TECHNICAL SPECIFICATIONS DOCUMENT

Laboratory Supplies, Laboratory Network Services, Molecular and Bioanalytical Solutions

SUPPRESS-LA-CLTSD-001

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NB: This document is issued solely for the preparation and evaluation of proposals. It is not a clinical protocol, laboratory manual, purchase order or contract.

Contents

1. Purpose, Scope and Interpretation

This document defines the minimum public-stage technical, quality, regulatory, logistics and data requirements for Lots A-K5 under SUPPRESS-LA-CRFP-001. It is designed to support competitive bidding without disclosing protocol-sensitive, commercially sensitive or security-sensitive information that is not required at the open stage.

This TSD is not a clinical protocol, laboratory manual, method SOP or specimen-processing instruction. Successful bidders must comply with the final protocol, laboratory manual, approved methods, quality agreements and site-specific instructions provided after appropriate confidentiality controls and contract execution.

Code	Meaning
M	Mandatory. Failure to comply may make the proposal non-responsive unless ACRN expressly accepts a justified alternative.
D	Desirable. Provides additional value or risk reduction but is not automatically disqualifying.
NDA	Additional detail is available only to shortlisted bidders after execution of an NDA and confirmation of need to know.
Contract	Final requirement, responsibility, threshold or operational detail will be agreed in the contract, SLA, quality agreement, data agreement or MTA.

2. Minimised Programme Technical Context

The programme requires a distributed laboratory model comprising local routine testing, regional specimen-management capacity and specialised reference testing. Required capabilities include clinical safety testing, HIV virology and immunology, infectious-disease diagnostics, -80°C specimen management, compliant biological shipment, bioanalytical drug concentration testing, HIV drug resistance genotyping and supporting molecular analysis.

The programme countries are Zimbabwe, South Africa and Uganda. Exact site names, site addresses, country/site allocations, sample forecasts, visit schedules, protocol time points, analytes, detailed matrices and courier routes are not part of the public TSD.

Service tier	Public functional description
Tier 1 - Local/site laboratory	Routine clinical testing, specimen receipt and processing, short-term or protocol-defined storage, result reporting and critical-result communication.
Tier 2 - Regional hub/biorepository	Centralised specimen receipt, inventory, aliquot-level traceability, -80°C archiving, courier coordination and compliant international shipment preparation.

Service tier	Public functional description
Tier 3 - Central reference laboratory	Specialised bioanalytical, resistance genotyping and optional pharmacogenetic services with validated methods, robust quality systems and secure data transfer.

3. Cross-Cutting Regulatory and Quality Requirements

The following standards apply only to the extent relevant to the offered product or service, the intended use, the destination jurisdiction and the final contract:

Standard or framework	Application
ICH E6(R3) Good Clinical Practice	Clinical trial activities, sponsor/vendor oversight, participant protection, data integrity and quality by design, where applicable.
WHO/TDR Good Clinical Laboratory Practice	Clinical trial laboratory operations and reconstruction of study laboratory data.
ISO 15189:2022 or CAP accreditation	Medical laboratory competence and quality for the accredited scope, where applicable.
ISO/IEC 17025:2017	Competence of testing laboratories, particularly specialised bioanalytical methods where applicable.
ICH M10 (2022) and applicable regional bioanalytical guidance	Bioanalytical method validation and study sample analysis for drug concentration methods.
Current IATA Dangerous Goods Regulations, Packing Instruction 650	Transport of UN3373 Biological Substance, Category B, where classification applies.
ISO 13485, GMP or equivalent	Quality management/manufacture of medical devices, IVDs, reagents or controlled products, as applicable.
Applicable national laws and licences	Laboratory licensing, import/export, customs, biosafety, occupational safety, environmental, data protection and professional practice.
Applicable electronic records controls	Validated/fit-for-purpose operation, audit trail and electronic signature controls, including 21 CFR Part 11 or equivalent where contractually or regulatorily applicable.

- Certificates must be current, authentic and accompanied by the relevant scope or schedule. Certification outside the offered scope does not establish compliance.
- Suppliers must disclose any material suspension, limitation, warning, recall, inspection finding or accreditation action relevant to the offered lot.

