

INTRODUCTION

This checklist is used in conjunction with the All Common (COM) and Laboratory General Checklists to inspect a cytogenetics laboratory section or department.

Cytogenetics inspectors should be pathologists, cytogeneticists or cytogenetic technologists who are actively involved with or have extensive experience in the practice of cytogenetics, are knowledgeable about current CAP Checklist and CLIA requirements, and have completed CAP Inspector Training. Inspectors should, to the greatest extent possible, be peers of the laboratory being inspected.



Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

LABORATORY SAFETY

The inspector should review relevant requirements from the Safety section of the Laboratory General checklist, to assure that the cytogenetics laboratory is in compliance. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

QUALITY MANAGEMENT

Inspector Instructions:

 READ	<ul style="list-style-type: none"> Sampling of quality monitoring records
 DISCOVER	<ul style="list-style-type: none"> Review records of culture and hybridization failures, and sub-optimal analyses for trends. Determine if the procedures and processes produce a thorough investigation with appropriate corrective action taken.

CYG.20200 Quality Indicators

Phase I



The laboratory monitors and evaluates key quality indicators, such as the following:

1. Control of pre-analytic variables (specimen collection and delivery)
2. Cytogenetic, in situ hybridization, and chromosomal microarray analysis test ordering practices

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:

READ 	<ul style="list-style-type: none"> • Sampling of QC policies and procedures • Sampling of QC records • Records of final report error investigation
ASK 	<ul style="list-style-type: none"> • How do you determine when QC is unacceptable and when corrective actions are needed?
DISCOVER 	<ul style="list-style-type: none"> • 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