

Prepublication Requirements

• Issued June 19, 2020 •



New and Revised Requirements Addressing Embryology, Molecular Testing, and Pathology

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical The Joint Commission Perspectives®. To begin your subscription, call 800-746-6578 or visit <http://www.jcrinc.com>.

Please note: Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

APPLICABLE TO LABORATORY ACCREDITATION PROGRAMS

Effective January 1, 2021

Environment of Care (EC) Chapter

EC.02.04.03

The laboratory inspects, tests, and maintains laboratory equipment.

Element(s) of Performance for EC.02.04.03

35. The embryology laboratory maintains the following: □ □ (D)
- Incubators with remote alarm systems and emergency power backup
 - Records of daily monitoring of incubator temperature and gas content using calibrated instrumentation
 - Microscopes suitable for oocyte recovery, semen analysis, determination of fertilization, manipulation of oocytes or embryos
 - Enough laboratory equipment to support the scope of the services provided
- Note:** Audible alarms for refrigerators are not required. Both audible and remotely monitored alarms are required for incubators and liquid nitrogen storage tanks used for cell and tissue storage.
36. The embryology laboratory equipment is maintained and operated according to manufacturers' instructions and is decontaminated, as needed. Deviations from manufacturers' instructions are documented to safeguard against negative impacts to the quality and safety of laboratory operations and specimens. □ □

EC.02.06.01

The laboratory establishes and maintains a safe, functional environment.

Element(s) of Performance for EC.02.06.01

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

28. Work areas have enough space and are configured to efficiently handle and house equipment and reagents. The features of work areas do not adversely affect test outcomes or compromise staff safety.
28. **Work areas have enough space and are configured to efficiently handle and house equipment and reagents. The features of work areas do not adversely affect test outcomes or compromise staff safety.**
Note: Walls and floors should be composed of materials easily washed and disinfected.
Carpeted flooring is not acceptable.
47. Embryology laboratories have the following special space requirements:
 - The laboratory is physically isolated from other activities. Use of toxic chemicals or radioisotopes, including toxic cleaning materials, in the laboratory is not permitted.
 - The laboratory is in proximity to the procedure room, and if not, necessary conditions are in place so that embryo viability is not compromised.
 - Incubators and their chamber space have sufficient volume for the positive identification of specimens.
 - “Wet areas” of the laboratory (for example, space used for media preparation, equipment, sterilization) are separated from the area in which oocytes and embryos are handled.

Human Resources (HR) Chapter

HR.01.02.03

One or more qualified professionals direct pathology and clinical laboratory services.

Element(s) of Performance for HR.01.02.03

9. A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications: R
- A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation
 - Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.
- Note: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.
9. **A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications:** R
- A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation.
 - Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.
 - Effective January 1, 2006, new embryology laboratory directors hold either High-Complexity Clinical Laboratory Director (HCLD) or Embryology Laboratory Director (ELD) certification from the American Board of Bioanalysis (AAB) or an equivalent board certification.
- Note 1:** The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.
- Note 2:** If the embryology laboratory is also performing andrology and other testing specialties under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) guidelines, the laboratory director also meets CLIA qualifications. (For more information on the qualifications of the laboratory director, refer to HR.01.02.03, EP 1)
- Note 3:** If the medical director also serves as the laboratory director, he or she designates a laboratory supervisor. (For more information on embryology laboratory supervisor qualifications, refer to HR.01.03.01, EP 4)
10. When the embryology laboratory director is off-site, he or she is readily available to staff by phone, email, or fax and also performs the following functions: □ □
- Establishes frequency of director on-site visits (minimum visits of once every quarter) to the laboratory that is actively treating patients
 - On-site review of accreditation procedures and on-site presence during The Joint Commission accreditation survey, if possible

HR.01.02.07

The laboratory determines how staff function within the organization.

Element(s) of Performance for HR.01.02.07

15. Embryology laboratory testing personnel have the following qualifications: □ D
- Bachelor's or master's degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution
 - Documented training that includes performing at least 30 assisted reproductive technology procedures under supervision
 - Documented annual competence for performing a satisfactory number of assisted reproductive procedures as established by the laboratory director

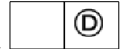
Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

HR.01.03.01

Staff are supervised effectively.

Element(s) of Performance for HR.01.03.01

4. The embryology laboratory supervisor has the following qualifications:
- Bachelor's or master's degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution
 - Documented training that includes performing at least 60 assisted reproductive technology procedures under supervision
 - Documented annual competence for performing at least 20 assisted reproductive technology procedures



Leadership (LD) Chapter

LD.04.05.09

The laboratory director is responsible for developing, implementing, and maintaining policies and procedures that guide and support the provision of services.

Element(s) of Performance for LD.04.05.09

11. The embryology laboratory director is responsible for no more than five separate laboratories of any type and is responsible for the following activities:
- Developing policies specific to the scope of embryology laboratory services
 - Communicating with the medical director on patient progress related to laboratory aspects of treatment
 - Upholding safe laboratory environmental conditions
 - Maintaining patient confidentiality throughout the embryology laboratory's assisted reproductive technology process
 - Verifying that staff are trained on assisted reproductive technology laboratory procedures and obtain the required number of annual continuing education hours for the laboratory procedures performed



Quality System Assessment for Nonwaived Testing (QSA) Chapter

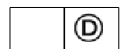
QSA.02.10.01

The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.

Note: This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires that the combination of controls and calibrators used each day of testing be rotated to check normal, alkalosis, and acidosis levels).