- Where accreditation is not available in a programme country, ACRN may consider a recognised stepwise quality status and documented qualification plan, subject to risk assessment and audit.

4. General Product and Supply Requirements - Lots A-G and K1-K4

Requirement	Specification	Grade
Regulatory and conformity status	Products must be legally supplied for the proposed intended use and destination. Provide applicable registration, CE/UKCA/FDA or other conformity evidence, or a justified RUO status where the use is research-only and legally permissible.	M
Authenticity and traceability	Original products from the manufacturer or authorised channel; lot/batch and expiry traceable from purchase through delivery; counterfeit or diverted product is prohibited.	M
Shelf life	Meet the lot-specific minimum shelf life at delivery. Shorter shelf life may be accepted only by prior written agreement with a documented consumption plan.	M
Packaging and labelling	Packaging must protect sterility, integrity and temperature. Labels must be legible and include manufacturer, product, lot/batch, expiry, storage conditions and applicable hazard information.	M
Cold chain	Temperature-sensitive items must be shipped in validated packaging with monitoring appropriate to the labelled storage range. Excursions must be reported immediately and supported by manufacturer disposition.	M
Change notification	Provide at least 60 days notice, or as soon as reasonably known, of material changes to formulation, design, manufacturing site, regulatory status, software, critical supplier or discontinuation.	M
Substitution	No substitution of manufacturer, catalogue number, lot strategy or critical specification without prior written approval.	M
Documentation	Provide packing list, certificate of analysis or conformance as applicable, safety data sheet, temperature record and other lot-specific documents with each shipment.	M
Complaints and recalls	Maintain processes for complaint investigation, field safety notices, recalls, replacement and CAPA, with prompt notification of events affecting supplied product.	M
Sustainability	Minimise unnecessary packaging and describe reusable, recyclable or lower-waste options where they do not compromise quality, sterility, safety or cold chain.	D

5. Lot-Specific Laboratory Supply Specifications

Lot A - Blood collection tubes and venipuncture consumables

ID	Component	Minimum specification	Grade	Bid-stage note
A-01	Evacuated EDTA blood collection tubes	K2 or K3 EDTA; nominal 3-4 mL; colour-coded cap; sterile single-use system; suitable regulatory/conformity evidence; lot traceable; minimum 12 months shelf life at delivery.	M	Bidder to state manufacturer, catalogue number, pack size and safety needle compatibility.
A-02	Serum separator tubes	Nominal 3.5-5 mL; gel separator and clot activator; sterile; leak resistant; suitable regulatory/conformity evidence; lot traceable; minimum 12 months shelf life at delivery.	M	
A-03	Paediatric EDTA microcollection tubes	Nominal 1-2 mL; suitable for paediatric whole-blood collection; sterile; lot traceable; minimum 12 months shelf life at delivery.	M	
A-04	Paediatric plain/serum microcollection tubes	Nominal 1-2 mL; sterile; leak resistant; lot traceable; minimum 12 months shelf life at delivery.	M	
A-05	Neonatal/infant safety lancets	Single use, sterile, auto-disabling/retracting; penetration depth approximately 0.85 mm or clinically equivalent; lot traceable.	M	Alternative depth may be proposed with intended-use evidence.
A-06	Tourniquets	Latex-free; single-use or validated reusable design that can be effectively cleaned and disinfected.	D	
A-07	Evacuated blood collection system needle/device	Closed system with safety-engineered needle/device; sterile, single use and compatible with offered tubes.	M	
A-08	Urine collection containers	Sterile or assay-appropriate clean container; leak-resistant; labelable; minimum 10 mL usable volume; lot traceable.	M	
A09	Pipette Tips	200, 1000microlitre pipette tips	M	

