PERFORMANCE WORK STATEMENT (PWS)

Outcome-Based Reagent Supply – ISTAT Analyzer Pine Ridge Indian Hospital Laboratory (PRSU)

1.0 OBJECTIVE (OUTCOME-BASED)

The objective of this contract is to ensure continuous uninterrupted availability of fully compliant reagent supplies required to operate the Abbott I-STAT analyzer in support of 24/7 clinical diagnostic services.
Successful performance is defined as:

- Zero disruption to testing capability due to supply failure
- Full compliance with cold-chain, expiration, and manufacturer requirements
- Delivery performance that aligns with laboratory demand without overstocking or shortages
- 100% usability of delivered products upon receipt

2.0 SCOPE (NON-PERSONAL SERVICES)

The Contractor shall provide end-to-end supply availability outcomes, including sourcing, quality assurance, cold-chain management, and delivery of all required reagents, calibrators, and controls. This is a non-personal services contract. The Government defines outcomes; the Contractor determines methods to achieve them.

3.0 PERFORMANCE OUTCOMES

The Contractor shall achieve the following **mission-critical outcomes**:

3.1 Continuous Supply Availability

- Laboratory always maintains 100% operational readiness for I-STAT testing

3.2 Product Usability

- All delivered products are immediately usable, compliant, and within acceptable shelf life

3.3 Regulatory & Manufacturer Compliance

- All products meet Abbott manufacturer specifications and applicable regulatory standards

3.4 Cold Chain Integrity

- All temperature-sensitive materials arrive within validated temperature ranges

4.0 PERFORMANCE METRICS (KPIs / SLAs / AQLs)

Performance Area	Metric / KPI	Service Level (SLA)	Acceptable Quality Level (AQL)
Supply Continuity	Stockout incidents impacting testing	Zero tolerance	0 incidents
On-Time Delivery	Deliveries within agreed schedule	≥ 95%	≥ 95%
Product Acceptance Rate	Deliveries accepted without rejection	≥ 98%	≥ 98%
Shelf-Life Compliance	Products meet longest available dating	100%	100%
Cold Chain Compliance	Temperature excursions	Zero tolerance	0 incidents
Lot Consistency	Single lot per shipment	100%	100%

5.0 QUALITY ASSURANCE SURVEILLANCE (OUTCOME-BASED)

The Government will evaluate performance using:

- Inspection at receipt (temperature, expiration, lot compliance)
- Inventory tracking (stock levels vs. usage rates)
- Deficiency reporting logs
- Trend analysis of delivery performance

Surveillance focuses on results, not contractor processes.
See attached QASP

6.0 INCENTIVES / DISINCENTIVES

6.1 Positive Performance Consideration

- Consistent high performance (≥ 98% across all metrics) may support:
    - Favorable CPARS ratings
    - Consideration for future awards

6.2 Remedies for Non-Performance

Failure to meet performance standards will result in:

- Mandatory replacement of non-compliant items at contractor expense
- Rejection of shipments
- Performance documentation impacting CPARS
- Increased surveillance
- Potential termination for cause or non-exercise of options

Critical Failures (Immediate Action Required):

- Any stockout impacting patient care
- Any cold-chain breach
- Repeated delivery failures

7.0 PERFORMANCE CONSTRAINTS

The Contractor shall operate within the following constraints:

- Only Abbott-certified products authorized for i-STAT analyzer
- Compliance with cold-chain logistics requirements
- No substitution without Contracting Officer approval

8.0 DEMAND FORECAST (ESTIMATED)

Estimated annual usage (for planning only):

- Troponin: ~450 tests
- ABG: ~1,400 tests
- Chem8: ~400 tests

The Contractor is responsible for aligning supply strategy to meet actual demand variability.

