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Crosswalk of Proposed Revisions to Cytogenetics Standards

2014 Standard	2014 Guidance	2016 Standard	2016 Guidance
Cytogenetics Standard 1 (CG S1) The laboratory shall request clinical information necessary for proper initiation of test procedures and interpretation of test results, including, for prenatal analysis, the gestational dating.	This may be accomplished by including an appropriate section on the test requisition. If the clinical information is not included with the specimen, the laboratory should request this information. If the clinical information is not received, the laboratory record should be so noted and the report should state that the clinical information was not provided and should include any limitations of the result due to this omission.	**Cytogenetics Sustaining Standard of Practice 2 (CG S2): Clinical Information** The laboratory shall request clinical information necessary for proper initiation of test procedures and interpretation of test results, including, for prenatal analysis, the gestational dating.	This may be accomplished by including an appropriate section on the test requisition. If the clinical information is not included with the specimen, the laboratory should request this information. If the clinical information is not received, the laboratory record should be so noted and the report should state that the clinical information was not provided and should include any limitations of the result due to this omission.
Cytogenetics Standard 2 (CG S2) The laboratory shall have a system to distinguish specimen types to assure proper processing, handling and analysis, to facilitate quality assurance review, and to segregate data for reporting.	The identification system should be part of the accession system in order to identify the specimen type.	**Cytogenetics Sustaining Standard of Practice 3 (CG S3): Specimen Type** The laboratory shall have a system to distinguish specimen types to assure proper processing, handling and analysis, to facilitate quality assurance review, and to segregate data for reporting.	The identification system should be part of the accession system in order to identify the specimen type.

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Cytogenetics Standard 5 (CG S5) The laboratory shall establish and implement a procedure for: a) contamination control in media; b) monitoring bacterial, viral, fungal and mycoplasma contamination; and, c) in-house growth support testing of tissue culture media.	a) Laboratories that choose not to routinely use antibiotics in cultures should document that individual cultures are routinely checked for signs of contamination. b) Laboratories that use commercially prepared media should retain the manufacturer's documentation that each shipment or lot of media has been subjected to appropriate quality control procedures. The user should visually examine each shipment for contamination, appearance, or evidence of exposure to extremes of temperature, and notify the media manufacturer of problems related to the quality of the media, including failure to support growth or provide expected colony size, or evidence of contamination. c) In-house growth support tests may include parallel testing of the mitotic index or cell doubling time of cultures and criteria for acceptance for growth support should be established. This may include growth support studies performed by the manufacturer if available.	**Cytogenetics Sustaining Standard of Practice 7 (CG S7): Media Quality Assurance** The laboratory shall establish and implement a procedure for: a) contamination control in media; b) monitoring bacterial, viral, fungal and mycoplasma contamination; and, c) in-house growth support testing of tissue culture media.	a) Laboratories that choose not to routinely use antibiotics in cultures should document that individual cultures are routinely checked for signs of contamination. b) Laboratories that use commercially prepared media should retain the manufacturer's documentation that each shipment or lot of media has been subjected to appropriate quality control procedures. The user should visually examine each shipment for contamination, appearance, or evidence of exposure to extremes of temperature, and notify the media manufacturer of problems related to the quality of the media, including failure to support growth or provide expected colony size, or evidence of contamination. c) In-house growth support tests may include parallel testing of the mitotic index or cell doubling time of cultures and criteria for acceptance for growth support should be established. This may include growth support studies performed by the manufacturer if available.