Element(s) of Performance for QSA.02.10.01

7. ~~The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each time the procedure is performed. The quality control results are documented. (See also QSA.13.06.01, EP 2)~~
- ~~Note: For polymer-based immunohistochemical methods, a negative control is not required.~~



Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

QSA.08.04.01

The laboratory establishes workload limits for staff who perform primary cytology screening.

Element(s) of Performance for QSA.08.04.01

5. For individuals who perform primary screening, the maximum total number of cytology slides staff may screen is 100 slides (or full slide equivalents) per 24-hour period for either gynecologic or nongynecologic specimens or both.
- For gynecologic specimens screened by automated or semiautomated screening devices, workload limits must comply with those specified by the manufacturer as approved by the US Food and Drug Administration (FDA).
- Note 1: For manual screening, liquid-based gynecologic preparations cannot be counted as a half slide. All gynecologic slide preparations (liquid-based or conventional) are counted as one full slide.
- Note 2: The workload limit for staff reading slides requiring 100% manual review may not exceed 100 slides, as a result of automated or semiautomated analysis or in the routine workload. When performing evaluations using automated and semiautomated screening devices, the laboratory conforms to current manufacturer's instructions.
- Note 3: Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one half or less of the total available slide may be counted as one half slide.
- Note 4: The 100-slide limit includes previously unevaluated gynecologic slides and nongynecologic slides, 10% rescreen slides, and review slides. Cytology technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100-slide workload limit.
- Note 5: The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecologic cases; previously examined nongynecologic cytology preparations; or tissue pathology slides examined by a cytology technical supervisor.

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For gynecologic specimens screened by automated or semiautomated screening devices, workload limits must comply with those specified by the manufacturer as approved by the US Food and Drug Administration (FDA).

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Note 5: The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecologic cases; previously examined nongynecologic cytology preparations; or tissue pathology slides examined by a cytology technical supervisor.

Note 6: A slide assessment that solely examines specimen adequacy and is not used for the diagnosis, prevention, or treatment of any disease or impairment, or for the assessment of a patient's health, is not considered to be a slide examination for purposes of determining workload. However, the time spent by the individual performing such specimen adequacy assessments must be used to prorate the maximum number of slides the individual can examine in a 24-hour period. Additional information is available from the Centers for Medicare & Medicaid Services at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-18-14-CLIA.pdf>.

QSA.08.08.01

Cytology reporting includes processes to communicate with the authorized person ordering the test and, if different, the individual responsible for using the test results.

Element(s) of Performance for QSA.08.08.01

Key: **D** indicates that documentation is required;

R indicates an identified risk area;

- 1. For all specimen results, cytology reports contain descriptive nomenclature [Ⓟ] that facilitates communication between the laboratory and the clinician. Ⓟ
Footnote ^{*}: Ali SZ, Cibas ES, eds. The Bethesda System for Reporting Thyroid Cytopathology: Definitions, Criteria and Explanatory Notes. New York: Springer, 2010.

- 1. For all specimen results, cytology reports contain descriptive nomenclature that facilitates communication between the laboratory and the clinician. Ⓟ
Note: Examples of recognized cytology reporting systems include the following:
Ali SZ, Cibas ES, eds. The Bethesda System for Reporting Thyroid Cytopathology: Definitions, Criteria, and Explanatory Notes, 2nd ed. Cham, Switzerland: Springer, 2017.
Nayar R, Wilbur DC, eds. The Bethesda System for Reporting Cervical Cytology: Definitions, Criteria, and Explanatory Notes, 3rd ed. Cham, Switzerland: Springer, 2015.
Rosenthal DL, Wojcik E, Kurtycz DF. The Paris System for Reporting Urinary Cytology, 1st ed Cham, Switzerland: Springer, 2015.
Faquin, WC, Rossi, ED, Baloch, Z, Barkan, GA, Foschini, M, Kurtycz, DFI, Pusztaszeri, M, Vielh P, eds. The Milan System for Reporting Salivary Gland Cytopathology, 1st ed. Cham, Switzerland: Springer, 2018.

QSA.10.01.01

Embryo laboratory procedures provide for accurate results.

Note: Embryos are examples of a tissue. For more information on tissue storage and issuance, see the "Transplant Safety" (TS) chapter.

Embryology laboratory procedures provide for accurate results.

Element(s) of Performance for QSA.10.01.01

- 1. The embryo laboratory has written procedures for each laboratory test performed. Ⓟ

- 1. **The embryology laboratory follows its written procedures for each laboratory test performed and follows recommendations from the American Society for Reproductive Medicine (ASRM) for embryo transfer. If not following ASRM recommendations, documentation of reasons for deviation are provided.** Ⓟ
Note: Procedures considered experimental are conducted under the supervision of a properly constituted institutional review board or equivalent committee.