Lot B - Dried blood spot collection cards and accessories

ID	Component	Minimum specification	Grade	Bid-stage note
B-01	DBS collection cards	Validated protein saver card suitable for HIV nucleic-acid and pharmacokinetic applications; Whatman 903 or demonstrably equivalent; at least four collection circles; protected individual packaging; lot traceable; minimum 18 months shelf life at delivery.	M	Equivalence evidence must address matrix performance and downstream assay compatibility.
B-02	Desiccant pouches	Individually packaged silica-gel desiccant with humidity indicator; compatible with DBS storage and transport.	M	
B-03	Moisture-barrier bags	Resealable, puncture-resistant moisture-barrier bag with label area; compatible with card and desiccant configuration.	M	
B-04	Neonatal/infant safety lancets	As requirement A-05.	M	
B-05	Capillary collection tubes	Low-volume capillary blood collection device, anticoagulant as specified, suitable for paediatric use; applicable conformity evidence.	D	Exact anticoagulant and capacity may be confirmed after NDA.
B-06	Heel warming device	Single-use infant heel warmer or equivalent controlled warming solution suitable for clinical use.	D	

Lot C - Specimen storage and transport components

ID	Component	Minimum specification	Grade	Bid-stage note
C-01	Cryovials	Nominal 1.8-2.0 mL; external thread; sterile; leak-resistant O-ring or equivalent seal; rated for at least -80°C; label-compatible; lot traceable; minimum 24 months shelf life at delivery.	M	
C-02	Cryoboxes	Approximately 100-position box or equivalent compatible with offered cryovials, -80°C storage and dry-ice transport; alphanumeric grid.	D	
C-03	Biological specimen transport packaging	Complete triple-packaging solution suitable for UN3373 Biological Substance, Category B and compliant with current IATA Dangerous Goods Regulations, Packing Instruction 650, where applicable; includes absorbent material and durable outer packaging.	M	Bidder must identify reusable and single-use components and supply compliance evidence.

ID	Component	Minimum specification	Grade	Bid-stage note
C-04	Temperature monitoring devices	Calibrated, tamper-evident or secure electronic data logger suitable for the required shipment temperature range; downloadable report; current calibration evidence.	D	
C-05	Medical Grade Sample Transport Boxes	UN3373 Graded sample transport boxes	M	

Lot D - General laboratory reagents and analyser-compatible consumables

ID	Component	Minimum specification	Grade	Bid-stage note
D-01	Syphilis screening and confirmatory reagents	RPR and TPHA/TPPA or validated equivalent, suitable for the national testing algorithm and intended clinical use; controls and instructions included.	M	
D-02	HBsAg reagents	Validated rapid test, immunoassay or analyser reagent appropriate to the offered platform and national requirements; controls and lot documentation included.	M	
D-03	HCV antibody reagents	Validated rapid test, immunoassay or analyser reagent appropriate to the offered platform and national requirements; controls and lot documentation included.	M	
D-04	Qualitative hCG reagents	Urine qualitative pregnancy test with claimed analytical sensitivity at or below 25 mIU/mL, or clinically equivalent; controls/verification material available.	M	
D-05	HIV-1 RNA viral load reagents	Reagents/cartridges for a validated quantitative HIV-1 RNA platform capable of reporting at or below 50 copies/mL. Exact installed platform and country allocation will be disclosed to shortlisted bidders under NDA.	M	Bidder should list supported platforms and catalogue numbers.
D-06	GC/CT NAAT reagents	Reagents/cartridges for validated qualitative detection of Neisseria gonorrhoeae and Chlamydia trachomatis from urine or other approved matrices. Exact installed platform will be disclosed after NDA.	M	
D-07	TB molecular testing reagents	Reagents/cartridges for validated detection of Mycobacterium tuberculosis complex and rifampicin resistance, or equivalent intended-	D	

ID	Component	Minimum specification	Grade	Bid-stage note
		use claim. Platform details may be disclosed after NDA.		
D-08	Haematology analyser reagents	Complete reagent, control and consumable set compatible with designated five-part differential haematology analysers. Exact models and site allocations will be disclosed after NDA.	M	Bidder should identify all supported analyser families.
D-09	Clinical chemistry analyser reagents	Reagents, calibrators, controls and consumables for ALT, AST, ALP, total bilirubin, LDH, urea and creatinine on designated analysers. Exact models and site allocations will be disclosed after NDA.	M	
D-10	Electrolyte analyser reagents	Reagents, standards, controls and consumables for sodium, potassium and chloride on designated analysers. Exact models and site allocations will be disclosed after NDA.	M	
D-11	CD-4 Analyser Reagents	Platform compatible CD4 reagents, calibrators, controls and consumables	M	

Lot E - Human milk and infant specimen collection components

ID	Component	Minimum specification	Grade	Bid-stage note
E-01	Human milk collection containers	Food-grade or medical-grade polypropylene; sterile; wide-mouth; nominal capacity at least 60 mL; leak-proof closure; labelable; minimum 18 months shelf life at delivery.	M	
E-02	Manual collection pump/kit	BPA-free, single-patient-use manual pump or collection kit suitable for aseptic collection and compatible with the offered container system.	D	Reusable pump hardware may be proposed only with validated single-patient consumables and cleaning controls.

