A Quality Management Toolkit for Molecular Genetic Testing

Presented by -

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Polling Question

Does your laboratory perform any human nucleic acid–based testing for heritable or acquired conditions?

☐ Yes

☐ No
Polling Question

Do you perform evaluation on the quality of molecular genetic laboratory services (eg, inspection, accreditation, quality manager)?

☐ Yes
☐ No
This document provides guidance for implementing international quality management system standards in laboratories that perform human molecular genetic testing for heritable or acquired conditions.
Background

- Global Increase in Molecular Genetic Testing Applications
- International Strides for Improving Quality Management in Genetic Testing Services
  - EuroGentest – Harmonizing genetic testing across Europe
  - International Organization for Standardization (ISO) 15189 (2012). Medical laboratories – Requirements for quality and competence
  - Increasing adherence to ISO and other national/international quality standards (eg, countries in Europe, Asia, Americas, other continents)
- CLSI Standards
  - Quality management systems (QMS) guidelines (eg, GP26-A4: Quality Management System: A Model for Laboratory Services)
  - Molecular methods guidelines (heritable diseases and oncology, molecular hematopathology, FISH, infectious diseases, new test implementation, etc.)
  - Before MM20: No CLSI document specifically addressed QMS implementation and maintenance in molecular genetic testing
Purposes of MM20

❖ Provide guidance for implementing and maintaining QMS in molecular genetic testing.
❖ Address specific QMS challenges in technical processes and laboratory/user interphases of molecular genetic laboratory services.
❖ Provide a resource to facilitate harmonized approaches to accreditation to international laboratory standards.
What’s “Special” in MM20?

- Extends international QMS standards/guidelines (eg, ISO 15189, CLSI document GP26) into molecular genetic testing services
- Incorporates recognized best practices for molecular genetic testing worldwide
- Follows new/extended path of workflow
- Applies quality system essentials (QSEs) to quality management and technical processes of molecular genetic testing
- Features many tools, job aids, resources
Contents Overview

- Scope
- Introduction
- Terminology
- Overview of the Process for Providing Molecular Genetic Testing Services and Path of Workflow
- Application of QSEs to Molecular Genetic Testing
- Quality Management for Technical Processes of Molecular Genetic Testing
- Personnel Qualifications, Responsibilities, and Competency
- References (90+)
- Appendixes (15)
- Tables (11)
Scope

❖ Guidance for Implementing and Maintaining QMS for Nucleic Acid–Based Human Molecular Genetic Testing
  ❏ Intended for heritable (including pharmacogenetic testing) and acquired conditions (eg, molecular oncology testing)
  ❏ Not intended to address molecular infectious disease testing, biochemical genetic testing, cytogenetic testing, specific technical processes of molecular cytogenetic testing, molecular testing for nonclinical purposes, or direct-to-consumer laboratory services
❖ Concordant with Use of ISO QMS Standards and Other CLSI Guidelines (eg, GP26, MM01, MM12, MM17, MM19)
## Table 1. Types of Genetic Tests Performed for Clinical and Health Assessment Purposes from MM20