Key: Ⓟ indicates that documentation is required; **R** indicates an identified risk area;

2. The **embryo** laboratory's procedures address the following:
- Infectious disease assessments
 - Evaluation and assessment of oocyte morphology and maturity, fertilization, and embryo quality
 - Insemination schedule relative to oocyte maturity
 - Volume, numbers, and quality of sperm used for insemination of each oocyte
 - Disposition of oocytes with an abnormal number of pronuclei
 - Disposition of excess oocytes
 - The time period following insemination for examination of oocytes to determine fertilization
 - Micromanipulation of oocytes and embryos, such as intracytoplasmic sperm injection, oocyte and embryo biopsy, and assisted hatching
 - Cryopreservation of specimens
 - Embryo transfer procedures, which include the following: the length of time embryos are cultured before transfer, the media and protein supplementation used for transfer (as applicable), disposition of excess embryos, types of catheters available (with circumstances for use of each), methods of transfer, and technique for posttransfer catheter check
 - Confirmation of patient identity and the identification of gametes and embryo samples
 - Obtaining informed consent

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2. The **embryology** laboratory's procedures address the following:
- Infectious disease assessments
 - Evaluation and assessment of oocyte morphology and maturity, fertilization, and embryo quality
 - Insemination schedule relative to oocyte maturity
 - Volume, numbers, and quality of sperm used for insemination of each oocyte
 - Disposition of oocytes with an abnormal number of pronuclei
 - Disposition of excess oocytes
 - The time period following insemination for examination of oocytes to determine fertilization
 - Micromanipulation of oocytes and embryos, such as intracytoplasmic sperm injection, oocyte and embryo biopsy, and assisted hatching
 - Cryopreservation of specimens
 - Embryo transfer procedures, which include the following: the length of time embryos are cultured before transfer, the media and protein supplementation used for transfer (as applicable), continuous monitoring of results that minimizes multiple pregnancies, disposition of excess embryos, types of catheters available (with circumstances for use of each), methods of transfer, and technique for posttransfer catheter check
 - Confirmation of patient identity and the identification of gametes and embryo samples
 - Sperm preparation protocols that include an abstinence period, type of container used, facilities for collection, and time period and conditions for sample collection
 - Preparation and labeling of biopsy samples
 - Selection of a reference laboratory for genetic testing
 - Chain of custody throughout the process (For more information, refer to QSA.10.03.01, EP 3)
 - Obtaining informed consent for all procedures prior to performance

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Key: **D** indicates that documentation is required;

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| <p>3. The embryo laboratory maintains a system that provides for patient identification and preparation; specimen collection, identification, and handling (transportation, processing, storage, preservation); and accurate recording and reporting of laboratory procedural outcomes.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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| <p>4. The embryo laboratory follows its procedures for each laboratory test it performs.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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| <p>4. <u>The number of embryos transferred is agreed upon by the physician and the treated patient(s), and patient(s) are provided with an accounting of the disposition of all sperm, eggs, and embryos consistent with the documentation in the laboratory's record.</u></p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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| <p>5. For tissue banks, policies and procedures address the following:</p> <ul style="list-style-type: none"> - Consent forms indicate that the tissue bank transfers specimens in and out of its facility - Limits of responsibility when transporting specimens using common package carriers - Documentation of the type of specimen, prefreeze quality and quantity, and identification of the gamete sources - Instructions for the thawing/warming of the specimens - Documentation of infectious disease status for all specimens to be stored - Assessment of the condition of transport containers before and after receipt of specimens - Storage of reproductive tissues in either liquid nitrogen or in the vapor phase of liquid nitrogen - Monitoring the oxygen level for rooms that are used to store liquid nitrogen tanks | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px; text-align: center;">D</td> </tr> </table> | | D |
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| <p>6. Laboratories establish periodic monitoring of liquid nitrogen tanks following recommendations from the American Society for Reproductive Medicine (ASRM).</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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QSA.10.02.01

The ~~embryo~~ laboratory has a process for method validation.

The **embryology** laboratory has a process for method validation.

Element(s) of Performance for QSA.10.02.01

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| <p>1. The embryo laboratory has written procedures for method validation.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px; text-align: center;">D</td> </tr> </table> | | D |
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| <p>2. The embryo laboratory determines performance measures and demonstrates that the procedures meet or exceed acceptable levels of performance.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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| <p>2. The <u>embryology</u> laboratory determines performance measures and demonstrates that the procedures meet or exceed acceptable levels of performance.</p> | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 20px;"></td> <td style="width: 20px;"></td> </tr> </table> | | |
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Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

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| 3. The <u>embrye</u> laboratory verifies through its performance improvement activities each procedure's continued acceptable level of performance. | <input type="checkbox"/> <input type="checkbox"/> |
| 3. The <u>embryology</u> laboratory verifies through its performance improvement activities each procedure's continued acceptable level of performance. | <input type="checkbox"/> <input type="checkbox"/> |
| 4. The <u>embrye</u> laboratory validates all assisted reproductive technology procedures selected or established by the <u>embrye</u> laboratory before routine patient use. | <input type="checkbox"/> <input type="checkbox"/> |
| 4. The <u>embryology</u> laboratory validates all assisted reproductive technology procedures selected or established by the <u>embryology</u> laboratory before routine patient use. | <input type="checkbox"/> <input type="checkbox"/> |
| 5. The embryology laboratory participates in the Centers for Disease Control and Prevention's (CDC) National Assisted Reproductive Technology Surveillance System (NASS).
Note: Information on NASS is available at https://www.cdc.gov/art/nass/index.html#collaborative . | <input type="checkbox"/> <input type="checkbox"/> |

QSA.10.03.01

The embrye laboratory maintains records during all phases of testing and reporting.

The embryology laboratory maintains records during all phases of testing and reporting.