Lot F - Specimen labelling materials

ID	Component	Minimum specification	Grade	Bid-stage note
F-01	Cryogenic specimen labels	Permanent, solvent- and moisture-resistant label material and adhesive rated for at least -80°C; compatible with small cryovials and barcode printing; remains legible through freeze-thaw and dry-ice transport.	M	Exact printer models, label dimensions and barcode schema

ID	Component	Minimum specification	Grade	Bid-stage note
				will be disclosed after NDA.
F-02	Thermal transfer ribbon/media	Compatible with the offered cryogenic labels and designated thermal printer; minimum 300 dpi print quality or equivalent; resistant to smearing and abrasion.	M	
F-03	Tamper-evident seals	Adhesive seal demonstrating visible evidence of opening and maintaining performance at the intended storage temperature.	D	

Lot G - Laboratory-grade personal protective equipment

ID	Component	Minimum specification	Grade	Bid-stage note
G-01	Nitrile examination gloves	Powder-free, non-sterile unless otherwise stated; AQL not greater than 1.5; sizes S-XL; compliant with ASTM D6319, EN 455 or equivalent; lot traceable; minimum 18 months shelf life at delivery.	M	State quantity per box and cartons per case.

6. Laboratory Service Specifications

6.1 Lot H - Tier 1 site laboratory services

Bidders must identify the countries and locations in which they are licensed and able to provide services. Exact study sites and anticipated workloads will be provided after NDA where required.

Assay area	Minimum capability	Indicative public-stage TAT	Grade
HIV-1 RNA viral load	Validated quantitative method with lower reporting capability at or below 50 copies/mL; broad subtype performance appropriate to programme countries.	Routine/priority testing generally within 2 business days; agreed batch testing not more than 21 calendar days.	M
CD4 count	Absolute CD4 count and percentage using a validated flow-cytometric or equivalent method.	Within 2 business days.	M
Full blood count	FBC with five-part differential or clinically equivalent validated capability.	Same day, normally within 8 hours of receipt.	M
Clinical chemistry	ALT, AST, ALP, total bilirubin, creatinine, urea, sodium, potassium, chloride and LDH using validated methods.	Same day, normally within 8 hours of receipt.	M

Assay area	Minimum capability	Indicative public-stage TAT	Grade
HIV serology	Testing in accordance with the applicable national diagnostic algorithm using approved/validated assays.	Same day.	M
HBV/HCV serology	HBsAg and HCV antibody testing using validated rapid or laboratory methods.	Same day or within 24 hours.	M
Syphilis serology	Screening and confirmatory capability consistent with the applicable national algorithm.	Same day or within 24 hours.	M
GC/CT	Validated nucleic-acid amplification test from approved matrix.	Within 24 hours.	M
Qualitative hCG	Validated urine qualitative pregnancy testing.	Same day, normally within 2 hours.	M
Early infant diagnosis	Validated HIV nucleic-acid testing from DBS and/or whole blood/plasma consistent with national requirements.	Within 5 business days.	M
TB molecular testing	Validated rapid molecular test for MTB and rifampicin resistance, where included in the awarded scope.	Within 24 hours.	D

6.1.1 Tier 1 quality, infrastructure and reporting

Requirement	Minimum public-stage requirement	Grade
Accreditation/quality status	ISO 15189 or CAP accreditation for the offered scope, or an ACRN-acceptable documented quality status and improvement plan where accreditation is not reasonably available.	M
GCLP and staff competence	Documented GCLP-aligned procedures; qualified personnel; current role-appropriate training and competency assessment.	M
EQA and IQC	Current satisfactory EQA performance for applicable analytes and documented internal QC with investigation before result release.	M
Equipment	Validated/verified analysers; current calibration, preventive maintenance and service support; controlled reagents and lot verification.	M
Biosafety	Appropriate biosafety level, risk assessments, PPE, certified safety cabinets where required and incident management.	M
Cold storage	Validated +2 to +8°C and, where required, -20°C/-80°C storage with continuous monitoring, alarms, excursion response and backup power.	M