9.0 DELIVERABLES (OUTPUT-DEFINED)

The Contractor shall deliver fully compliant, ready-to-use reagent systems, including:

- Test reagents
- Calibrators
- Multi-level quality control materials
- See attached Shipping Schedule

Acceptance Criteria (Output-Based):

A delivery is considered acceptable only if:

- Products are within acceptable expiration range
- Temperature compliance is verified
- Correct items and quantities are delivered
- Single lot number per shipment
- No visible damage or compromise

10.0 PRODUCT REQUIREMENTS

Catalog Number	Description
3P85-51	CG4+ Reagent Box/25
09P31-26	Chem8 Reagent Box/25
05P71-01	Tri Control Level 1
05P72-01	Tri Control Level 2
05P73-01	Tri Control Level 3
03P90-25	Troponin Reagent Box/25
06P17-09	Troponin Control Level 1
06P17-10	Troponin Control Level 2
06P17-11	Troponin Control Level 3

11.0 DELIVERY LOCATION

Pine Ridge Indian Hospital Laboratory
607 Indian Health Road
Pine Ridge, SD 57770

12.0 PERIOD OF PERFORMANCE

12 months (365 days) from date of award

13.0 ROLES AND RESPONSIBILITIES

Contractor

- Accountable for achieving all defined outcomes
- Responsible for logistics, quality, and compliance

Government (COR)

- Monitors performance outcomes

- Verifies acceptance criteria
- Documents deficiencies

14.0 INVOICING (PERFORMANCE-BASED)

Invoices shall:

- Reflect only accepted deliveries
- Be submitted via IPP
- Include supporting documentation (shipment, temperature compliance if applicable)

Payment is contingent upon meeting performance outcomes.

15.0 JUSTIFICATION (MISSION-CRITICAL OUTCOME)

This requirement directly supports:

- Emergency Department diagnostic capability
- Critical Access Hospital (CAH) compliance
- The Joint Commission (TJC) standards

Failure to meet outcomes results in:

- Immediate patient care risk
- Diagnostic delays
- Regulatory non-compliance

16.0 DEFINITIONS (FOR ENFORCEMENT CLARITY)

- **Stockout:** Any instance where required testing cannot be performed due to lack of supplies
- **Short-Dated:** Insufficient shelf life to support normal consumption cycle
- **Cold Chain Failure:** Any temperature excursion outside manufacturer specifications
- **Non-Compliant Delivery:** Any shipment failing acceptance criteria

QUALITY ASSURANCE SURVEILLANCE PLAN (QASP)

Reagent Supply – ISTAT Analyzer
Pine Ridge Indian Hospital Laboratory (PRSU)

1.0 PURPOSE

This QASP defines the systematic methods the Government will use to monitor, evaluate, and document Contractor performance against the Performance Work Statement (PWS).
Surveillance is outcome-based, focusing on measurable results, not contractor processes, in accordance with non-personal services contracting principles.

2.0 PERFORMANCE MANAGEMENT APPROACH

Performance will be assessed using:

- Key Performance Indicators (KPIs)
- Service Level Agreements (SLAs)
- Acceptable Quality Levels (AQLs)

All surveillance is tied directly to mission-critical outcomes:

- Continuous testing capability
- Product usability upon delivery
- Cold-chain integrity
- Compliance with manufacturer requirements

3.0 PERFORMANCE METRICS & SURVEILLANCE PLAN

Performance Objective	Performance Standard / KPI	AQL	Surveillance Method	Frequency	Data Source
Supply Continuity	No stockouts impacting testing	0 incidents	Inventory review; deficiency log	Weekly / As Occurs	Lab inventory records
On-Time Delivery	Deliveries meet scheduled dates	≥ 95%	Delivery log review	Each Delivery	Receiving records
Product Acceptance	Deliveries accepted without rejection	≥ 98%	Inspection at receipt	Each Delivery	Receiving/inspection logs
Shelf-Life Compliance	Longest available expiration dating	100%	Visual inspection; expiration verification	Each Delivery	Product labels

Performance Objective	Performance Standard / KPI	AQL	Surveillance Method	Frequency	Data Source
Cold Chain Integrity	No temperature excursions	0 incidents	Review temp indicators/loggers	Each Delivery	Shipping documentation
Lot Consistency	Single lot per shipment	100%	Inspection of shipment contents	Each Delivery	Packing slips

