

MOLECULAR BIOLOGY 101

REFERENCES AND RESOURCES

CLIA Program

Regulatory Information Resources

- CMS CLIA website (program info, statistics, etc.)
<http://www.cms.hhs.gov/clia/>
- CLIA and LDT FAQs http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf
- CLIA Subpart K Part 1 (verification, QA) <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/apcsubk1.pdf>
- CLIA Subpart K Part 2 (standards, mycobacteriology) <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/apcsubk2.pdf>
- CLIA Subpart M (personnel and staffing) www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/apcsubm.pdf
- CDC CLIA website (CLIAC, regulations, etc.)
<http://wwwn.cdc.gov/clia/>
- FDA CLIA website (complexity categorizations, waiver)
<http://www.fda.gov/cdrh/CLIA/index.html>

FDA Regulatory Resources

- FDA (laboratory develop tests)
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm>
- FDA (in-vitro diagnostics)
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm>

Other Resources

- Burd, Eileen. Validation of Laboratory-Developed Molecular Assays for Infectious Diseases. 2010. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2901657>
- Update on FDA Reclassification, Gitterman, Steve. APHL 2013 TB Conference
http://www.aphl.org/conferences/proceedings/Documents/2013/2013-National-TB-Conference/ID_2013August12_23_Gitterman.pdf

CLSI References

- MM03 A2 Molecular methods for infectious diseases
- MM06-A2 Quantitative methods for infectious diseases
- MM09-A2 NAA sequencing methods—covers Sanger, Massively parallel, NGS, validation, QA.
- MM19-A Establishing Molecular testing in clinical labs
- MM22 -A Microarrays for infectious diseases <http://clsi.org/standards/>

Other Resources

- Pyrosequencing video: <http://www.youtube.com/watch?v=jyIChBxTKkw->
- CDC Advanced Molecular Detection (AMD) for TB site <http://www.cdc.gov/amd/project-summaries/detecting-tuberculosis-accurately.html>
- Heat-kill/viability study <http://www.ncbi.nlm.nih.gov/pubmed/15667662>