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)*

- *Refer to CYG.43200 for in situ hybridization*

Evidence of Compliance:

✓ Records of alternative control procedures

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): [42CFR493.1256(h)].

REPORTS

Reporting requirements for use of analyte-specific reagents and other reagents used in laboratory-developed tests are included in the All Common Checklist (COM.40850).

Inspector Instructions:

	• Sampling of reporting policies and procedures • Sampling of patient preliminary and final reports for completeness, appropriate use of ISCN edition and recommendations for genetic consultation or additional studies • Sampling of TAT statistics
	• How does your laboratory maintain records of verbal/telephone preliminary reports? • What is your course of action when turnaround times exceed limits?
	• Search for reporting errors. Determine whether the investigation was thorough and appropriate corrective action was taken.

CYG.31825 Preliminary Reports **Phase I**

Provision of preliminary reports (especially verbal, telephone reports) is recorded on the final report.

CYG.31875 Final Report Elements **Phase II**

The final reports contain all of the following required elements:

1. **Name and address of testing laboratory**
2. **Patient name**
3. **Unique identifying number**
4. **Patient date of birth**
5. **Name of physician, or authorized person ordering test**
6. **Specimen source**
7. **Date specimen received in the laboratory**
8. **Date of report**
9. **Clinical indication(s) for the test**
10. **Number of cells counted, analyzed, and karyograms prepared, as applicable**
11. **Band resolution (required only for constitutional cases), as applicable**
12. **Banding methods, as applicable**
13. **Comment on adequacy of specimen, if indicated**