4.0 SURVEILLANCE METHODS

4.1 Inspection at Receipt

- Verify product type, quantity, and condition
- Confirm expiration dates meet requirements
- Validate single lot shipment compliance
- Review temperature indicators/loggers

4.2 Inventory Monitoring

- Track stock levels against usage rates
- Identify potential shortages or overstock risks
- Confirm Contractor is aligning deliveries with demand

4.3 Deficiency Tracking

- Document all non-compliant deliveries
- Track trends and repeat issues
- Maintain audit-ready performance records

4.4 Trend Analysis

- Evaluate Contractor performance over time
- Identify systemic risks (e.g., recurring delays, dating issues)
- Support performance decisions (options, CPARS, remedies)

5.0 ROLES AND RESPONSIBILITIES

5.1 Contracting Officer (CO)

- Holds authority for contractual actions
- Approves remedies, modifications, or termination actions

5.2 Contracting Officer Representative (COR)

- Primary performance monitor
- Performs inspection and acceptance
- Documents performance and deficiencies
- Recommends corrective actions to CO

5.3 Laboratory Staff (Technical Support)

- Assist COR with technical validation of products
- Report usability issues or testing impacts

6.0 ACCEPTANCE CRITERIA

A shipment is **acceptable** only if all of the following are met:

- Correct products and quantities delivered
- No damage or compromise to materials
- Temperature compliance verified
- Longest available expiration dating
- Single lot number per shipment

Failure in any category results in **rejection**.

7.0 DEFICIENCY CLASSIFICATION

7.1 Critical Deficiencies (Immediate Impact)

- Stockout impacting patient testing
- Cold-chain failure
- Delivery of unusable or expired products

Action: Immediate notification to CO; corrective action required; potential escalation

7.2 Major Deficiencies

- Repeated late deliveries
- Failure to meet expiration requirements
- Mixed lot shipments

Action: Documented deficiency; corrective action plan required

7.3 Minor Deficiencies

- Administrative errors (labeling, paperwork)
- Isolated, non-recurring issues

Action: Document and monitor trends

8.0 CORRECTIVE ACTION PROCESS

When deficiencies occur:

1. COR documents issue
2. Contractor is notified
3. Contractor provides corrective action plan (if required)
4. COR monitors resolution
5. Repeat issues escalate to CO

9.0 REMEDIES FOR NON-PERFORMANCE

Failure to meet performance standards may result in:

- Rejection and replacement at contractor expense
- Increased surveillance
- Negative CPARS evaluation
- Non-exercise of option periods
- Termination for cause (if performance failure persists)

10.0 PERFORMANCE DOCUMENTATION

The COR shall maintain:

- Delivery logs
- Inspection records
- Deficiency reports
- Performance trend data

All records shall be **audit-ready** and support:

- Invoice approval
- CPARS evaluations
- Contract decision-making

11.0 INVOICE VALIDATION

Invoices will only be approved when:

- Deliveries meet all acceptance criteria
- No unresolved deficiencies exist
- Quantities match accepted deliveries

Invoices not meeting these conditions will be **rejected or delayed**.

TECHNICAL EVALUATION FACTORS
(LPTA – Reagent Supply Contract for Abbott i-STAT Analyzer Supplies)
Pine Ridge Indian Hospital Laboratory (PRSU)

The Government will evaluate quotations using a Lowest-Priced Technically Acceptable (LPTA) source selection process in accordance with FAR Part 13 and FAR 15.101-2, as applicable. Award will be made to the Offeror responsible submitting the lowest evaluated price that is determined to be technically acceptable.

Technical acceptability shall be determined on an Acceptable/Unacceptable basis. Quotes rated "Unacceptable" under any technical factor may be eliminated from further consideration.
The Government intends to evaluate quotations based on the following factors:

FACTOR 1 – TECHNICAL CAPABILITY

The Offeror shall demonstrate the capability to provide continuous, complaint, and uninterrupted reagent supply support for the Abbott i-STAT analyzer system in accordance with the Performance Work Statement (PWS).
The Offeror shall provide sufficient documentation demonstrating:

1.1 Ability to Obtain Abbott i-STAT Supplies

The Offeror shall demonstrate the ability to procure and supply genuine Abbott i-STAT products required under this contract through authorized distribution channels.

