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Development Stages in Scope
Diagnostics and Devices

Feasibility Demonstration: Characterization of Preliminary Candidates(s) and Feasibility Demonstration: Begin R&D, data collection, and analysis in order to verify feasibility. Explore alternative concepts, identify and evaluate critical technologies and components, and begin characterizing specifications required. Demonstrate the performance of candidate diagnostic targets and high-risk components. Develop a business case for the proposed product.

Optimization: Optimization and Preparation for Assay, Component, and Instrument Development. Prepare for test system development. Finalize diagnostic target(s) and methods for detecting or quantitating target(s). Develop detailed plans and finalize critical design requirements. Execute commercial agreements with key external development partners. Identify manufacturing resources, vendor sourcing, and experimental designs.

Product Development: Reagents, components, subsystems and modules - Develop reagents and buffers. Build and test non-GLP prototypes of components and subsystems. Code and unit test software. Begin pilot scale manufacturing preparations. Develop protocols for assay and integration testing Initiate reagent stability testing. Hold pre-IDE meeting with FDA.

System Integration and Testing: Integrate and test alpha and beta instruments/devices, software and assays, evaluating performance and updating specifications. Implement design improvements to address defects discovered during testing. Produce and evaluate pilot lots of reagents and beta (pilot) instruments. Increase the maturity of software. Prepare for clinical testing. Complete short-term stability testing of reagents.