Requirement	Minimum public-stage requirement	Grade
Specimen management	Controlled receipt, acceptance/rejection, processing, chain of custody, storage, retrieval and disposal.	M
Result reporting	Secure structured reporting with traceable amendments and ability to meet agreed data-transfer format and TAT.	M
Critical results	Immediate notification under a mutually agreed critical-value list and escalation procedure, generally within one hour of verification.	M
Business continuity	Documented alternate testing, utility, equipment, staffing and communication arrangements.	M

6.2 Lot I - Tier 2 regional hub and biorepository services

Function	Minimum public-stage requirement	Grade
Specimen receipt and accessioning	Documented receipt, reconciliation, acceptance/rejection, chain of custody and deviation management.	M
Aliquot-level inventory	Validated or fit-for-purpose specimen management system providing unique identifiers, location history, status, movements, amendments and disposal records.	M
-80°C archiving	Validated storage with continuous monitoring, alarms, qualified backup power, contingency capacity and documented emergency response.	M
Courier coordination	Qualified courier network, auditable chain of custody, packaging support, pickup monitoring and escalation.	M
International shipments	Import/export coordination, current IATA-trained personnel, compliant packaging, manifests, permits and temperature monitoring as applicable.	M
Inventory reconciliation	Scheduled reconciliation and discrepancy resolution at a frequency agreed in the SLA.	M
Kit and consumable coordination	Ability to receive, store and distribute laboratory kits and maintain agreed buffer stock without revealing internal allocation strategy.	D
Continuity and disaster recovery	Redundant storage and documented transfer/recovery arrangements that protect specimen identity and integrity.	M

6.3 Lot J - Tier 3 central reference laboratory services

Service	Minimum public-stage capability	Indicative TAT	Grade
Drug concentration bioanalysis	LC-MS/MS or equivalent quantitative capability for one or more antiretroviral analytes in plasma, DBS and other protocol-specified human	Routine study batches generally within 8 weeks;	M

Service	Minimum public-stage capability	Indicative TAT	Grade
	matrices; method validation and study sample analysis in accordance with ICH M10 and applicable regional guidance.	urgent timelines by agreement.	
HIV drug resistance genotyping	Validated Sanger, NGS or equivalent workflow capable of clinically interpretable HIV-1 resistance results across relevant subtypes. Exact genomic regions, primer design, controls, reporting threshold and interpretation rules are NDA-controlled.	Within 21 calendar days from accepted specimen or batch release, unless otherwise agreed.	M
Pharmacogenetic/genomic analysis	Capability to perform validated or fit-for-purpose genotyping from suitable human specimens, with secure analysis and reporting. Exact genes/variants and triggers are NDA-controlled.	By agreed batch plan.	D
Method development/transfer	Documented feasibility, development, validation, transfer and cross-validation capability, including acceptance criteria, deviations and reports.	Project plan proposed by bidder.	M
Specimen archiving	Secure monitored storage and aliquot-level traceability for retained specimens and extracts for the contractually specified period.	Continuous.	M

6.3.1 Tier 3 validation and quality requirements

Area	Minimum requirement	Grade
Bioanalytical validation	Address accuracy, precision, selectivity, sensitivity, calibration model, carry-over, dilution integrity, matrix effect, stability, reinjection reproducibility, incurred sample reanalysis and partial/cross-validation as applicable under ICH M10.	M
Molecular method validation	Document analytical sensitivity/specificity, precision/reproducibility, contamination control, subtype inclusivity, coverage, reporting threshold, controls, invalid/repeat criteria and interpretation verification.	M
Accreditation and QMS	ISO/IEC 17025, ISO 15189, CAP or comparable recognised accreditation appropriate to the method is preferred; GCLP-aligned QMS is mandatory.	M/D
Data integrity	Traceable raw data, processing, review, approvals, audit trails, version control, change control and secure retention.	M
Proficiency testing	Relevant EQA/proficiency testing where available, or justified alternative performance monitoring where no suitable scheme exists.	M

