4. NEW POCT IMPLEMENTATION FORM

Requesting Unit: _____

Test being requested: _____

Pre-Approval

1. Decide on testing to be provided
    a. Instruments/kits to purchase
        i. Does new device/test Intended Use include your patient population? Examples include infants/children, oncology patients, and critically ill.
        ii. Does the new device/test have new and innovative technology?
        iii. Will new device/test improve patient outcomes?
            1. Examples include fewer call backs, improved TAT, more efficient treatment, or healthcare follow ups?
        iv. Does the new device/test offer a clinical sensitivity/specificity similar to current testing being offered?
        v. Does the new device/test being implemented have customer service and operator training provided by the manufacturer or distributor?
            1. Does the manufacturer or distributor provide installation and customer support, or is this outsourced to a third party?
        vi. Review device/test system requirements such as:
            1. Frequency of QC, ability to enable IQCP, calibration and calibration verification requirements (if applicable).
    b. Reagents/supplies to purchase
        i. Direct sale versus reagent rental agreements
        ii. Ensure enough quantities are available to complete performance verification and training. This can be coordinated with the manufacturer/distributor.
        iii. Review reagent and supply shelf life
    c. Physical specifications for area, including space
        i. Ensure appropriate environment of care is available and ready for refrigerated and frozen supplies, if applicable.
        ii. Ensure the space meets the power requirements, has appropriate lighting, and has network/computer/internet connectivity (if needed).
    d. Review Instrument Features
        i. If onboarding a new instrument, does this device have all the features your facility needs/desires? Some examples are:
            1. Operator ID/Operator lockout, QC lockout, various reference range entry, result recording (connectivity, print out, fax, etc.), data storage for patient, QC and PT results.

Rollout

1. Validation Plan
    a. Waived-follow manufacturer's instructions
    b. Non-Waived
        i. IQCP (the IQCP can reduce the frequency of CLIA-mandated, daily QC, in lieu of manufacturer-engineered QC processes for the POCT device)
            1. IQCP Creation
            2. IQCP Approval
        ii. Validation plan created
            1. Plan approved/denied by medical director
    c. Ensure supplies for validation
    d. Validation plan executed
    e. Validation approved or additional validation required, per medical director
2. Device and Supply Acquisition

    a. Programs instruments, as needed
3. Test Location
    a. Determine appropriate physical location for devices and supplies
    b. Determine if refrigerator/freezer is needed
4. Document Creation
    a. Procedure Creation
        i. Creation
        ii. Approval by CLIA medical director
    b. Training Document Creation
        i. Observation checklist creation
        ii. PowerPoint or training resources
            1. Vendor provided
            2. Self-developed
    c. Additional Document Creation
        i. Creation of other necessary documents, as needed
            1. QC Log
            2. Maintenance Log
            3. Patient Result Log
            4. Temperature Log
        ii. Approval of additional documents
5. IT Requirements
    a. Which software packages are needed?
        i. Purchase of servers/software /drivers, if needed
    b. IT Builds
        i. Test Results
        ii. Test Result Units
        iii. Reference Ranges
        iv. Critical Ranges
        v. LIS builds (if needed)
        vi. Middleware builds
        vii. EMR builds
    c. IT Testing
        i. System Validation/Verification
        ii. Approval of System Validation/Verification
6. Operator Training
    a. After 90% of staff have completed the training, testing can begin
    b. Provides instrument access to devices for all operators, as applicable
    c. Training may be performed by vendor representative
7. New Test Go Live
    a. Production validation
    b. Audits to ensure method and regulatory compliance
    c. New test is added to the site's test menu
    d. New test is added to the regulatory agency menu, if applicable

Signature: _____ **Date:** _____