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Cytogenetics Standard 6 (CG S6) The laboratory shall prepare replicate independently established cultures: a) for prenatal specimens, a minimum of three cultures shall be set up for each specimen; b) for other tissue or fibroblast cultures, a minimum of three cultures shall be set up for each specimen; and, c) for all other specimens, duplicate cultures shall be set up.	Analyzed cells should be selected from at least two independently established cultures, except for routine blood cultures when the laboratory has pre-determined that adequate numbers and quality of cells with consistent results are obtained from a single culture.	**Cytogenetics Sustaining Standard of Practice 6 (CG S6): <u>Replicate Cultures</u>** The laboratory shall prepare replicate independently established cultures: a) for prenatal specimens, a minimum of three cultures shall be set up for each specimen; b) for other tissue or fibroblast cultures, a minimum of three cultures shall be set up for each specimen; and, c) for all other specimens, duplicate cultures shall be set up.	Analyzed cells should be selected from at least two independently established cultures, except for routine blood cultures when the laboratory has pre-determined that adequate numbers and quality of cells with consistent results are obtained from a single culture.
Cytogenetics Standard 7 (CG S7) Prenatal cultures shall be split between two incubators used exclusively for prenatal cultures with independent electrical circuits and emergency alarms.	If such arrangements are not feasible, the laboratory should establish a written protocol for prompt handling of prenatal cultures in the event of an equipment failure that might adversely affect viability and test outcome.	**Cytogenetics Sustaining Standard of Practice <u>10 (CG S10): Redundant Incubation</u>** Prenatal cultures shall be split between two incubators used exclusively for prenatal cultures with independent electrical circuits and emergency alarms.	If such arrangements are not feasible, the laboratory should establish a written protocol for prompt handling of prenatal cultures in the event of an equipment failure that might adversely affect viability and test outcome.

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Cytogenetics Standard 8 (CG S8) Independently established prenatal cultures shall be processed so as to maintain individual culture integrity.	Processing includes setting up, feeding, and harvesting cultures, and labeling slides.	**Cytogenetics Sustaining Standard of Practice 11 (CG S11): Replicate Processing** Independently established prenatal cultures shall be processed so as to maintain individual culture integrity.	Processing includes setting up, feeding, and harvesting cultures, and labeling slides.
Cytogenetics Standard 9 (CG S9) The laboratory shall establish and implement procedures to ensure utilization of accepted intervals of culture to optimize cell division.	Approximate processing times vary for each diagnostic area, but generally should fall within the following time frames: Blood: 48-72 hours; 96 hours for special methods Amnio: 6-14 days Tissue: 1-6 weeks Bone Marrow - Direct: 72 hours Others: As established by the laboratory.	**Cytogenetics Sustaining Standard of Practice 12 (CG S12): Culture Intervals** The laboratory shall establish and implement procedures to ensure utilization of accepted intervals of culture to optimize cell division.	Approximate processing times vary for each diagnostic area, but generally should fall within the following time frames: Blood: 48-72 hours; 96 hours for special methods Amnio: 6-14 days Tissue: 1-6 weeks Bone Marrow - Direct: 72 hours Others: As established by the laboratory.

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Cytogenetics Standard 10 (CG S10) The laboratory shall prepare a minimum of two karyotypes per specimen: a) if more than one cell line is detected, a minimum of one karyotype per cell line; b) using photographic or other image reproduction techniques; c) using banded cells which meet the laboratory's pre-established criteria for banding quality and resolution; and, d) identified with the metaphase source and specimen identifiers.	c) The laboratory shall identify individual chromosomes by banding methods, including G, Q or R or other methods that allow identification of all homologs. The laboratory shall document policy and review procedures to ensure that the intended chromosome band resolution, or other appropriate measure for non-banded preparations, is attained and is appropriate to the specimen and clinical information provided in order to rule out the cytogenetic abnormality(ies) reasonably expected based on the clinical information provided. The average band resolution attained should be included in the result report (Cytogenetics Standard 21c). If the band resolution attained is not optimal for the clinical indications for testing, appropriate comments and recommendations should be included in the result report (Cytogenetics Standard 21d, e, f). d) The metaphase may be identified by vernier location, and/or film and frame number	**Cytogenetics Sustaining Standard of Practice <u>13 (CG S13): Karyotyping</u>** The laboratory shall prepare a minimum of two karyotypes per specimen: a) if more than one cell line is detected, a minimum of one karyotype per cell line; b) using photographic or other image reproduction techniques; c) using banded cells which meet the laboratory's pre-established criteria for banding quality and resolution; and, d) identified with the metaphase source and specimen identifiers.	c) The laboratory shall identify individual chromosomes by banding methods, including G, Q or R or other methods that allow identification of all homologs. The laboratory shall document policy and review procedures to ensure that the intended chromosome band resolution, or other appropriate measure for non-banded preparations, is attained and is appropriate to the specimen and clinical information provided in order to rule out the cytogenetic abnormality(ies) reasonably expected based on the clinical information provided. The average band resolution attained should be included in the result report (Cytogenetics Standard 21c). If the band resolution attained is not optimal for the clinical indications for testing, appropriate comments and recommendations should be included in the result report (Cytogenetics Standard 21d, e, f). d) The metaphase may be identified by vernier location, and/or film and frame number