Element(s) of Performance for QSA.10.03.01

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| 1. The <u>embrye</u> laboratory maintains records and dates of laboratory testing and reporting. | <input type="checkbox"/> <input type="checkbox"/> |
| 1. The <u>embryology</u> laboratory maintains records and dates of laboratory testing and reporting. | <input type="checkbox"/> <input type="checkbox"/> |

2. The **embryo** laboratory records include the following: □ □
- Each patient's assisted reproductive technology cycle
 - Semen assessment before and after processing and concentration for insemination
 - Outcome of insemination or micromanipulation procedures (for example, fertilization)
 - Outcome of any culture (for example, cleavage)
 - Relative timing of protocol events (for example, incubation hours)
 - Assessment of the developmental status and quality of all embryos at transfer
 - Verification that no embryos remain in the catheter following completion of transfer
 - The identity and lot numbers of media and media supplements used in each phase of the procedure
 - The identity of the laboratory staff who handled the specimens and performed the procedures
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- Each patient's assisted reproductive technology cycle
 - Semen assessment before and after processing and concentration for insemination
 - Outcome of insemination or micromanipulation procedures (for example, fertilization)
 - Outcome of any culture (for example, cleavage)
 - Relative timing of protocol events (for example, incubation hours)
 - Assessment of the developmental status and quality of all embryos at transfer
 - Verification that no embryos remain in the catheter following completion of transfer
 - The identity and lot numbers of media and media supplements used in each phase of the procedure
 - The identity, training, and evaluations of the laboratory staff who handled the specimens and performed the procedures
3. The embryology laboratory's protocols for chain of custody include the following: □ (D) □
- Handling of all specimens throughout the procedure, including the movement of all specimens and proper identification to match every item with the right patient
 - Documentation of written confirmations with a double-check by a different staff member prior to cycle events (for example, insemination and embryo transfer) for accurate identification of gametes and confirmation that embryos match the correct patient
 - When electronic witnessing is used, the method is validated, and all gamete sources are included
 - Audit trail of all equipment used for each tissue and identity of the individual(s) handling each tissue
 - Disposal of all cells and tissues including the identity of the individual(s) performing the procedure
- Note:** Chain of custody should be traceable and patient identification verifiable at all phases of specimen handling and during culture, storage, and disposition.
4. When sample processing is performed in another laboratory that is not part of the accreditation survey (for example, a separate andrology laboratory), the processing laboratory is CLIA-certified and incorporated into the chain of custody protocols. □ □
- Note:** If the embryology laboratory refers testing to another accredited reference laboratory, the embryology laboratory must document current accreditation status of all its reference laboratories, including laboratories used for preimplantation genetic testing.

Key: (D) indicates that documentation is required; R indicates an identified risk area;

QSA.10.04.01

The ~~embryo~~ laboratory documents quality control methods for the media it uses.

The **embryology** laboratory documents quality control methods for the media it uses.

Element(s) of Performance for QSA.10.04.01

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|---|---|--|---|
| <p>1. The embryo laboratory documents the following for the media it uses:</p> <ul style="list-style-type: none"> - Procedures for the quality control of culture media - Completion of a visual check for physical damage to the media container and evidence of media contamination before its use - For each batch of culture media prepared in-house, the pH, osmolality, and culture suitability using a bioassay system appropriate for performing these activities - The lot number, the date prepared, the method of sterilization, and the expiration date for each batch of media - For each batch of commercially prepared culture media, evidence that media undergo a quality control process using a bioassay system appropriate for performing these activities, unless documentation of quality control performed by the manufacturer meets this requirement - Evidence that manufacturers' specifications for using media are followed - Any media supplementation testing (for example, protein) using a bioassay system, when needed, unless documentation of quality control performed by the manufacturer meets this requirement - Blood-based media supplements (for example, human fetal cord serum) prepared in-house and used in testing for human immunodeficiency virus (HIV), Type 1; human immunodeficiency virus (HIV), Type 2; hepatitis B virus (HBV); hepatitis C virus (HCV); human T-cell lymphotropic virus (HTLV), Type 1; and other diseases that may be deemed appropriate according to the laboratory's written procedures | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px; text-align: center;">D</td> </tr> </table> | | D |
| | D | | |
| <p>1. The <u>embryology</u> laboratory documents the following for the media it uses:</p> <ul style="list-style-type: none"> - Procedures for <u>preparation and</u> quality control of culture media - Completion of a visual check for physical damage to the media container and evidence of media contamination before its use - For each batch of culture media prepared in-house, the pH, osmolality, and culture suitability using a bioassay system appropriate for performing these activities - The lot number, the date prepared, the method of sterilization, and the expiration date for each batch of media - For each batch of commercially prepared culture media, evidence that media undergo a quality control process using a bioassay system appropriate for performing these activities, unless documentation of quality control performed by the manufacturer meets this requirement - Evidence that manufacturers' specifications for using media are followed - Any media supplementation testing (for example, protein) using a bioassay system, when needed, unless documentation of quality control performed by the manufacturer meets this requirement - Blood-based media supplements (for example, human fetal cord serum) prepared in-house and used in testing for human immunodeficiency virus (HIV), Type 1; human immunodeficiency virus (HIV), Type 2; hepatitis B virus (HBV); hepatitis C virus (HCV); human T-cell lymphotropic virus (HTLV), Type 1; and other diseases that may be deemed appropriate according to the laboratory's written procedures | <table border="1" style="border-collapse: collapse; width: 40px; height: 20px;"> <tr> <td style="width: 15px; height: 15px;"></td> <td style="width: 15px; height: 15px; text-align: center;">D</td> </tr> </table> | | D |
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QSA.10.05.01

The ~~embryo~~ laboratory has a method of tracking cryopreserved ~~specimens~~.

The **embryology** laboratory has a method of tracking cryopreserved **oocytes, sperm, embryos, and other human tissues**.