<table>
<thead>
<tr>
<th>Intent of Test</th>
<th>Description</th>
</tr>
</thead>
</table>
| Preimplantation testing                | - Performed on early embryos resulting from *in vitro* fertilization in order to decrease the probability of implanting an embryo with a specific genetic condition producing an affected fetus  
- Generally offered to couples with a high probability of having a child with a serious disorder  
- Provides an option to increase the likelihood of having healthy fetuses in assisted pregnancies |
| Fetal/prenatal testing                 | - Performed during a pregnancy to assess the health status of a fetus  
- Performed when there is an increased risk of having a child with a genetic condition as indicated by maternal age, family history, ethnicity, and other factors  
- May be performed as a stand-alone test or in conjunction with a multiple marker screen or fetal ultrasound examination |
| Newborn/neonatal screening             | - Performed for infants shortly after birth to identify genetic disorders and other conditions that can be treated early in life                                                                 |
| Diagnostic testing                     | - Used to identify, confirm, or exclude a known or suspected genetic disorder in a symptomatic individual  
- Can be performed before birth or at any time during a person’s life                                                                 |
| Carrier testing                        | - Performed to identify individuals who have a gene mutation for a disorder inherited in an autosomal recessive or X-linked recessive manner  
- Offered to individuals who have family members with genetic conditions or who are identified carriers, and individuals in ethnic or racial groups known to have higher carrier rates for particular conditions |
| Predisposition or susceptibility testing| - Identifies genetic risk factor(s) that predispose an individual to a hereditary disorder (eg, *BRCA1/BRCA2* testing for increased, heritable risk for breast, ovarian, and other cancers) or a common disease (eg, diabetes) |
| Presymptomatic testing                 | - Used to detect mutations associated with disorders that appear after birth, often later in life  
- Can be helpful to asymptomatic individuals with a family history of a genetic disorder  
- Can include presymptomatic testing (eventual development of symptoms is certain when the gene mutation is present, eg, testing of trinucleotide repeats in the *HD* gene for Huntington disease) and predictive testing (eventual development of symptoms is likely, eg, testing of germline *RET* mutations for multiple endocrine neoplasia type 2) |
| Prognostic testing                     | - Evaluates the likely outcome or course of disease (eg, disease progression, risk for metastatic malignancy, cancer recurrence or relapse) |
| Pharmacogenetic and pharmacogenomic testing | - Pharmacogenetic testing may examine individual variations in single-nucleotide polymorphisms and haplotype markers to help personalize medical care and treatments based on genetic information  
- Pharmacogenomic testing examines the impact of many pharmacogenetic polymorphisms or multiple genes involved in drug metabolism pathways |
| Cancer diagnosis and treatment monitoring | - Uses genetic markers to determine stratification to effective treatment regimens (eg, *BRAF*, *EGFR*, and *KRAS*)  
- Monitors treatment efficacy such as minimal residual disease (eg, *BCR-ABL1*) and targeted therapeutics (eg, imatinib) |
Need for Specific Quality Management System Guidance

❖ **Quality Laboratory Services**
   - Most appropriate examination procedures
   - Best suited sample(s)
   - Accurate and timely results with proper interpretation
   - Accurate and timely communications

❖ **Quality Management Challenges for Molecular Genetic Testing**
   - Diverse spectrum of testing services
   - Expanding applications impacting all medical disciplines
   - New users and clients continuously faced by laboratories
   - Laboratory’s continuing need to-
     - Consider new examination methods/procedures.
     - Update existing examination procedures.
     - Ensure effective communications with users and clients.

❖ **Prerequisites for Providing Testing Services**
   - Planning and preparation activities to ensure QMS/readiness for introducing or providing molecular genetic testing services
   - Validation/verification of new or updated examination procedures before receiving test requests/testing patient samples
Molecular Genetic Laboratory Path of Workflow

Laboratory Service Users
- Clinical Needs

Clinical Decision
- Informed decision making, patient preparation, sample collection, test requisition

Performance validation/verification
- Test information and advisory service
- Sample and test request

Planning and preparation

Preexamination

Examination

Postexamination
- Test report and advisory service

Laboratory Service Path of Workflow

QUALITY SYSTEM ESSENTIALS
- Documents and Records
- Information Management
- NCE Management
- Personnel
- Purchasing and Inventory
- Equipment
- Process Management
- Organization
- Customer Focus
- Facilities and Safety

Assessments

Continual Improvement

International • National • Regional • Local • Organizational Requirements

Medical Laboratory

Abbreviation: NCE, nonconforming event.
Quality System Essentials for Molecular Genetic Testing

- Discuss implementation of 12 QSEs in molecular genetic testing services (Section 6 in MM20).
  
  6.1 Organization  
  6.2 Personnel  
  6.3 Documents and Records  
  6.4 Advisory Services  
  6.5 Assessment  
  6.6 Management of Nonconforming Events  
  6.7 Information Management  
  6.8 Continual Improvement  
  6.9 Use of Referral Laboratories  
  6.10 Evaluation of Vendor Qualification  
  6.11 Laboratory Equipment  
  6.12 Facilities, Environment, and Safety

- Describe policies and procedures to specifically address QMS needs in providing molecular genetic testing services.
### Table 3. QSEs in MM20 and Correlation to ISO 15189 and CLSI QMS Guidelines (abridged)*