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	of photograph.		of photograph.
Cytogenetics Standard 12 (CG S12) The laboratory shall analyze a minimum number of metaphases as indicated below: a) a minimum of 20 metaphases, except for prenatal, in situ, which requires 15 metaphases; and, b) count cells from at least two cultures for all specimens except peripheral blood for constitutional chromosome abnormality analysis.	Analyzed means to establish the number of centric chromosomes in a metaphase AND evaluate individual chromosomes in their entirety, i.e., each metaphase is critically analyzed, including chromosome count, sex chromosome complement, cytogenetic aberrations and vernier location. The minimum count will often be exceeded when multiple cell lines are observed. Based on a laboratory's pre-established criteria, cells from replicate cultures may be analyzed. When mosaicism is suspected on the basis of a phenotype that does not fit with the karyotype, when sex chromosome abnormalities are suspected, or when single trisomic cells are found during a study, an analysis of at least 50 cells is recommended.	**Cytogenetics Sustaining Standard of Practice <u>16 (CG S16): Metaphase Analysis</u>** The laboratory shall analyze a minimum number of metaphases as indicated below: a) a minimum of 20 metaphases, except for prenatal, in situ, which requires 15 metaphases; and, b) count cells from at least two cultures for all specimens except peripheral blood for constitutional chromosome abnormality analysis.	Analyzed means to establish the number of centric chromosomes in a metaphase AND evaluate individual chromosomes in their entirety, i.e., each metaphase is critically analyzed, including chromosome count, sex chromosome complement, cytogenetic aberrations and vernier location. The minimum count will often be exceeded when multiple cell lines are observed. Based on a laboratory's pre-established criteria, cells from replicate cultures may be analyzed. When mosaicism is suspected on the basis of a phenotype that does not fit with the karyotype <u>or</u> when sex chromosome abnormalities are suspected~~, or when single trisomic cells are found during a study,~~ an analysis of at least 50 cells is recommended.

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Cytogenetics Standard 15 (CG S15) For laboratories conducting spontaneous breakage studies a normal (negative control) shall be included with each culture event.		**Cytogenetics Sustaining Standard of Practice 14 (CG S14): Spontaneous Breakage Studies** For laboratories conducting spontaneous breakage studies a normal (negative control) shall be included with each culture event.	
Cytogenetics Standard 16 (CG S16) For laboratories conducting breakage studies on presumed positive specimens, a normal (negative control) and if possible an abnormal control for the condition in question shall be included with each culture event.		**Cytogenetics Sustaining Standard of Practice 15 (CG S15): Presumed Positive Breakage Studies** For laboratories conducting breakage studies on presumed positive specimens, a normal (negative control) and if possible an abnormal control for the condition in question shall be included with each culture event.	
Cytogenetics Standard 17 (CG S17) The laboratory shall establish and implement a protocol for checking microscope stage vernier readings, and making corrections as necessary.		**Cytogenetics Sustaining Standard of Practice 9 (CG S9): Vernier Readings Procedure** The laboratory shall establish and implement a protocol for checking microscope stage vernier readings, and making corrections as necessary.	

