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 • Sampling of QC records • 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**

All errors that are identified in the final report are thoroughly investigated, and the results of such investigations are recorded.

NOTE: The results of such investigations must be recorded and reviewed as part of the ongoing laboratory QM process.

CYG.30350 Specimen Handling — Phase II

Records indicate the media used, culture conditions, probes used, and incubation times for all preparations.

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services, Clinical laboratory improvement amendments of 1988; final rule. Fed Register. 2003(Jan 24): [42CFR493.1276(b)(1)]

CYG.30360 QC Handling — Phase II

The laboratory tests control specimens in the same manner and by the same personnel as patient/client samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:

- ✓ Records reflecting that QC is run by the same personnel performing patient testing

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7166 [42CFR493.1256(d)(8)]; 2) *ibid,* 2003(Jan 24):3708 [42CFR493 1256(d)(7-8)].

CYG.30550 QC Confirmation of Acceptability — Phase II

Personnel review control results for acceptability before reporting patient/client results.

Evidence of Compliance:

- ✓ Records of control result approval

REFERENCES
1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7166 [42CFR493.1256(f)]

CYG.30600 Alternative Control Procedures — Phase II

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Specific examples for cytogenetics include:

- *Confirming the presence of similar karyotypic changes in two independently established cultures analyzed by two different technologists*
- *For SNP array, correlating the results from the SNP and copy number data*
- *Correlating the results obtained by one method with another when a combination of methods are performed (eg, correlating G-banded chromosome analysis with FISH results or genomic array)*