<table>
<thead>
<tr>
<th>QSEs in MM20</th>
<th>Quality Management Requirements in ISO 15189</th>
<th>General QSEs in CLSI Document GP26</th>
</tr>
</thead>
</table>
| 6.1 Organization                      | 4.1 Organization and management  
                                      4.2 Quality management system  
                                      4.15 Management review  
                                      Annex C.1 General                                                               | Organization                        |
| 6.2 Personnel                         | 5.1 Personnel                                                                                                                                                                                                                     | Personnel                          |
| 8. Personnel Qualifications, Responsibilities, and Competency |                                                                                                                                                                                                                                  |                                    |
| 6.3 Documents and Records             | 4.3 Document control  
                                      4.13 Quality and technical records  
                                      Annex C.7 Storage and retention of medical records                                                                                                                   | Documents and Records               |
| 6.4 Advisory Services                 | 4.7 Advisory services  
                                      Annex C.2 General principles                                                                                                                                                | Customer Focus                      |
| 6.5 Assessment                        | 4.11 Preventive action  
                                      4.14 Internal audits  
                                      4.15 Management review  
                                      5.6 Assuring quality of examination procedures                                                                                                                           | Assessment                          |

* From MM20.
Example: Quality System Essential Assessment

- **Quality Indicators (QIs)** – providing examples in the laboratory’s path of workflow

- **Internal Audits**
  - Horizontal – for general processes in the path of workflow (e.g., acceptance of sequencing reactions)
  - Vertical – for a specific laboratory process (e.g., following a sample from sample receipt to result reporting)

- **External Assessment**
  - Voluntary and mandatory
  - Accreditation vs (third-party) certification

- **Management Review**
### Example: Quality System Essential Assessment (cont’d)

Table 4. Examples of QIs in a Molecular Genetic Testing Laboratory’s Path of Workflow (abridged from MM20)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Examples of Quality Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning and preparation</td>
<td>• Documentation of critical points outlined in Section 5.1</td>
</tr>
<tr>
<td></td>
<td>• Number of molecular genetic tests offered</td>
</tr>
<tr>
<td></td>
<td>• Number of new tests in production</td>
</tr>
<tr>
<td>Validation/verification of test performance</td>
<td>• Evidence of a validation plan</td>
</tr>
<tr>
<td></td>
<td>• Identification of appropriate performance characteristics specified</td>
</tr>
<tr>
<td>Preexamination</td>
<td>• The number of unacceptable samples received compared to the total number of samples received</td>
</tr>
<tr>
<td></td>
<td>• Adequacy of patient information on test requisitions</td>
</tr>
<tr>
<td>Examination</td>
<td>• Frequency of failed nucleic acid extraction</td>
</tr>
<tr>
<td></td>
<td>• Sample switching</td>
</tr>
<tr>
<td>Postexamination</td>
<td>• Accuracy and completeness of the test reports</td>
</tr>
<tr>
<td></td>
<td>• Turnaround time (TAT)</td>
</tr>
<tr>
<td>General</td>
<td>• Laboratory personnel competency</td>
</tr>
<tr>
<td></td>
<td>• User satisfaction</td>
</tr>
<tr>
<td></td>
<td>• Appropriateness in use of molecular genetic testing services</td>
</tr>
</tbody>
</table>
Example: Quality System Essential Information Management

- Laboratory Information Systems (LIS) Considerations
  - Direct interface/compatibility with electronic medical records (for test ordering and reporting)
  - Patient information (eg, race/ethnicity, indication for testing, family history) collected and directly entered with test requests
  - Accommodating all fields/elements of molecular genetic test reports
  - Monitoring examination procedures, quality control (QC) tracking, follow-up on TAT

- Accessibility and Retrievability

- Confidentiality and Security

- Data Management
  - Maintaining databases of sequence variants (eg, sequence variants identified in the laboratory and literature, reference sequences, disease-specific mutation databases)
  - Monitoring/updating as variants are reclassified
  - Ensuring consistency of result interpretation
Path of Workflow – Technical Processes

- Planning and Preparation
- Validation/Verification of Test Performance
- Processes for providing examination services to laboratory users
  - Preexamination activities
  - Examination activities
  - Postexamination activities
Planning and Preparation

Fundamental Management Considerations for Providing Molecular Genetic Test Services

- Ensuring all QSEs are in place and adequate for new tests/test services
- Determining preparedness for all applicable requirements
- Determining needs and demands, benefits and costs
- Identifying personnel competencies, training needs, and responsibilities
- Identifying special issues
  - Informed consent
  - Genetic counseling
  - Intellectual property/licensing concerns
  - Ethical issues (testing of minors, use of tested samples, confidentiality)
Planning and Preparation (cont’d)

- Technical Aspects to Consider

  - Specific intended use (and examination method to be used), different planning issues
    - Diagnostic testing
    - Carrier testing
    - Presymptomatic testing
    - Prenatal diagnosis

  - Documenting clinical validity and utility
    - Indications
    - Contraindications

  - Planning for validation/verification of test performance
Validation/Verification of Test Performance