Area	Minimum requirement	Grade
Inspection readiness	No unresolved critical data integrity or quality issue affecting the proposed service; ability to support sponsor/regulatory inspection and audit.	M
Quality agreement	Execution before receipt or analysis of study specimens.	Contract

7. Molecular Component Specifications - Lots K1-K5

Two-stage technical disclosure: The public requirements below are outcome-based. Exact installed instruments, target regions, primer sequences, thermal cycling conditions, library chemistry, multiplex design, bioinformatics pipeline configuration, interfaces and validation panels will be disclosed only to shortlisted bidders under NDA.

7.1 Lot K1 - Viral RNA extraction systems and reagents

ID	Requirement	Minimum specification	Grade
K1-01	Automated extraction reagents	Reagents suitable for automated extraction of HIV-1 RNA from EDTA plasma on a designated installed platform; lot traceable; consistent recovery suitable for downstream amplicon sequencing; input and elution ranges to be stated.	M
K1-02	Manual backup method	Independent manual or semi-automated viral RNA extraction kit suitable for EDTA plasma and downstream RT-PCR; applicable regulatory/RUO status disclosed.	M
K1-03	Ancillary reagents	Compatible carrier RNA, lysis buffer, elution buffer, proteinase or other required components; nuclease free where applicable; clearly stated storage and shelf life.	M
K1-04	Performance evidence	Provide recovery, inhibition, reproducibility and low-input performance data, plus compatibility with common downstream one-step RT-PCR methods.	M
K1-05	Platform compatibility	Exact platform will be disclosed after NDA; bidder must be willing to support compatibility verification or method bridging.	NDA

7.2 Lot K2 - One-step RT-PCR reagents and custom oligonucleotides

ID	Requirement	Minimum specification	Grade
K2-01	One-step RT-PCR master mix	High-fidelity one-step reverse-transcription PCR system suitable for structured/variable HIV RNA and long or multi-	M

ID	Requirement	Minimum specification	Grade
		target amplicons; robust inhibitor tolerance; minimum pack size and reaction volume stated.	
K2-02	Controls and water	Nuclease-free water and compatible positive/negative control strategy; control materials must be lot traceable and handled to minimise contamination risk.	M
K2-03	Custom primer design and synthesis	Capability to design, manufacture, purify and quality-control multi-primer sets spanning NDA-controlled HIV resistance targets and relevant subtype diversity.	M
K2-04	Oligonucleotide quality	Appropriate purification; identity confirmation by mass spectrometry or equivalent; stated yield and purity; sequence confirmation; certificate of analysis/synthesis supplied.	M
K2-05	Confidential technical transfer	Primer sequences, pools, concentrations, amplicon sizes, reference materials and validation acceptance criteria will be supplied or agreed after NDA.	NDA

7.3 Lot K3 - Long-read sequencing library preparation and consumables

ID	Requirement	Minimum specification	Grade
K3-01	Library preparation	Amplicon-compatible library preparation and barcoding solution for a designated long-read sequencing platform, with sufficient multiplex capacity and reproducible library yield.	M
K3-02	Sequencing consumables	Flow cells or equivalent sequencing consumables meeting current manufacturer release specifications and accompanied by QC documentation.	M
K3-03	Ancillary reagents	Required end-preparation, ligation, cleanup beads, buffers and controls, supplied as complete compatible sets or clearly itemised.	M
K3-04	Technical support	Application support for run setup, QC, troubleshooting, lot changes and chemistry/software updates.	M
K3-05	Exact chemistry and platform	Instrument model, flow-cell chemistry, barcode configuration, target throughput and acceptance criteria will be disclosed after NDA.	NDA

7.4 Lot K4 - Nucleic acid quantification reagents

ID	Requirement	Minimum specification	Grade
K4-01	High-sensitivity RNA assay	Fluorescence-based assay suitable for low-concentration RNA; validated range and limit stated; compatible with designated fluorometer; controls/standards included.	M

