

LIMS Modernization Vendor Evaluation & Readiness Framework

18 questions for CIOs and Lab Directors to evaluate vendors against your requirements, not the demo

How to use this Framework

Work through Part 1 in a room with your CIO, Lab Director, VP of Engineering, and whoever owns compliance, before any vendor conversations. If your scores are low, that work comes first.

Use Part 2 for every vendor you're seriously evaluating. Score each vendor separately and compare side by side at the end.

Score	What it means
0	Not supported. Not on the vendor's roadmap.
1	Possible but requires significant custom development or manual workaround.
2	Partially supported, or confirmed on the roadmap with a specific date in writing.
3	Fully supported today. The vendor can point to reference customers as proof.

Part 1: Are you ready to evaluate vendors?

Question - Why it matters	Score (0-3) + Notes
<p>1. Do you have a written scope agreement from the CIO, the Lab Director, the VP of Engineering, and your compliance officer?</p> <p>Verbal agreement doesn't survive budget pressure or personnel changes. Without a written scope document, the project will expand without anyone formally agreeing to it.</p>	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Note :
<p>2. Have you mapped every integration you need with data standard and direction, before looking at any vendor?</p> <p>This map is how you evaluate vendors, not their demo. Most labs skip this and discover integration gaps six months into implementation.</p>	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Note :
<p>3. Do you know where PHI lives in your current system, including FASTQ files, VCFs, and variant reports?</p> <p>Genomic data hides PHI in unexpected places. This map becomes your HIPAA risk assessment and drives your RBAC design in the new system.</p>	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Note :
<p>4. Have you identified your shadow systems, the spreadsheets and workarounds built around your LIMS's gaps?</p> <p>Shadow systems contain real workflows and sometimes real patient data. Discovering them at go-live is one of the most common causes of migration failures.</p>	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Note :

Part 1 score: ____ / 12 score below 8? Complete this internal work before evaluating any vendor.

Part 2: Vendor evaluation - 14 questions that cut through the demo

A. Architecture

Question - Why it matters	Score (0-3) + Notes
<p>1. Is the architecture modular? Can you update one layer without re-validating the entire system?</p> <p>In a regulated lab, every update that touches a validated workflow triggers re-validation. A monolithic system makes this painful. Ask: if we change our annotation pipeline, what else needs re-validating?</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>2. Can the vendor provide reference customers at your throughput level and your regulatory framework?</p> <p>Not a case study. A name and direct contact at a clinical genomics lab running your sample volumes. If they can't provide this, treat scalability claims as unverified.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>3. Is their REST API complete, documented, and publicly available without an NDA?</p> <p>Poor API documentation means you'll be dependent on the vendor for every future integration. A good API is a long-term independence guarantee.</p>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>

B. Instrument and bioinformatics pipeline integration

Question - Why it matters	Score (0-3) + Notes
<p>4. Does the LIMS trigger your pipeline via API and record the exact pipeline version, reference genome, and parameters against the sample?</p> <p>This is what CLIA and CAP inspectors ask for. If a CLIA inspector asks you to trace a patient result to the pipeline run that produced it, can you answer from the LIMS? Ask the vendor to demonstrate it on a test sample.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>5. Does it natively connect to your specific instrument models without a custom development project per instrument?</p> <p>Ask about your exact instrument models and run manager versions. If each new instrument needs weeks of custom work, you're buying recurring engineering costs for the life of the contract.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>6. Does it automatically ingest VCF files and QC metrics and link them to the sample record without manual transfer?</p> <p>Manual linkage is a time drain and a documentation gap. The pipeline outputs should attach to the sample record automatically.</p>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>

C. EHR integration

Question - Why it matters	Score (0-3) + Notes
<p>7. Has the vendor tested their integration with your specific EHR version, not just FHIR in general?</p> <p>Ask for a reference customer running your EHR version. If they can't name one, their EHR integration is theoretical, not proven.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>8. Does it go both ways, orders in from the EHR, and results and amendments back out automatically?</p> <p>Test the amendment scenario: what happens when a variant is reclassified months later? That updated result must reach the ordering physician without anyone manually uploading it.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>9. If their FHIR support is incomplete, do they have a delivery date written into the contract?</p> <p>'On our roadmap' with no date is not a commitment. A specific date with a contractual remedy if missed is.</p>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>

D. Compliance

Question - Why it matters	Score (0-3) + Notes
<p>10. Is every sample interaction recorded in a complete, tamper-evident, exportable audit trail?</p> <p>Tamper-evident means no user, not even a system admin, can edit or delete an entry. Ask to see a sample audit trail export. This is the most commonly cited deficiency in CLIA LIMS inspections.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>11. Does the vendor provide IQ/OQ/PQ (Installation Qualification (IQ), Operational Qualification, Performance Qualification) validation documentation as a standard deliverable, not a template you write yourself?</p> <p>A validation package should come from the vendor as part of the implementation. If it's an expensive add-on, include that in your total cost calculation.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>12. Does the system support field-level RBAC and enforceable MFA, not just screen-level access controls?</p> <p>A genetic counselor should assess variant classifications but not raw FASTQ files. Screen-level RBAC cannot do this. Field-level can. Ask for a live demonstration of how access controls are configured.</p>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>

E. Vendor Viability

Question - Why it matters	Score (0-3) + Notes
<p>13. Can they give you two reference customers, direct contacts, not filtered through a vendor account manager at comparable clinical genomics labs?</p> <p>What you hear from those calls will tell you more than everything in the RFP process combined. Ask to speak without the vendor on the line.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>14. How much re-validation effort does a minor system update require, and can they scope it to only what changed?</p> <p>If every update trigger full system re-validation, you're buying significant ongoing compliance overhead for the life of the contract. Ask for a specific answer in person-days.</p> <hr/>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>
<p>15. Is there a defined hypercare period after go-live, and does the support team have genomics domain knowledge?</p> <p>A live clinical LIMS can't tolerate 48-hour support tickets. P1 response times and a minimum 60-day hypercare period should be in writing in the contract.</p>	<p><input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</p> <p>Note :</p>

Part 2 score: ____ / 45

Section	Max	Your score
Part 1: Readiness	12	
A. Architecture	9	
B. Instrument & Pipeline	9	
C. EHR Integration	9	
D. Compliance	9	
E. Vendor Viability	9	
TOTAL	57	

Total	Band	What to do
0 – 18	Critical gaps	Pause vendor evaluation. Complete the internal readiness work first. Gaps discovered now are free to fix. Gaps discovered mid-implementation are very expensive.
19 – 32	Needs work	You can proceed, but address Critical-item gaps before signing. Get written vendor commitments. Budget a 30% contingency on integration costs.
33 – 45	Ready	Good shape. Focus contract negotiation on the lowest-scoring sections. Get roadmap commitments with dates in writing.
46 – 54	Optimal	Proceed with confidence. Use remaining gaps as contractual deliverables with specific dates.