

- 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:

 READ	<ul style="list-style-type: none"> 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
 ASK	<ul style="list-style-type: none"> How does your laboratory maintain records of verbal/telephone preliminary reports? What is your course of action when turnaround times exceed limits?
 DISCOVER	<ul style="list-style-type: none"> 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