantee an error-free laboratory but it does yield a high quality laboratory that detects errors and prevents them from recurring.