

Steps for market assessment, feasibility, and design of laboratory tests

- Perform technology assessment

- Investigate clinical usefulness and intended use

- Perform feasibility assessment

- Assess legal right to use/perform marketing assessment

- If applicable, assess potential patentability of technology

- Assess potential reimbursement strategies

Steps for test development (required to determine final product/test)

- Ensure all necessary laboratory accreditations are in place (state or otherwise)

- Determine which marker(s) will be part of the test

- Obtain materials to develop tests:
 - Instrument systems evaluated and chosen for fitness for purpose

 - Reagents, calibrators, and controls—purchased or spiked in-house in appropriate matrix

 - Primer/probes for target, and test kits

 - Vendor selection

 - Lab supplies—reagents, master mix, pipette tips, extraction units, etc.

- Perform analytical validation and ensure all data are stored and accessible

- Perform clinical validation and ensure all data are stored and accessible

- Create and document standard operating procedures (SOPs)