ID	Requirement	Minimum specification	Grade
K4-02	High-sensitivity DNA assay	Fluorescence-based assay suitable for low-concentration DNA and post-library QC; validated range and limit stated; controls/standards included.	M
K4-03	Broad-range DNA assay	Broad-range fluorescence assay for higher-concentration amplicons or pools.	D
K4-04	Assay vessels	Optically compatible tubes or vessels specified by the reagent/instrument manufacturer; lot consistent and free from fluorescence interference.	M
K4-05	Instrument model	Exact installed fluorometer and preferred pack configuration will be disclosed after NDA.	NDA

7.5 Lot K5 – HIV resistance bioinformatics solution

Requirement	Minimum public-stage specification	Grade
Analytical workflow	Support basecalling/import, read QC, alignment/assembly, variant calling, consensus generation, resistance interpretation and review for amplicon-based HIV sequencing data.	M
Validation and version control	Documented intended use, validation/verification, version locking, controlled updates, release notes, change impact assessment and reproducible reanalysis.	M
Audit trail and data integrity	Unique user accounts, role-based access, traceable changes, immutable or protected audit logs, review/approval status and retention of result history.	M
Cybersecurity	Encryption in transit and at rest, secure authentication, least privilege, logging, vulnerability/patch management, backup/restore, incident response and secure support access.	M
Deployment	On-premises, private-cloud or vendor-hosted options may be proposed. Hosting location, subprocessors, connectivity dependency, offline/continuity arrangements and data-export capability must be disclosed.	M
Reporting	Human-readable resistance report and structured machine-readable export. Exact report fields, interpretation algorithm and interfaces are NDA-controlled.	M
Interoperability	Documented API, file or other secure integration capability with standard EDC/LIMS/data platforms. Exact systems and data mappings are NDA-controlled.	M

Requirement	Minimum public-stage specification	Grade
Training and support	Role-based training, administrator documentation, user support, incident escalation, version notifications and defined support hours/TAT.	M
Exit and continuity	Complete export of data, metadata, audit trails and configurations in usable formats; transition assistance; source-code escrow or equivalent continuity protection may be negotiated for proprietary critical solutions.	D/Contract

8. Data Integrity, Privacy and Information Security

Area	Minimum requirement	Applies to
Data minimisation	Use coded identifiers and collect only data required for the service. No unnecessary direct identifiers on specimens, shipment documents or analytical files.	Laboratories, couriers, software
Access control	Unique accounts, role-based access, least privilege, prompt access removal and periodic access review.	Electronic systems
Audit trail	Traceable creation, modification, review, approval and deletion/voiding; original and amended values retained with reason and user/time attribution.	Laboratories, software
Secure transfer	Approved encrypted transfer channel; no study data through personal email, consumer file sharing or unapproved removable media.	All data processors
Backup and recovery	Documented backups, restore testing, recovery objectives and protection against accidental deletion, ransomware and single-point failure.	Electronic systems
Incident management	Documented detection, containment, investigation, notification, evidence preservation and CAPA for privacy, cybersecurity and data-integrity events.	All data processors
Data location and subprocessors	Disclose hosting/processing locations and subprocessors; no change without required approval; comply with approved cross-border transfer arrangements.	Software and data services
Return/deletion	Return or export data in an agreed usable format and securely delete remaining copies when instructed, subject to legal/regulated retention requirements.	All data processors

9. Specimen Management and Shipment - Service Providers

Detailed protocol processing instructions, draw windows, aliquot volumes, centrifugation conditions, kit configurations and rejection rules are NDA-controlled and will be incorporated into the laboratory manual and quality agreement. At public stage, bidders must demonstrate the following capabilities:

- documented chain of identity and chain of custody from receipt through testing, storage, transfer and disposal;
- controlled acceptance/rejection and deviation management, with timely communication to the designated clinical or laboratory contact;
- time- and temperature-controlled processing and storage according to protocol-defined requirements;
- validated or qualified shipping containers, permits, manifests, dry-ice or refrigerated logistics, temperature monitoring and IATA-trained personnel;
- aliquot-level inventory, location history, freeze-thaw tracking and reconciliation;
- contingency arrangements for courier delay, temperature excursion, equipment failure and border/customs disruption.