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Cytogenetics Standard 18 (CGS18) Records for each case shall include: media used, reactions observed, culture conditions including incubation times, adverse observations, subculturing information (if any), number of cells analyzed and additional cells counted, type of banding utilized, the number of cells from which karyotypes were prepared and karyotypes prepared.		**Cytogenetics Sustaining Standard of Practice 25 (CG S25): Required Records** Records for each case shall include: media used, reactions observed, culture conditions including incubation times, adverse observations, subculturing information (if any), number of cells analyzed and additional cells counted, type of banding utilized, the number of cells from which karyotypes were prepared and karyotypes prepared.	

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Cytogenetics Standard 19 (CGS19) The laboratory shall have a system for maintaining and retrieving the entire case record, including the original metaphase and interphase images and karyotypes, when applicable, for the required 25 years.	This applies to image analysis software as well.	**Cytogenetics Sustaining Standard of Practice <u>26 (CG S26): Records Retention</u>** The laboratory shall have a system for maintaining and retrieving, <u>for the required 25 years,</u> the entire case record, including, <u>when applicable,</u> the original: a) metaphase and interphase images and karyotypes b) <u>metaphase and interphase FISH images representative of results</u> c) <u>CMA analysis file(s) that include relative copy number and genotype, as applicable, and data quality metrics values.</u>	This applies to image analysis software as well.

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Cytogenetics Standard 21 (CG S21) In addition to the requirements of Part 58, the final report shall include: a) use of the current International System for Human Cytogenetic Nomenclature (ISCN); b) the number of cells analyzed and, when applicable, the number from which karyotypes were prepared; c) band resolution attained; d) in cases of culture failure or where a definitive diagnosis is not possible, suggestions for additional testing; e) an interpretation of findings; f) a statement on limitations of the test, including possible inaccuracies; and, g) suggestions as to whom the physician and/or patient may consult for discussion of prognosis implications of abnormal results (e.g., genetic counseling).	A summary and interpretation of the results are recommended.	**Cytogenetics Sustaining Standard of Practice 21 (CG S21): <u>Reporting</u>** In addition to the requirements of Part 58, the final report shall include: a) use of the current International System for Human Cytogenetic Nomenclature (ISCN); b) the number of cells analyzed and, when applicable, the number from which karyotypes were prepared; c) band resolution attained; d) in cases of culture failure or where a definitive diagnosis is not possible, suggestions for additional testing; e) an interpretation of findings; f) a statement on limitations of the test, including possible inaccuracies; g) suggestions as to whom the physician and/or patient may consult for discussion of prognosis implications of abnormal results (e.g., genetic counseling);	A summary and interpretation of the results are recommended. a) Results may be reported in other formats in addition to ISCN

		h) Reports that include FISH results must include: 1) number of cells analyzed 2) probe target and vendor 3) cutoff values for interphase FISH, and i) Reports that include CMA must include: 1) platform description, including number and distribution of probes 2) genome build used for analysis and interpretation.	
Cytogenetics Standard 22 (CG S22) Reports shall contain the signature of the qualified person who reviewed, approved and/or diagnosed the case.	For purposes of this standard, a qualified person is a director or assistant director who holds a valid New York State certificate of qualification in Cytogenetics. Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password).	**Cytogenetics Sustaining Standard of Practice 22 (CG S22): Report Signatory** Reports shall contain the signature of the qualified person who reviewed, approved and/or diagnosed the case. Use of an electronic signature must be limited to the qualified person to ensure secure authorization and documentation for each occurrence.	For purposes of this standard, a qualified person is a director or assistant director who holds a valid New York State certificate of qualification in Cytogenetics. ~~Laboratories using electronic signatures should have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password).~~

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Cytogenetics Standard 24 (CG S24) The laboratory shall have the capability to track a specimen from accession number to karyotypes, when applicable, and report, to microscope slide and conversely.		**Cytogenetics Sustaining Standard of Practice 5 (CG S5): Specimen Tracking** The laboratory shall have the capability to track a specimen from accession number to microscope slide, karyotypes, FISH images, and CMA results, when applicable, and to report and conversely.	