- Develop validation/verification procedures.
  - The intended use of the test (e.g., carrier testing, fetal testing, diagnostic testing)
  - Target genes, sequences, mutations
  - Expected patient population
  - Test methods to be compared or the method of choice to be used
  - Type(s) of samples to be used
  - Analytical performance characteristics to be determined
  - Sources of reference materials
  - How performance specifications will be analyzed
  - How test limitations should be defined (e.g., rate of allele drop-out, interfering mutations, polymorphisms)
  - Corrective actions when problems occur
Validation/Verification of Test Performance (cont’d)

- Identify samples/materials for analytical validation/verification
  - Adequate number, type, and variety of samples for establishing test performance specifications and defining limitations
  - Control materials, calibration materials, other reference materials
- Determine analytical performance characteristics; define performance specifications and limitations.
- Document results/findings.
- Prepare operational procedures for examination of patient samples.
- Perform ongoing validation.
Preexamination Activities

❖ Begin with the laboratory informing users about:
  - The molecular genetic tests it performs
  - Test selection
  - Patient preparation (if needed)
  - Sample collection, handling, transport, submission with test requisitions (e.g., sample collection/submission manual)

❖ Information provided by laboratory aids health care providers and other users in:
  - Considering indications for testing/recognizing the need for a genetic test
  - Selecting indicated test(s)
  - Shared decision making between a health care provider and the patient/pretest genetic counseling leading to informed consent as indicated
  - Sending test request with patient sample(s) to laboratory

❖ Advisory services regarding consideration/selection of genetic tests
❖ Test referring process in case of sample referral
Preexamination Activities (cont’d)

- Recognize need for testing in patient care, select test
- Informed decision making with patients
- Patient preparation
  - Patient identification
  - Genetic counseling
  - Sample collection, labeling
  - Complete test requisition

Clinical Users

- Sample transport, Transmission of test request

Medical Laboratory

- Service manual, website, etc.
- Provide test information
- Preexamination Activities
  - Test performance validation/verification information
- Receive and evaluate test request and sample; accession

Examination Activities

- External Medical Laboratory (Referral laboratory)
### Preexamination Activities (cont’d)

**Table 7. Responsibilities/Procedures Needed for Preexamination Processes (abridged from MM20)**

<table>
<thead>
<tr>
<th>What Happens</th>
<th>Who Is Responsible/Involved</th>
<th>Information/Procedures From the Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory provides information on test request, sample collection, and submission to users</td>
<td>Laboratory</td>
<td>• Service manual/user information brochures&lt;br&gt;• Instructions for sample collection&lt;br&gt;• Test requisition forms</td>
</tr>
<tr>
<td>Pretest consultation/genetic counseling needed</td>
<td>Health care providers</td>
<td>• Intended use of the test&lt;br&gt;• Performance specifications/limitations&lt;br&gt;• Laboratory consultation (contact information)</td>
</tr>
<tr>
<td>Informed consent obtained (as required)</td>
<td>• Health care providers&lt;br&gt;• Patients</td>
<td>• Intended use of the test&lt;br&gt;• Performance specifications/limitations&lt;br&gt;• Informed consent form&lt;br&gt;• Laboratory consultation (contact information)</td>
</tr>
<tr>
<td>Decision made to order the test</td>
<td>• Health care providers&lt;br&gt;• Patient/family</td>
<td>• Service manual&lt;br&gt;• User information/brochures</td>
</tr>
<tr>
<td>Patient preparation needed</td>
<td>• Health care providers&lt;br&gt;• Patients</td>
<td>• Instructions for sample collection</td>
</tr>
<tr>
<td>• Patient identified (with 2 identifiers)&lt;br&gt;• Primary sample collection, labeling, handling, and preparation for transport</td>
<td>• Person collecting samples&lt;br&gt;– Nurses&lt;br&gt;– Phlebotomists</td>
<td>• Instructions for sample collection, labeling, handling, transport&lt;br&gt;• Instructions for providing sample submission information with test requisitions/entering information in LIS</td>
</tr>
</tbody>
</table>
Examination Activities

- Selection of test procedures according to user needs/expectations
- Sample preparation/processing (eg, nucleic acid extraction/purification)
- Examination procedures
- QC procedures
- Documentation of test results and findings

QC Plan/Program

- Describe how all steps of analytical examination procedures are monitored.
- Essential elements:
  - Types of controls/control materials
  - Frequency and placement of controls
  - Analysis and recording of QC results
  - Pass/fail criteria
  - Corrective and preventive actions
  - Alternative control procedures when control materials are not available
### Table 8. Responsibilities/Procedures for Examination Processes (abridged from MM20)