10. Receipt, Acceptance and Non-Conformance

Criterion	Public acceptance standard	Required supplier response
Shelf life	Meets the lot-specific minimum or an approved exception.	Replace or provide an approved documented disposition.
Physical/sterile integrity	No damage, leakage, contamination, deformation or packaging breach.	Immediate segregation, investigation and replacement of affected units.
Lot/document match	Product, lot/batch, expiry and quantity match purchase order and supplied certificates.	Correct documentation or replace/quarantine as directed.
Temperature	Shipment maintained within labelled/approved range with complete temperature evidence.	Provide excursion assessment and manufacturer stability disposition; replace if acceptability is not demonstrated.
Quantity and identity	Correct item, pack size and quantity delivered.	Resolve discrepancy within the contractually agreed period.
Custom molecular components	Meet agreed synthesis, sequencing-consumable or software acceptance criteria disclosed after NDA.	Re-synthesis, replacement, remediation or service extension at supplier cost where non-conformance is attributable to the supplier.

11. Required Bid-Stage Evidence

Bidder type	Minimum evidence
Product supplier	Product data sheets; manufacturer and authorised-distributor evidence; catalogue/pack details; conformity/regulatory evidence; sample CoA/CoC and SDS; shelf-life statement; lead time; cold-chain method; recall/change process; references.
Tier 1/2 laboratory or biorepository	Licences; accreditation certificates and scopes; assay menu/methods; recent EQA evidence; quality organisation; equipment/capacity summary; TAT; sample logistics; storage/monitoring; business continuity; references.
Tier 3 reference laboratory	Accreditation/quality status; method capability summaries; validation approach; instrument/capacity summary; matrix experience; sample requirements; TAT; raw data/review controls; security; audit history disclosure; references.
Molecular reagent/oligonucleotide supplier	Technical data; quality/manufacturing controls; synthesis/purification/identity methods; compatibility evidence; lot QC; stability; application support; change notification; references.
Bioinformatics/software provider	Intended use; architecture summary; deployment options; validation approach; cybersecurity controls; data-flow and hosting disclosure; audit-trail examples; integration options; support SLA; business continuity; references.

12. Post-NDA and Contract-Stage Deliverables

Only bidders with a genuine need to know will receive additional information. Depending on lot, the post-NDA or contract-stage deliverables may include method feasibility data, detailed validation protocols/reports, platform compatibility confirmation, sample and site forecasts, interface specifications, specimen manuals, site-specific logistics, data protection assessments, quality agreements, method transfer plans, installation/qualification documentation and final SLAs.

13. Documentation with Each Shipment or Service Batch

- packing list or batch manifest with product/service description, catalogue or method identifier, lot/batch, quantity, expiry and destination;
- certificate of analysis and/or certificate of conformance, as applicable;
- current safety data sheet for hazardous chemical or biological materials;
- temperature-monitoring record and shipment condition report for temperature-controlled items;

- custom oligonucleotide synthesis/identity/purity certificate where applicable;
- analytical batch report, QC summary, deviation statement and approved result file for laboratory services, as specified in the quality agreement;
- any import/export, dangerous goods, chain-of-custody or release documentation required by law or contract.

14. Lot Change, Method Change and Discontinuation

Suppliers must notify ACRN before implementing any material change that could affect product or service performance, validated status, regulatory status, data integrity, compatibility, availability or continuity. For critical products and methods, the contract may require advance notice longer than 60 days, comparability evidence, bridging/partial validation, stock transition and prior written approval.

Appendix T1 - Technical Response Checklist

Item	Bidder confirmation / reference
Lot(s) and countries covered	
Compliance matrix completed	
All deviations clearly identified	
Regulatory/conformity evidence attached	
Quality certificates and scopes attached	
Capacity and lead time/TAT stated	
Cold-chain/logistics approach stated	
Business continuity summary attached	
Data security information attached where applicable	
Subcontractors and locations disclosed	
NDA-controlled information required to finalise offer identified	

Appendix T2 - NDA-Controlled Disclosure

The separate document SUPPRESS-LA-NDA-SCHEDULE-001 identifies protocol, systems, workflow, forecast and procurement information that is excluded from this public TSD and may be provided only under controlled conditions.