Molecular In My Pocket™...
Establishing a Molecular Laboratory - Best Practices Around the Globe

Pre-Analytical	DO	DON'T
Quality Management and Quality Control	• Have a written quality management (QM) program that ensures quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing. • Note that a good QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.	• Don't forget to investigate and document all incidents/errors and corrective actions. • Don't forget to define a periodic review of results by a qualified person. • Don't forget to put a laboratory policy in place to ensure compliance with applicable federal, state, and local laws and regulations.
Test Menu Design	• Determine and verify the best tests for your location and patient population. • Determine the best available tests for actionable/treatable mutations and diagnoses. • Check the impact of turn-around time requirements on the test menu.	Don't try to do <u>every</u> available test in the world; test selection should reflect the needs of your community.
Collection, Transport, Preparation, and Storage of Specimens	• Prepare written procedures consistent with good laboratory practice that describe methods for 1. patient identification, 2. patient preparation, 3. specimen collection and labeling, 4. specimen preservation, and 5. conditions for transportation and storage before testing. • Use <u>at least two</u> patient-specific identifiers.	Don't forget to check for any laws in your country that specify different requirements.
Physical Facilities	• Ensure that checks on instrument/equipment maintenance and function are reviewed periodically. • Make sure that there is enough space so that quality of work, safety of personnel, and patient care services are not compromised. • Verify whether dedicated areas for pre- and post-amplification, depending on your test menu, are required. • Check these other important points: fire prevention, electrical safety, chemical safety, radiation safety, environmental safety	Don't forget to observe the workflow in <u>each</u> area so as to avoid contamination during molecular procedures.
Federal/State/Local Regulations	Verify local laws and regulations for a clinical laboratory and determine the minimum requirements for staff training.	Don't assume that USA regulations are valid for other countries.
Personnel	• Define all laboratory personnel policies and job descriptions that outline qualifications and duties for all positions. • Keep personnel files with records of educational qualifications (e.g. copies of diplomas, transcripts, primary source verification reports), laboratory personnel licenses (where required), training and continuing education for each employee. • Check local regulation requirements for ascertaining the competency of the laboratory person who will sign off on laboratory reports.	• Never allow non-trained personnel to perform tests. • Don't forget to check local regulations for minimal training requirements for each kind of test. • Don't forget to check local regulations for minimal competence requirements for each role in the test process.
Laboratory Safety	• Have required laboratory safety policies and procedures including bloodborne hazard control and chemical hygiene plans. • Have required written laboratory policies and procedures for infection control that comply with national, state, and local guidelines on occupational exposure to bloodborne pathogens and to the institution's exposure control plan.	• Don't forget to be prepared for emergencies (evacuation plan, disasters) • Don't forget to verify local regulations for buying, and storage of, dangerous products. • Never forget your personal protective equipment (gloves, gowns, masks and eye protectors, etc.)!

Analytical	DO	DON'T
Procedure Manual	• Have a complete laboratory procedure manual available for each test at the workbench or in the work area. • Have procedure manuals containing necessary instructions to perform each test. • Review procedure manuals periodically.	• Don't use inserts provided by manufacturers as a procedure manuals. • Don't forget to notify all personnel of any alterations in procedure manuals and, when necessary, retrain staff.

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Assay Validation	Make sure that all tests in the laboratory menu must are validated before use (Accuracy, Precision, Analytical Sensitivity, Analytical Specificity, Analytical Interferences, and Reportable Range, as applicable).	Don't forget to verify local regulations for test validation requirements.
Reagents	• Always follow manufacturer instructions for handling and storing reagents, cartridges, test cards, etc. • Properly label all reagents, calibrators, controls, stains, chemicals, and solutions with the following elements: Content and quantity, concentration or titer, storage requirements, date prepared, filtered or reconstituted by laboratory, and expiration date. • Dispose of waste according to local, state, or federal regulations.	• Never use any reagent after the expiration date. • Never use a reagent that is not properly identified.
Controls	Ensure that all procedures have the proper controls in order to assure the quality of the test. This must be defined in <u>each</u> procedure manual. Good practice includes wipe tests and harmonization of instruments.	Never validate a test with missing controls or use controls out of the expected range.
Proficiency Testing	• The best practice is to have an External Quality Assessment (EQA) program for every test performed in the laboratory. Each EQA program has a different periodicity, but proficiency tests are performed twice a year on average. • Treat proficiency test samples in the same way as any patient sample.	• Never send proficiency test samples out to reference laboratories. • Don't forget any test on the laboratory menu. • If there is no EQA, remember to organize an alternative PT.

Post-Analytical	DO	DON'T
Results Reporting	• The best practice for a report is to have <u>at least</u> the following elements: 1. Name and address of testing laboratory 2. Patient name and identification number, or unique patient identifier 3. Name of physician of record, or legally authorized person ordering test, as appropriate 4. Date of specimen collection, and if appropriate, time of collection 5. Date of release of report (if not on the report, this information should be readily accessible) 6. Time of release of report, if applicable (if not on the report, this information should be readily accessible) 7. Specimen source, when applicable 8. Test result(s) and units of measurement, when applicable; 9. Reference intervals, as applicable 10. Conditions of specimen that may limit adequacy of testing 11. Limitations of the test, where applicable 12. Methodology used • Always ensure that internal and external storage and transfer of laboratory data maintains patient confidentiality and security.	• Don't forget to check the minimal reporting requirements for a laboratory report in your country. • Don't forget to follow best practice guidelines for the type of report you are issuing.
Records	• Retain laboratory records for the appropriate time as defined in your laboratory policies. • Check these important points: Data safety, IT structure, LIS	Don't forget that retention of records must comply with federal, state, and local laws and regulations (use always the more stringent one). For testing on minors (under the age of 21), stricter state regulations may apply.

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