The Offeror shall provide:

- Documentation demonstrating the ability to purchase Abbott i-STAT supplies from an Abbott-authorized distributor, or approved supply source
- Evidence that all products proposed are genuine Abbott-manufactured products intended for use on the Abbott i-STAT analyzer platform
- Documentation demonstrating sufficient supply access and distribution capability necessary to maintain uninterrupted product availability throughout contract performance

Acceptable documentation may include:

- Distributor relationship documentation
- Supplier agreements
- Recent invoices or purchase history
- Letters of supply capability
- Other documentation demonstrating established access to Abbott i-STAT products

The Government reserves the right to verify product sourcing and authenticity.

Failure to provide sufficient documentation demonstrating the ability to obtain and supply authentic Abbott i-STAT products may result in the quotation being determined technically unacceptable.

1.2 Supply Chain Capability

The Offeror shall demonstrate the capability to:

- Maintain uninterrupted reagent availability
- Preventing stockouts impacting patient testing
- Support a 24/7 hospital laboratory operation
- Provide all required reagents, controls, calibrators, and consumables identified in the PWS

1.3 Cold Chain & Shipping Management

The Offeror shall demonstrate:

- Procedures for maintaining cold-chain integrity during storage and shipment
- Ability to provide temperature-controlled shipping when required
- Methods for monitoring and documenting temperature compliance
- Ability to replace compromised shipments at no additional cost to the Government

1.4 Product Quality & Shelf-Life Compliance

The Offeror shall demonstrate the ability to:

- Deliver products with acceptable expiration dating
- Provide single-lot shipments when required
- Deliver products free from damage or contamination
- Ensure delivered products are immediately usable upon receipt

1.5 Delivery Performance

The Offeror shall demonstrate:

- Ability to meet delivery/shipping schedules
- Capability to respond to urgent supply needs
- Ability to maintain delivery performance standards identified in PWS and QASP

FACTOR 2 – PAST PERFORMANCE

The Government will evaluate the Offeror's recent and relevant past performance associated with:

- Clinical laboratory supply contracts
- Reagent distribution contracts
- Medical supply logistics
- Temperature-controlled medical shipping services

The Offeror shall provide:

- A minimum of two (2) recent and relevant references performed within the last three (3) years
- Contract number (if applicable)
- Organization name
- Point of contact
- Telephone number and email address
- Brief description of services performed

The Government may evaluate:

- Quality of performance
- Timeliness of delivery
- Product reliability
- Responsiveness to issues
- History of supply continuity
- Customer satisfaction

The Government may also use information obtained from:

- CPARS
- PPIRS (if applicable)
- Government records
- Other sources reasonably available to the Government

FACTOR 3 – PRICE

The Government will evaluate price for:

- Completeness
- Fairness and reasonableness
- Mathematical accuracy
- Compliance with solicitation requirements

The Offeror shall submit:

- Unit pricing
- Extended pricing
- Total evaluated price

- Any applicable shipping or handling costs

The Government may determine a quotation unacceptable if pricing is materially unbalanced or unrealistic.

TECHNICAL ACCEPTABILITY STANDARDS

To be rated "Acceptable," the quotation must clearly demonstrate the Offeror:

- Is able to procure and supply genuine Abbott i-STAT supplies from an Abbott-authorized distributor, or approved supply source
- Can maintain uninterrupted supply continuity
- Can meet cold-chain and delivery requirements
- Can provide compliant and usable products
- Can meet all PWS performance standards and QASP metrics

Failure to provide sufficient supporting documentation may result in an "Unacceptable" rating.

BASIS FOR AWARD

Award will be made to the Offeror responsible whose quotation:

1. Is determined Technically Acceptable
2. Meets all solicitation requirements
3. Represents the Lowest Evaluated Price to the Government

No tradeoffs will be conducted under this LPTA evaluation methodology.