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Cytogenetics Standard 25 (CG S25) The laboratory shall establish critical limits for turn-around-times of certain tests important for prompt patient management decisions, which minimally include: a) final reports of prenatal analyses are provided within 15 days in at least 95% of cases; b) final reports of peripheral lymphocyte and bone marrow analyses are provided within 28 days in at least 90% of cases; c) preliminary reports for STAT fetal blood or STAT neonatal blood samples are available within 72 hours in at least 90% of cases; and, d) final reports for non-neoplastic fibroblast analysis are provided within six weeks in at least 90% of cases.	The laboratory should have a policy to ensure that later gestational age specimens are given priority so that results are released prior to the 25th week of gestation in order to allow patient decisions regarding pregnancy termination.	**Cytogenetics Sustaining Standard of Practice 4 (CG S4): Turn Around Times** The laboratory shall establish critical limits for turn-around-times for all clinical tests, including standard methods, fluorescent in-situ hybridization (FISH), and chromosomal microarray analysis (CMA).	TAT targets should be based on criteria that include specimen type and indication/reason for referral. The laboratory should have a policy to ensure that later gestational age specimens are given priority so that results are released prior to the 25th week of gestation in order to allow patient decisions regarding pregnancy termination. Chromosomal microarray analysis (CMA) as used in these standards is intended to include array-based tests for copy number and/or heterozygosity/homozygosity including but not limited to array comparative genomic hybridization (aCGH).

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Cytogenetics Standard 26 (CG S26) The laboratory shall monitor and document the nature and rate of cultures that fail to yield metaphases, and take remedial action in all cases.	This should be an ongoing quality assurance monitor.	**Cytogenetics Sustaining Standard of Practice 8 (CG S8): Culture Quality Assurance** The laboratory shall monitor and document the nature and rate of cultures that fail to yield metaphases, and take remedial action in all cases.	This should be an ongoing quality assurance monitor.
Cytogenetics Standard 27 (CG S27) The laboratory shall establish and implement procedures to obtain follow-up information for confirmation of all prenatal diagnosis.	The responsibility of obtaining this information cannot be delegated. Discrepancies of phenotypic sex and abnormal outcome should be fully evaluated. This is the only means a laboratory has to obtain predictive value of the analysis.	**Cytogenetics Sustaining Standard of Practice 24 (CG S24): Prenatal Diagnosis Confirmation** The laboratory shall establish and implement procedures to obtain follow-up information for confirmation of all prenatal diagnosis.	The responsibility of obtaining this information cannot be delegated. Discrepancies of phenotypic sex and abnormal outcome should be fully evaluated. This is the only means a laboratory has to obtain the predictive value of the analysis.

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Cytogenetics Standard 28 (CG S28) The laboratory shall notify practitioners wishing to order a cytogenetic test that informed consent is required and shall make available to the practitioner test-specific information for patient use in decision-making and the informed consent process. These materials shall include: a) general description and statement of purpose for the test; b) indication that the individual may wish to obtain professional genetic counseling prior to giving consent; c) a statement that a positive result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may want to consider further independent testing, consult their physician or pursue genetic counseling; d) a general description of the disease or condition related to the test; e) the level of certainty that a positive test result serves as a predictor of the	Informed consent is not required for cancer cytogenetic testing. Laboratories should be aware that cytogenetic testing is also covered by Section 79-l of the Civil Rights Law. Reasonable effort should be made to obtain patient consent and document the process. While patient consent forms are recommended to be on file in the laboratory; the referring physician may sign the test requisition or other form indicating that she or he conveyed the required information to the patient and obtained consent. g) Research testing may be performed on residual specimen pursuant to a research protocol approved by an institutional review board provided that: i. the subject, or the subject's authorized representative, has provided written	**Cytogenetics Sustaining Standard of Practice <u>1 (CG S1): Informed Consent Materials</u>** The laboratory shall notify practitioners wishing to order a cytogenetic test that informed consent is required and shall make available to the practitioner test-specific information for patient use in decision-making and the informed consent process. These materials shall include: a) general description and statement of purpose for the test; b) indication that the individual may wish to obtain professional genetic counseling prior to giving consent; c) a statement that a positive result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may want to consider further independent testing, consult their physician or pursue genetic counseling; d) a general description of the disease or condition related to the test; e) the level of certainty that a positive test result serves as	Informed consent is not required for cancer cytogenetic testing. Laboratories should be aware that cytogenetic testing is also covered by Section 79-l of the Civil Rights Law. Reasonable effort should be made to obtain patient consent and document the process. While patient consent forms are recommended to be on file in the laboratory; the referring physician may sign the test requisition or other form indicating that she or he conveyed the required information to the patient and obtained consent. g) Research testing may be performed on residual specimen pursuant to a research protocol approved by an institutional review board provided that: i. the subject, or the subject's authorized representative, has provided written