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

Element(s) of Performance for QSA.10.05.01

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| <p>1. The embryo laboratory labels each cryopreservation container with the date the specimen was frozen and the patient's name or unique identifier.</p> | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
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| <p>2. The embryo laboratory maintains documentation in duplicate log books or files for each liquid nitrogen storage tank.</p> | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| <p>2. The <u>embryology</u> laboratory maintains documentation in duplicate for the following:
 - <u>Inventory of each liquid nitrogen storage tank</u>
 - <u>Sample type (oocytes, sperm, embryos, and other human tissue)</u>
 - <u>Sperm and oocyte sources</u>
 (See Also QSA.10.07.01, EP 4)</p> | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| <p>3. The documentation for each liquid nitrogen storage tank used in the embryo laboratory includes the following:
 - The patient name or unique identifier
 - A description of each cryopreservation container's contents
 - The freezing procedure used
 - The date each cryopreservation container was frozen
 - The type and location of the cryopreservation container
 - Final disposition or disposal of the cryopreserved specimen(s)</p> | <input type="checkbox"/> <input type="checkbox"/> |
| <p>3. The documentation for each liquid nitrogen storage tank used in the <u>embryology</u> laboratory includes the following:
 - The patient name or unique identifier
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 - The freezing procedure used
 - The date each cryopreservation container was frozen
 - The type and location of the cryopreservation container
 - Final disposition or disposal of the cryopreserved specimen(s)</p> | <input type="checkbox"/> <input type="checkbox"/> |

QSA.10.06.01

The ~~embryo~~ laboratory ~~uses policies and procedures for the receipt or transfer of cryopreserved specimens that maintain specimen identification and integrity.~~

The embryology laboratory follows its policies and procedures for maintaining specimen identification and integrity during the receipt or transfer of cryopreserved oocytes, sperm, embryos, and other human tissues.

Element(s) of Performance for QSA.10.06.01

- | | |
|---|--|
| <p>1. If cryopreserved specimens are received or transferred to other facilities, the embryo laboratory has written policies and procedures for the receipt or transfer of cryopreserved specimens.</p> | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| <p>1. If cryopreserved <u>oocytes, sperm, embryos, and other human tissues</u> are received or transferred to other facilities, the <u>embryology</u> laboratory has written policies and procedures for the receipt or transfer of cryopreserved specimens.</p> | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

2. The ~~embryo~~ laboratory policies and procedures for the receipt or transfer of cryopreserved specimens include the following: □ □
- Methods to maintain specimen identification and specimen integrity
 - Methods of transportation
 - Method for verifying the identification and number of cryopreservation containers received or transferred
2. **The embryology laboratory policies and procedures for the receipt or transfer of cryopreserved oocytes, sperm, embryos, and other human tissues include the following:** □ □
- **Methods to maintain specimen identification and specimen integrity**
 - **Methods of transportation**
 - **Method for verifying the identification and number of cryopreservation containers received or transferred**
 - **Plan to provide for continuation of patient care in the event of an emergency or natural disaster**
3. For transferred specimens, the ~~embryo~~ laboratory documents the following: □ (D)
- Freezing procedure used
 - Copies of patient release forms
 - Log sheets that accompany the cryopreserved specimens
3. **For transferred specimens, the embryology laboratory documents the following:** □ (D)
- **Freezing procedure used**
 - **Copies of patient release forms**
 - **Log sheets that accompany the cryopreserved specimens**
4. The ~~embryo~~ laboratory follows its policies and procedures for the receipt or transfer of cryopreserved specimens: □ □
4. **The embryology laboratory's policies and procedures for the continuation of patient care in the event of an emergency or natural disaster include the following:** □ □
- **Emergency transfer of specimens to designated alternative storage facilities that are continuously monitored for stability in the event of mechanical failures or loss of coolant**
 - **Timely notification to patients regarding the location and status of their cryopreserved specimens**
 - **Methods used in the event of equipment failure, including back-up tanks**
 - **Physician's final decision on the course of treatment**
 - **Communication with the patient and partner on embryo transfer options; cryopreservation of oocytes, zygotes, or embryos; or abandonment of the cycle altogether**
- Note: The most prudent course of action in the event of a disaster may be to discontinue treatment for that cycle.**

QSA.10.07.01

The ~~embryo~~ laboratory retains its records.

The embryology laboratory retains its records.

Element(s) of Performance for QSA.10.07.01

Key: (D) indicates that documentation is required;

(R) indicates an identified risk area;

1. The ~~embryo~~ laboratory retains its records for 10 years beyond the date of final disposition or disposal of all specimens obtained during each patient’s assisted reproductive technology cycle, or longer if required by federal, state, or local laws. □ □

1. **The embryology laboratory retains its records for 10 years beyond the date of final disposition or disposal of all specimens obtained during each patient’s assisted reproductive technology cycle, or longer if required by federal, state, or local laws.** □ □

2. The ~~embryo~~ laboratory retains its records on site for two years. □ □

2. **The embryology laboratory retains all paper records on-site for two years.** □ □

3. **The embryology laboratory’s electronic records have safeguards against data loss.**
Note: When automated data processing is used, procedures are established to prevent inaccurate input or output of data and programming errors. □ □

4. **The embryology laboratory’s clinic and patient records are copied (paper) or backed up (electronic) periodically. If both paper and electronic records are maintained, copied paper records are kept in a secure (preferably remote), predetermined location. (See Also QSA.10.05.01, EP 2)**
Note: Revisions to any records have an audit trail that identifies all altered information, date of revision, and the individual who made the revision. □ □

3. In the event of closure, the ~~embryo~~ laboratory makes provisions for records to be maintained for the time frames required.
Note: Transfer of cryopreserved specimens to another facility constitutes final disposition or disposal for the transferring facility. □ □

5. **In the event of closure, the embryology laboratory makes provisions for records to be maintained for the time frames required.**
Note: Transfer of cryopreserved specimens to another facility constitutes final disposition or disposal for the transferring facility. □ □

QSA.13.03.01

The laboratory ~~documents its receipt of surgical specimens and maintains the identity of the specimens throughout processing and storage.~~

The laboratory receives, processes, evaluates, and stores surgical specimens.

