**3. Provision of sufficient clinical information to ensure that the proper choice of growth medium, probe sets, and analytic techniques are made**

REFERENCES
1) Clinical and Laboratory Standards Institute (CLSI). *Developing and Using Quality Indicators for Laboratory Improvement.* 2nd ed. CLSI guideline QMS12. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.

**CYG.20800 Procedure Failures** **Phase II**

**The number or frequency of culture failures, hybridization failures, and/or suboptimal analyses is recorded, and there are records of corrective action when adverse trends occur.**

# QUALITY CONTROL (QC)

## SUPERVISION OF QUALITY CONTROL

## Inspector Instructions:

| | |
|---|---|
|   | • Sampling of QC policies and procedures<br>• Sampling of QC records<br>• Records of final report error investigation |
|   | • How do you determine when QC is unacceptable and when corrective actions are needed? |
|   | • Select several occurrences in which QC is out of range and determine whether the steps taken follow the laboratory procedure for corrective action. |

**CYG.30066 Monthly QC Review** **Phase II**

**The laboratory director or designee reviews and assesses quality control data at least monthly.**

*NOTE: QC data may include specimen handling, culture failures, new media QC, new reagent lot verification, etc. The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.*

*The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.*

**Evidence of Compliance:**
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

**CYG.30325 Reporting Error Investigation** **Phase II**