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disease; f) the persons or organizations to whom the test result may be disclosed; g) a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and, h) provision for the signature of the individual subject of the test or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual.	informed consent for the specific research; ii. the sample has been permanently stripped of identifying information; and iii. the research participant has consented to the de-identification.	a predictor of the disease; f) the persons or organizations to whom the test result may be disclosed; g) a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and, h) provision for the signature of the individual subject of the test or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual.	informed consent for the specific research; ii. the sample has been permanently stripped of identifying information; and iii. the research participant has consented to the de-identification.

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Cytogenetics Standard 29 (CG S29) Laboratories must obtain the subject's written consent, or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual, before records, findings or results may be re-disclosed to any individual or organization other than those authorized on the test requisition to receive the result.		**Cytogenetics Sustaining Standard of Practice 23 (CG S23): Consent to Release** Laboratories must obtain the subject's written consent, or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual, before records, findings or results may be re-disclosed to any individual or organization other than those authorized on the test requisition to receive the result.	

NEW STANDARDS:

Cytogenetics Sustaining Standard of Practice 17 (CG S17): Laboratory Developed FISH Analysis For laboratory-developed FISH tests, the laboratory shall analyze a number of cells appropriate to the specimen type, reason for referral, and aberrations expected. At a minimum, the laboratory must analyze: 1) for metaphase FISH a) to detect nonmosaic microdeletion – 10 cells b) to characterize abnormal chromosome – 5 cells c) for mosaic aberrations or samples expected to be mosaic based on indications – 20 cells 2) interphase FISH a) constitutional studies - 50 nuclei	Unexpected results may require analysis of more cells. FDA-approved/cleared tests should be analyzed as described in the package insert or its equivalent. FISH for microduplications should include analysis of interphase nuclei. Lab should have policies for "borderline" results near cutoff values A pathologist must guide identification of tumor cells in tissue sections

b) acquired studies i) suspension culture – 100 cells ii) tissue section – 50 tumor cells.	
Cytogenetics Sustaining Standard of Practice 18 (CG S18): Metaphase Preparation Acceptability Laboratories must establish criteria to determine the acceptability of standard metaphase chromosome preparations and document acceptability of each preparation prior to reporting.	Criteria may describe circumstances (for example, irreplaceable sample) under which a preparation not meeting acceptability criteria might be reported.
Cytogenetics Sustaining Standard of Practice 19 (CG S19): FISH Hybridization Acceptability Laboratories must establish criteria to determine the acceptability of each FISH hybridization and document the acceptability of each hybridization prior to reporting. Such criteria must include: a) signal intensity b) background/noise c) appropriate internal (normal homolog and/or control probe) and/or external controls.	
Cytogenetics Sustaining Standard of Practice 20 (CG S20): FISH Analysis Accuracy With respect to Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy, the laboratory minimally must confirm accuracy of FISH testing based on procedure, test design (fusion, breakapart, enumeration, etc) and specimen type (suspension, smear/touch, fixed tissue section, etc).	