Element(s) of Performance for QSA.13.03.01

1. **The laboratory establishes an acceptable time frame for transport of surgical specimens to the laboratory for gross examination, dissection, and fixation.**
Note: Delayed fixation can lead to inaccurate immunohistochemical staining results and diminished immunoreactivity. For these reasons, fixation should start immediately after surgical removal of the tissue. □ □

4. The laboratory documents its receipt of surgical specimens. □ (D)

2. **The laboratory documents its receipt of surgical specimens.** □ (D)

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

- 2. The laboratory has written policies and procedures that define how the identity of surgical specimens is maintained throughout processing, evaluation, and storage. (D)
- 3. The laboratory has written policies and procedures that define how the identity of surgical specimens is maintained throughout processing, evaluation, and storage.** (D)
- 3. The laboratory maintains the identity of the surgical specimens throughout processing, evaluation, and storage.
- 4. The laboratory maintains the identity of the surgical specimens throughout processing, evaluation, and storage.

QSA.13.04.01

Surgical specimens sent to the laboratory are examined by or under the supervision of a qualified individual.

Element(s) of Performance for QSA.13.04.01

- 9. Cancer pathology reports use a synoptic format. * (D)
Footnote *: Additional information can be found in ~~Cancer Program Standards 2012: Ensuring Patient-Centered Care~~ by the Commission on Cancer of the American College of Surgeons at <https://www.facs.org/-/media/files/quality%20programs/cancer/coc/programstandards2012.ashx>.
- 9. **Cancer pathology reports use a synoptic format. *** (D)
Footnote *: Additional information can be found in **Cancer Program Standards 2016: Ensuring Patient-Centered Care** by the Commission on Cancer of the American College of Surgeons at https://www.facs.org/-/media/files/quality-programs/cancer/coc/2016-coc-standards-manual_interactive-pdf.ashx?la=en.

QSA.13.06.01

The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

Element(s) of Performance for QSA.13.06.01

- 2. The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented. (See also ~~QSA.02.10.01, EP 7~~) (D)
Note: For example, immunohistochemical (IHC) stains have positive and negative controls, and for periodic acid-Schiff (PAS) stains, documentation of typical cellular staining characteristics is acceptable. For polymer-based immunohistochemical methods, a negative control is not required.
- 2. **The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented.** (D)
Note: For example, immunohistochemical (IHC) stains have positive and negative controls, and for periodic acid-Schiff (PAS) stains, documentation of typical cellular staining characteristics is acceptable. For polymer-based immunohistochemical methods, a negative control is not required.

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

4. The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each time the procedure is performed. The quality control results are documented. ☐ ☐ (D)
Note: For polymer-based immunohistochemical methods, a negative control is not required.
5. For laboratories that develop immunohistochemistry tests that include primary antibodies commercially distributed as analyte-specific reagents (ASRs), the laboratory establishes the clinical performance characteristics of the assay. ☐ ☐
Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document I/LA28 (Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays).

QSA.13.07.01

The laboratory retains histological specimens for patient care purposes.

Element(s) of Performance for QSA.13.07.01

1. Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are permanently identified, stored for preservation purposes, and organized for retrieval. ☐ ☐
1. Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are identified, stored for preservation purposes, and organized for retrieval. ☐ ☐

QSA.13.08.01

The histopathology laboratory ~~conducts surveillance of patient results and related records as part of its quality management plan.~~

The histopathology laboratory follows its written quality management plan.

Element(s) of Performance for QSA.13.08.01

1. The histopathology laboratory's quality management plan addresses the following: ☐ ☐ (D)
 - Documentation of verbal orders and reports
 - Management of all consultation and peer case review
 - Prevention of cross-contamination during grossing
 - Criteria for adequacy of each surgical slide specimen for diagnosis
 - Correlation with ancillary studies (for example, immunohistochemistry, special stains, cytology, flow cytometry, cytogenetics, molecular testing)
 - Authentication of interpretive surgical pathology reports (See also DC.02.03.01, EP 2)
 - Quality control of the stains used in the evaluation of each surgical specimen (See also QSA.13.06.01, EPs 2 and 3)
 - Periodic maintenance of equipment, including decontamination of cryostat (See also EC.02.04.03, EP 7)
2. The histopathology laboratory's written policies and procedures for Mohs surgery specify processing of Mohs frozen sections, reporting of each Mohs surgical procedure, and the associated quality control procedures specific to Mohs surgical specimens. ☐ ☐ (D)

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

- 4. The histopathology laboratory has written policies and procedures for surveillance activities that include a review of the correlation of the intraoperative consultation with the final pathology diagnosis report. D

- 3. The histopathology laboratory has written policies and procedures for surveillance activities that include a review of the correlation of the intraoperative consultation with the final pathology diagnosis report.** D

- 2. The histopathology laboratory conducts an investigation and takes corrective action on disparities that exist between an initial intraoperative consultation and a report of pathology diagnosis. The disparities and corrective action are documented. D

- 4. The histopathology laboratory conducts an investigation and takes corrective action on disparities that exist between an initial intraoperative consultation and a report of pathology diagnosis. The disparities and corrective action are documented.** D

QSA.15.01.01

The laboratory uses written policies and procedures for molecular testing.