<table>
<thead>
<tr>
<th>What Happens</th>
<th>Who Is Responsible/Involved</th>
<th>Procedures/Documents for the Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection of appropriate examination procedure</td>
<td>Laboratory director</td>
<td>• Validated/verified examination procedures</td>
</tr>
<tr>
<td></td>
<td>Technical supervisor</td>
<td></td>
</tr>
<tr>
<td>Sample preparation (eg, nucleic acid extraction/</td>
<td>Laboratory personnel</td>
<td>• Extraction/purification of genomic DNA from sample types</td>
</tr>
<tr>
<td>purification, quantification, characterization)</td>
<td></td>
<td>• Extraction/purification of RNA from specific sample types for real time PCR analyses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Determination of quantity and quality of extracted DNA/RNA samples</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Storing of extracted DNA/RNA samples</td>
</tr>
<tr>
<td>Preparation of controls and/or calibrators</td>
<td>Laboratory personnel</td>
<td>• Preparation and storage of stock solutions of control materials for (name[s] of examination)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Preparation, dilution, and disposal of controls for (name[s] of examination)</td>
</tr>
<tr>
<td>Reagent preparation /lot validation</td>
<td>Laboratory personnel</td>
<td>• Preparation and lot validation of reagents</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Authorized examination procedure</td>
</tr>
<tr>
<td>Nucleic acid amplification</td>
<td>Laboratory personnel</td>
<td>• Authorized unidirectional workflow procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Authorized amplification procedures</td>
</tr>
<tr>
<td>Determination of genotype</td>
<td>Laboratory personnel</td>
<td>• Detection/evaluation of analytical and QC results</td>
</tr>
<tr>
<td>Target detection/quantification</td>
<td>Laboratory personnel</td>
<td>• Authorized examination procedure</td>
</tr>
</tbody>
</table>
Postexamination Activities

- Reviewing examination results
- Providing laboratory interpretation
- Generating examination reports
- Transmitting test reports to the test requestor or other clinical users
- Providing laboratory consultation regarding test results, result interpretation, follow-up examinations or services
- Archiving of examination records, reports, and tested patient samples

Recommended Contents of Molecular Genetic Test Reports

Procedures for Releasing/Reporting Test Results
- Who may release test results and to whom
- Maintaining confidentiality of patient/family information
- Monitoring accidental disclosure and documenting corrective actions

Procedures for Corrected, Revised, Amended Reports
Postexamination Activities (cont’d)

Table 10. Responsibilities/Procedures Needed for Postexamination Activities (abridged from MM20)

<table>
<thead>
<tr>
<th>Action</th>
<th>Who Is Responsible</th>
<th>Examples of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review test results</td>
<td>Laboratory testing personnel/</td>
<td>• Reviewing and evaluating test results</td>
</tr>
<tr>
<td></td>
<td>technical supervisor</td>
<td>• Reviewing test results relating to test requests</td>
</tr>
<tr>
<td>Generate test reports</td>
<td>Technical supervisor</td>
<td>• Generating patient-specific test reports</td>
</tr>
<tr>
<td></td>
<td>Authorized personnel</td>
<td></td>
</tr>
<tr>
<td>Provide final test result(s)</td>
<td>Laboratory director, technical</td>
<td>• Generating patient-specific test reports</td>
</tr>
<tr>
<td>and interpretation(s)</td>
<td>supervisor, or designee</td>
<td></td>
</tr>
<tr>
<td>Approve test report with</td>
<td>Laboratory director or</td>
<td>• Generating, reviewing, and approving patient-specific test reports</td>
</tr>
<tr>
<td>interpretation</td>
<td>designee</td>
<td></td>
</tr>
<tr>
<td>Transmit test reports to</td>
<td>Authorized laboratory personnel</td>
<td>• Transmitting patient-specific test reports to authorized person(s)</td>
</tr>
<tr>
<td>authorized person.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communicate with authorized</td>
<td>Laboratory director, clinical consultant,</td>
<td>• Laboratory policy for advisory services</td>
</tr>
<tr>
<td>users</td>
<td>or designee</td>
<td></td>
</tr>
<tr>
<td>Archive test reports</td>
<td>Laboratory personnel</td>
<td>• Archiving/storage/retention of reports and examination records</td>
</tr>
<tr>
<td>Store tested samples</td>
<td>Laboratory personnel</td>
<td>• Archiving/storage/retention of residual patient samples</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Current local and national laws and regulations</td>
</tr>
<tr>
<td>Monitor and document TAT</td>
<td>General supervisor, quality manager, or</td>
<td>• Monitoring and documenting TAT</td>
</tr>
<tr>
<td></td>
<td>designee</td>
<td>• Quality assessment</td>
</tr>
</tbody>
</table>
Ensuring Quality of Patient Testing