Element(s) of Performance for QSA.15.01.01

- 1. The laboratory has written policies and procedures for molecular testing. D

- ~~15. The laboratory follows its policies and procedures for molecular testing.~~

- 1. The laboratory follows its written policies and procedures for molecular testing.** D

QSA.15.02.01

~~The laboratory's verification studies for molecular testing include representatives from each specimen type expected to be tested in the assay and specimens representing the scope of reportable results.~~

The laboratory performs validation studies for molecular testing.

Element(s) of Performance for QSA.15.02.01

- 1. The laboratory's ~~verification~~ studies for molecular testing include positive and negative representatives from each specimen type expected to be tested in the assay.

- 1. The laboratory's validation studies for molecular testing include positive and negative representatives from each specimen type expected to be tested in the assay.**

- 2. The laboratory's ~~verification~~ studies for molecular testing include specimens representing the scope of reportable results.

- 2. The laboratory's validation studies for molecular testing include specimens representing the scope of reportable results.**

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

- | | |
|---|--|
| 3. The laboratory performs verification studies for molecular testing. The verification studies are documented. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 3. The laboratory's <u>validation</u> studies for molecular testing <u>cover all steps from extraction to final results.</u>
<u>Note: When a laboratory does not perform all or part of the testing process on-site, the laboratory performing the test is responsible for documenting proper validation of the entire testing process (for example, next-generation sequencing and bioinformatics).</u> | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |

QSA.15.03.01

The laboratory establishes quality control limits, reference ranges, and reportable ranges for molecular testing.

The laboratory establishes a quality management system for molecular testing.

QSA.15.03.03 was moved from QSA.15.04.01 and there was a new standard added at QSA.15.04.01

QSA.15.03.03

The laboratory uses quality control materials to verify each test run of patient samples for molecular testing.

Element(s) of Performance for QSA.15.03.03

- | | |
|---|--|
| 1. The laboratory has written quality control procedures for each molecular testing system or methodology, including the frequency of quality control testing. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 2. Molecular testing procedures are consistent with current practice standards for this or similar methodologies, and are at least as rigorous as those required or recommended by the manufacturer. | <input type="checkbox"/> <input type="checkbox"/> |
| 3. The laboratory follows its quality control procedures for molecular testing. | <input type="checkbox"/> <input type="checkbox"/> |
| 4. For each molecular amplification procedure, the laboratory uses two control materials. If reaction inhibition is a source of false negative results, the laboratory uses a control material capable of detecting the inhibition. The quality control results are documented. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
| 5. For each electrophoretic run, the laboratory uses the following markers:
- Molecular weight markers of known size that span the expected range of band distribution
- Visual or fluorescent markers to establish the endpoint of electrophoresis | <input type="checkbox"/> <input type="checkbox"/> |

QSA.15.04.01

The laboratory uses quality control materials to verify each test run of patient samples for molecular testing.

The laboratory validates next-generation sequencing bioinformatics pipelines.

Element(s) of Performance for QSA.15.04.01

- | | |
|--|--|
| 4. The laboratory has written quality control procedures for each molecular testing system or methodology, including the frequency of quality control testing. | <input type="checkbox"/> <input checked="" type="checkbox"/> (D) |
|--|--|

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

1. A qualified medical professional with appropriate training in next-generation sequencing interpretation reviews all validation components and oversees the validation process. This review is documented. (See also HR.01.02.03, EP 8)	<input type="checkbox"/>	<input checked="" type="checkbox"/> (D)
2. Molecular testing procedures are consistent with current practice standards for this or similar methodologies, and are at least as rigorous as those required or recommended by the manufacturer.	<input type="checkbox"/>	<input type="checkbox"/>
2. Validation is only performed after completion of design, development, and optimization of a bioinformatics pipeline and includes all components used in the analysis.	<input type="checkbox"/>	<input type="checkbox"/>
3. The laboratory follows its quality control procedures for molecular testing.	<input type="checkbox"/>	<input type="checkbox"/>
3. Bioinformatics pipeline validation matches and aligns with the laboratory environment where the test is performed.	<input type="checkbox"/>	<input type="checkbox"/>
4. For each molecular amplification procedure, the laboratory uses two control materials. If reaction inhibition is a source of false negative results, the laboratory uses a control material capable of detecting the inhibition. The quality control results are documented.	<input type="checkbox"/>	<input checked="" type="checkbox"/> (D)
4. Bioinformatics pipeline validation meets its intended clinical use, specimen, and variant types detected by the next-generation sequencing test.	<input type="checkbox"/>	<input type="checkbox"/>
5. For each electrophoretic run, the laboratory uses the following markers: –Molecular weight markers of known size that span the expected range of band distribution –Visual or fluorescent markers to establish the endpoint of electrophoresis	<input type="checkbox"/>	<input type="checkbox"/>
5. The identity of the sample is preserved throughout each step of the next-generation sequencing bioinformatics pipeline.	<input type="checkbox"/>	<input type="checkbox"/>
6. Supplemental validation is performed when a significant change is made to any component of the bioinformatics pipeline.	<input type="checkbox"/>	<input type="checkbox"/>

QSA.15.05.01

The laboratory's molecular testing reports include specific testing information.