- Proficiency Testing/External Quality Assessment (PT/EQA)
  - Existing programs for commonly performed molecular genetic tests (eg, CAP, CF [European] Network, EMQN, EuroGentest, UK NEQAS)
  - Differences between PT/EQA samples and actual patient samples: greater benefits from challenging more steps of the testing process
  - Section 7.3.3 in MM20 and CLSI documents GP27, MM01, MM14, and MM19

- Alternative Performance Assessment
  - Interlaboratory comparison and intralaboratory evaluation when sample exchange is not available
  - As frequent as would be required by participation in formal PT/EQA
  - Rigorous in review and interpretation of results

- Management of Performance Assessment Results
  - Important part of the laboratory’s quality assurance plan
  - Documentation of assessment, results, and corrective actions
  - Written policies on review and retention of performance assessment results

Abbreviations: CAP, College of American Pathologists; CF, cystic fibrosis; EMQN, European Molecular Genetics Quality Network; UK NEQAS, United Kingdom External Quality Assessment Service.
Personnel Qualifications, Responsibilities, Competency

Figure 5. An Example of a Medical Laboratory Organizational Structure from MM20
Personnel Competency Assessment

- Methods for Competency Assessment for Laboratory Management
  - Appropriate levels of continuing education units
  - Peer-reviewed journal articles studied
  - Membership/participation in professional organizations
  - Credentials and maintenance of certification activities
  - Proficiency slides or samples examined
  - Interlaboratory sample exchanges with interpretation
  - Assessment at annual review or other time, documented with appropriate form (see Appendix O in MM20)

- Personnel competency assessment for testing personnel
  - Determining when competency assessment is needed
  - Key elements of competency assessment program for testing personnel (see Table 11 in MM20)
Appendixes in MM20

Appendix A. Example of a Laboratory Quality Manual
Appendix B. A Crosswalk of Quality Standards of ISO 15189 and Clinical Laboratory Improvement Amendment Regulations in Relation to Quality System Essentials
Appendix C. Example Molecular Genetic Test XYZ Training Form
Appendix D. Sample Training Grid
Appendix E. Quality Management Documents and Records for the Path of Workflow of Molecular Genetic Testing
Appendix F. Required or Recommended Retention Practices Related to Records and Reports of Molecular Genetic Testing
Appendix G. Example of a Completed Nonconforming Event Record
Appendix H. Sample Process for Corrective and Preventive Action Activities/Review
Appendix I. Recommended or Required Test Report Content
Appendix J. Sample Failure Modes and Effects Analysis
Appendix K. Informed Consent for Molecular Genetic Testing
Appendix L. Example of a Molecular Genetic Test Requisition Form
Appendix M. Examples of Molecular Genetic Test Reports
Appendix N. Recommended Practices for Retention of Residual Patient Samples
Appendix O. Competency Assessment Examples
Appendix A. Example of a Laboratory Quality Manual
Document Development Committee

- International participation: ≈ 40 expert individuals from Belgium, Brazil, Canada, Italy, Japan, Kenya, Korea, New Zealand, United States
- Coordination with other CLSI committees
  - Consensus Committee on Molecular Methods: Dr. Rick Nolte (Chairholder)
  - Consensus Committee on Quality Systems and Laboratory Practices: Dr. Devery Howerton (Vice-Chairholder)
  - Document Development Committees
    - MM01: Drs. Kristin Monaghan and Barbara Zehnbauer (Co-Chairholders)
    - MM19: Dr. Jean Amos Wilson (Co-Chairholder)

- Writing team:
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  - Rajyasree Emmadi, MD, FCAP
  - Renée M. Howell, PhD
  - Joshua D. Levin, PhD
  - François Rousseau, MD, MSc, CSPQ, FRCPC
  - Maren T. Scheuner, MD, MPH, FACMG
Polling Question

Will MM20 be helpful for your practice?

☐ Yes

☐ No
Questions?
Thank You!

Please enter suggestions into the comment box, or e-mail bkc1@cdc.gov.