Element(s) of Performance for QSA.15.05.01

1. The laboratory reports for molecular testing include the following information: The testing methodology used.	<input type="checkbox"/>	<input checked="" type="checkbox"/> (D)
2. The laboratory reports for molecular testing include the following information: The limitations of the method used.	<input type="checkbox"/>	<input checked="" type="checkbox"/> (D)
3. The laboratory reports for molecular testing include the following information: Any interpretation of findings.	<input type="checkbox"/>	<input checked="" type="checkbox"/> (D)
4. The laboratory reports for molecular testing include the following information: Any recommendations for additional testing.	<input type="checkbox"/>	<input checked="" type="checkbox"/> (D)
1. The laboratory reports for molecular testing include the following information: _The testing methodology used _The limitations of the method used _Interpretation of findings _Any recommendations for additional testing	<input type="checkbox"/>	<input checked="" type="checkbox"/> (D)

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

- 5- For assays developed by the laboratory, ~~the~~ laboratory reports for molecular testing include a statement that the assay was developed by the laboratory. (D)
- 2. For assays developed by the laboratory, laboratory reports for molecular testing include a statement that the assay was developed by the laboratory.** (D)
- 6- The laboratory reports for molecular testing include the disclaimer required by federal regulations for analytic specific reagents (ASR).
 Note: Federal regulations require that the following disclaimer accompany the test result on the report: "This test was developed and its performance characteristics determined by (laboratory name). It has not been cleared or approved by the US Food and Drug Administration (FDA)."
 (D)
- 3. The laboratory reports for molecular testing include the disclaimer required by federal regulations for analytic-specific reagents (ASR).**
Note: Federal regulations require that the following disclaimer accompany the test result on the report: "This test was developed and its performance characteristics determined by (laboratory name). It has not been cleared or approved by the US Food and Drug Administration (FDA)." (D)
- 7- Molecular testing reports filed in the patient's clinical record that require specific interpretation are authenticated by the individual qualified * by the Clinical Laboratory Improvement Amendments (CLIA '88) to make the interpretation.
 Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m>.
- 4. Molecular testing reports filed in the patient's clinical record that require specific interpretation are authenticated by the individual qualified * by the Clinical Laboratory Improvement Amendments (CLIA '88) to make the interpretation.**
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#sp42.5.493.m>.

QSA.16.01.01

The laboratory ~~uses~~ policies and procedures for molecular genetic testing.

The laboratory follows its policies and procedures for molecular genetic testing.

Element(s) of Performance for QSA.16.01.01

1. The laboratory ~~has written~~ policies and procedures for molecular genetic testing that address recommendations for referral for genetic counseling. (D)
- 1. The laboratory's policies and procedures for molecular genetic testing address recommendations for referral for genetic counseling.** (D)

Key: (D) indicates that documentation is required; (R) indicates an identified risk area;

- 2. The laboratory ~~has written~~ policies and procedures for molecular genetic testing that address the reporting of results when additional information necessary for interpreting test results is not received by the laboratory.

	D
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 Note: Additional information might be required to provide for accurate test interpretation and reporting of results.

- 2. **The laboratory's policies and procedures for molecular genetic testing address the reporting of results when additional information necessary for interpreting test results is not received by the laboratory.**

	D
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Note: Additional information might be required to provide for accurate test interpretation and reporting of results.

- 3. The laboratory ~~has written~~ policies and procedures for molecular genetic testing that ~~establish~~ turnaround time requirements, as appropriate (for example, results of certain genetic screening tests require that the laboratory establishes an acceptable turnaround time for immediate diagnosis, so that the clinician can diagnose and provide a critical patient recommendation in a timely manner).

	D
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- 3. **The laboratory's policies and procedures for molecular genetic testing specify turnaround time requirements, as appropriate (for example, results of certain genetic screening tests require that the laboratory establishes an acceptable turnaround time for immediate diagnosis, so that the clinician can diagnose and provide a critical patient recommendation in a timely manner).**

	D
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- 4. The laboratory ~~follows its~~ policies and procedures for molecular genetic testing.

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- 4. **The laboratory's policies and procedures for molecular genetic testing address the clinical validity and clinical utility of each individually requested test based on published literature and professional recommendations (for example, Clinical and Laboratory Standards Institute document MM20 [Quality Management for Molecular Genetic Testing]).**

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Note: For molecular genetic tests, clinical validity refers to the ability of a test to detect the presence or absence of a disease and corresponds to associations between genotype and phenotype. Clinical utility refers to identifying the outcome associated with specific test results.

QSA.16.02.01

Molecular genetic testing reports include specific testing information.

Element(s) of Performance for QSA.16.02.01

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

- | | |
|---|--|
| 1. The laboratory reports for molecular genetic testing include the following information: Indication for testing. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 2. The laboratory reports for molecular genetic testing include the following information: List of genes or alleles tested. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 3. The laboratory reports for molecular genetic testing include the following information: Any recommendations for referral to a genetic counselor. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 4. The laboratory reports for molecular genetic testing include the following information: Detection rate of the test. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 5. The laboratory reports for molecular genetic testing include the following information: Standard nomenclature for genes and mutations. | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 6. The laboratory reports for molecular genetic testing include the following information: Clinical implications of any detected mutation(s). | <input type="checkbox"/> <input checked="" type="checkbox"/> D |
| 1. Laboratory reports for molecular genetic testing include the following information:
_ Indication for testing
_ List of genes or alleles tested
_ Recommendations for referral to a genetic counselor
_ Detection rate of the test
_ Standard nomenclature for genes and mutations
_ Clinical implications of any detected mutation(s) | <input type="checkbox"/> <input checked="" type="checkbox"/> D |

Key: **D** indicates that documentation is required;

R indicates an identified risk area;